

FILED

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COURT OF APPEALS
DIVISION III
STATE OF WASHINGTON
By _____

No. 318338-III

**COURT OF APPEALS, DIVISION III
OF STATE OF WASHINGTON**

**PAMELA CLONINGER, individually, and as Personal
Representative of the ESTATE OF GLEN CLONINGER; BROOKE
CLONINGER, individually; BLAKE CLONINGER, individually;
BRITTNEY CLONINGER, individually,**

Appellants,

V.

**KIM CHEN, D.O and JANE DOE CHEN, husband and wife;
ANESTHESIA ASSOCIATES OF SPOKANE, P.S.; and
DEACONESS MEDICAL CENTER,**

Respondents.

APPELLANTS' REPLY BRIEF

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I. OVERVIEW OF DEFENDANTS' ARGUMENT

There are a variety of arguments submitted by all parties in this case. At the end of the day, the basic disagreement appears to boil down to a fundamental legal issue meriting appellate clarification: Does Washington law require willful destruction or intentional disregard concerning loss of evidence in order to support a spoliation instruction, or does negligent breach of a party's independent duty to preserve medical evidence suffice under these circumstances?

II. REBUTTAL ARGUMENT

A. Critical Legal Points Not Addressed by Defendants.

While the Defendants continue to claim only the traditional rule of Spoliation applies, requiring either willful destruction of evidence of conscious disregard of its materiality, they ignore more recent case law, together with the trend of authority, concluding equivalent culpability, and therefore spoliation, occurs in claims involving loss of material medical documentation in those cases where a health care provider has negligently breached a separate duty requiring reasonable effort to preserve critical medical documentation. The distinction between these principles seems to be the thrust of this appeal. Further, without access to the evidence, it is difficult to gauge the extent of harm or prejudice, unlike Dr. Chen argues.

Notably overlooked, or, otherwise not addressed by the Defendant,

was the following:

1. The observations made by Professor Karl Tegland in 5A, WASHINGTON PRACTICE, EVIDENCE LAW AND PRACTICE, § 402 (5th ed. 2007), wherein Professor Tegland notes breach of separate duty to preserve evidence may constitute spoliation¹ and goes on to observe:

Some jurisdictions have made it easier to arrive at a finding of spoliation by easing, or even eliminating, the traditional Requirement of proof that the evidence was destroyed in bad Faith.

*This movement seems to have begun in cases involving destroyed or altered medical records. The movement may be spreading to other sorts of cases. Washington's appellate courts have not yet stated directly that they will follow this trend, but it would not be surprising if they chose to do so.*² (Italics in original.)

It is a little 'surprising' no reported Washington case has yet addressed Professor Tegland's observation, one way or the other, and is a compelling reason for clarification, particularly given the evolution of the spoliation doctrine enunciated by this Court in *Henderson v. Tyrrell*, 80 Wn. App. 592, 910 P.2d 522 (1996). Still, there remains compelling authority set forth in Appellants' Opening Brief the Defendants did not address. This authority included:

1 See, Appellant's Opening Brief, p. 30.

2 Appellants' Opening Brief, pp. 32-33.

1. ***Delaughter v. Lawrence County Hospital, 601 S.2d 818 (Miss. 1992).***

Delaughter involved the loss and alleged reconstruction of a medical record, similar to the allegations in this case, approving a spoliation instruction and acknowledging the concept there is no ‘vanishing presumption,’ for loss of evidence, regardless of a health care provider’s argument, absent a compelling reason for the loss of medical records.

Related, Deaconess cites *Veit v. Burlington Northern Santa Fe Corp.*, 150 Wn. App. 369, 207 P.3d 1282 (2009) on multiple occasions in support of an argument the trial court must have ‘substantial evidence’ to support a spoliation instruction based on a party’s loss of evidence. What the Defendants failed to point out was that portion of the *Veit* opinion addressing spoliation was ***unpublished***, making reference and reliance on it improper. That fact aside, the Plaintiffs do not seek a sanction in this case, only a correct enunciation of the law. In that same regard, it is also a fact, once raised, that *Veit* found a compelling reason for loss of evidence because a laptop containing the alleged material videotape was stolen from the vehicle of the defendant’s agent. This circumstance concerning loss of data is strikingly similar to the loss of data hypothesized in *Delaughter* if a

hospital were destroyed by fire and could therefore justify the loss of data.³

These hypothesized circumstances did not occur in *Delaughter*, and there is no claim similar circumstances occurred in Deaconess Hospital at the time of Mr. Cloninger's care. Instead, there was simply a basic failure to recognize the need to preserve evidence, a form of negligent spoliation as urged by the Plaintiffs in this case.

2. *Public Health Trust v. Valcin*, 507 S.2d 596 (Fla. 1987).

The *Valcin* decision upheld a similar spoliation instruction based on the loss of medical documentation and separate breach of duty. The case enunciates the practical burden imposed upon the plaintiff when critical medical evidence is lost and appears to be the first case acknowledging there is no 'vanishing presumption' associated with loss of critical medical evidence, regardless of a hospital's presumptive explanation on that one, narrow point. *Valcin* remains applicable authority in cases where substantive medical evidence is lost or otherwise not retained by the provider in the absence of a compelling explanation rising above a mere negligence argument.

3. *Sweet v. Sisters of Providence*, 895 P.2d 484 (Al. 1995).

³ *Delaughter*, 601 S.2d at 821-822.

As noted in Appellants' Opening Brief, this appears to have been a primary case the *Henderson* court relied upon in reaching their decision, and remains applicable. *Sweet* specifically found the rebuttable presumption associated with spoliation of evidence applies to a health care provider who negligently alters or loses medical records.⁴

In fact, none of the cases relied upon by the Defendants involve lost or altered medical records, and for that reason do not address a separate breach of duty by a third party – the clarification of law urged by the Plaintiffs in this case. Instead, virtually all of the authority cited by the Defendants involve in one way or another direct premises liability claims in which culpability of the defendant would still be required. The Plaintiffs do not advocate a change to that basic spoliation rule. Even then, Washington cases at least acknowledge a separate breach of duty can form the basis for spoliation, despite the fact none of the reported (and even unreported) cases have directly addressed the issue: *See, Henderson v. Tyrrell, supra; Tavai v. Walmart Stores, Inc.*, 176 Wn. App. 122, 307 P.3d 811 (2013).

B. Judicial Discretion and Jury Instructions.

The Defendants devote much of their Response Briefing to

⁴ *Sweet, supra* at p. 491.

argument the trial court's refusal to give a Spoliation Instruction was correct, either because there was not enough evidence to support the instruction, or alternatively, the instruction proposed by the Plaintiffs was an erroneous characterization of the law. Additionally, Deaconess claims any standing to request a spoliation instruction was abandoned because the corporate negligence claim against Deaconess was voluntarily withdrawn. These arguments miss the point.

1. Discretion of the Trial Court.

Both Defendants claim there must be an 'abuse of discretion' on the part of the trial judge in order to support the Plaintiffs' request for a new trial based on failure to give a critical, proposed jury instruction. This is an unnecessarily pejorative comment about a very knowledgeable trial judge and not an accurate statement of the law.

A trial judge is not required to possess a crystal ball about what the law should be – instead a judge can only know, and must apply, what the law has been as enunciated. In this case the law, at least in Washington, has not addressed the burden of proof regarding spoliation of medical records and breach of separate duty in that regard. Rather, enunciated authority, beginning with *Henderson v. Tyrrell*, *supra*, and a handful of other, more minor cases which have not addressed the issue directly, have held a first-party's loss or destruction of evidence occurs when there has

been intentional or willful destruction of evidence. This was the basis of the trial court's ruling on the Plaintiffs' proposed instruction.⁵ There have been no Washington decisions directly addressing a third-party's (Deaconess') separate breach of duty based on a policy to preserve such documentation, and instead only some dicta mentioned in passing.

The Plaintiffs in this case do not directly criticize the trial court's failure to give the proposed spoliation instruction as an error of existing law. Instead, the Plaintiffs urge this appellate court clarify the law as it currently exists concerning another party's breach of separate duty to preserve evidence. Under these circumstances, the trial court's ruling is not criticized based on an alleged abuse of discretion, but instead it is urged this Court review the Spoliation Doctrine *de novo* as applied to the circumstances of this case, providing clarification to the court and to counsel addressing the separate, negligent breach of duty to preserve evidence.

2. *Plaintiffs' Proposed Jury Instruction.*

Variously, the Defendants criticize the Plaintiffs' proposed instruction on spoliation, claiming it is not an accurate statement of the law. Yet according to the Defendants, there was no spoliation instruction

⁵ See RP 52 re: pre-trial rulings.

appropriate at all, and the Defendant has not and did not provide an alternative instruction. Neither did the trial court. The rebuttal to this appeal is premised entirely on the argument no spoliation instruction was appropriate, rather than any serious argument the instruction as proposed was not an accurate statement of the law. No one at the time of trial claimed otherwise.

The Plaintiffs' proposed instruction read:

If Deaconess Medical Center failed to produce evidence which was under their control and reasonably available to them and not reasonably available to the plaintiff, then you may infer that the evidence was unfavorable to the defendant who could have produced it and did not.⁶

Inadvertently, the Plaintiffs proposed two slightly differing instructions as Dr. Chen's brief points out. The first applied to both Defendants separately and was contained in pretrial briefing, though never actually submitted as a jury instruction, a fact applicable to Plaintiffs' administrative oversight as the trial neared conclusion. (CP 120-133.)

At the conclusion of trial, after the trial court ruled Dr. Chen was the ostensible agent of Deaconess, Plaintiffs proposed a similar but modified instruction applicable to Deaconess in view of the court's ruling, albeit with a couple of 'sics,' based on their ostensible agent, Dr. Chen.

⁶ Plaintiffs' Proposed Instruction 'A': CP 574-576.

Finally, both Defendants claim the spoliation instruction was not given solely because it allegedly misstated the law. Dr. Chen's brief points out the trial court did not disclose the reasoning for refusal of the Plaintiffs' proposed instruction (RP 540), but had already done so in pretrial motions (RP 52), indicating wrongful intent conscious disregard was required. Neither the Defendants or the court ever stated the proposed instruction was an improper statement of the law.⁷

The Plaintiffs' proposed instruction on spoliation, particularly negligent spoliation, came entirely from the instruction approved in *Ellwein v. Hartford Ins. Co.*, 142 Wn.2d 766, 783, 15 P.3d 640 (2001). This instruction was first proposed in Plaintiffs' pretrial motions, supported with the argument contained in Plaintiffs' briefing and the *Ellwein* citation. No one claimed the instruction as proposed was inappropriate. Instead, the only position enunciated was that a spoliation instruction was improper in the abstract, absent direct evidence of intentional misconduct or other wrongdoing associated with the loss of evidence.⁸

As stated in *Sweet v. Sisters of Providence, supra*, a plaintiff's proposed instruction might be technically incorrect, but that fact does not

⁷ See Chen Brief, p. 8.

⁸ *Supra*, at RP 52.

obviate the reality some instruction on the subject should be given. In this case, the parties and the trial court remain free to re-craft a spoliation instruction based on input from this Court, if in fact there is well-founded disagreement on the propriety of the plaintiffs' proposed instruction.

3. *Corporate Negligence vs. Spoliation.*

The Response Brief of Deaconess criticizes the Plaintiff's ultimate withdrawal of a corporate negligence claim against Deaconess, even after the Court's ruling Dr. Chen was the ostensible agent of the hospital.⁹ Further, the Deaconess brief claims it "is more than a little ironic for the Estate to now assign error to the trial court's refusal to instruct the jury on the same alleged breach of duty under the auspices of spoliation."¹⁰

There should be no confusion that Spoliation and Corporate Negligence are two differing and distinct concepts. *See Pedroza v. Bryant*, 101 Wn.2d 226, 677 P.2d 166 (1984) and *Douglas v. Freeman*, 117 Wn.2d 242, 814 P.2d 1160 (1991); *see also*, WPI 105.02.02. All require a proximate cause to support a corporate negligence action, an error which cannot logically occur after the damage has been inflicted. The former, Spoliation, is a rule of evidence (and even of equity); the latter is a separate tort allegation. The two are not necessarily related, especially in

⁹ *See*, Court's Instructions to Jury, No. 7, CP 536.

¹⁰ Deaconess Response Brief, FN 1.

this case. For that basic reason, there was no request to instruct the jury “on the same alleged breach of duty.”

Corporate negligence, as applied to Deaconess Hospital, was a theory first espoused in the case of *Pedroza v. Bryant*.¹¹ That case, and a handful of later decisions not relevant to this appeal, generally hold a hospital may be liable to a third party for negligent failure to credential a surgeon or to adopt pertinent rules and regulations addressing patient safety. *Pedroza, supra*, and those cases following, none of which are cited by Deaconess, further hold such negligence must be a proximate cause of injury.

In this case there was never a claim the Defendant’s failure to follow their own Sentinel Event Policy was a proximate cause of injury to Mr. Cloninger, and Deaconess appears to confuse these concepts. In fact, once Mr. Cloninger’s Sentinel Event occurred and he suffered catastrophic hypoxic brain damage, there could not have been any further proximate cause of his fatal injury. Instead, the Plaintiffs have alleged the failure of Deaconess, including Dr. Chen as their ostensible agent, to preserve the critical evidence for later review was the negligent spoliation of evidence, and prevented the Plaintiffs from proving what would otherwise have been

¹¹ *Pedroza v. Bryant*, 101 Wn.2d 226, 677 P.2d 166 (1984).

a compelling case against Dr. Chen and Deaconess based on improper airway management. In some jurisdictions, the intentional loss of evidence would make for a separate tort of Spoliation,¹² but in this case there is no allegation of intentional destruction of evidence and thus no separate claim for the tort of Spoliation. Regardless, the failure to follow applicable hospital policy and preserve the evidence has not been alleged as a proximate cause of injury to the decedent after the fact, and could not properly be the basis for a separate tort allegation under the circumstances.

Under these facts, where the trial court specifically found Dr. Chen the ostensible agent of Deaconess Hospital, it was not 'ironic' the Estate withdrew the corporate negligence claim, but instead a recognition of the applicable law.

4. *Factual Issues Re: the Anesthesia Monitor.*

There are several arguments advanced by the Defendants which are not entirely accurate, though not necessarily germane to this Court's ruling on the legal issue of negligent spoliation.

First, both Defendants, but particularly Deaconess Hospital, vehemently argues the monitor, when reconfigured for the next surgery, was set to "factory default settings" as the Defendants' briefs repetitively

¹² *Sweet v. Sisters of Providence, supra.*

state, instead of those setting configured by previous providers. At least one of those providers, Dr. James King, acknowledged he had configured a monitor in the manner alleged by the Plaintiffs, demonstrating evolving signs and physical patterns.¹³

Second, the argument by the Defendants, inferring the Plaintiffs' claim about what information the anesthesia monitor might have contained, is disingenuous. Deaconess personnel erased the monitor, not 42 minutes after the surgery, but 42 minutes after a one hour and 55 minute code response following the surgery, when a minimal heartbeat was obtained; Deaconess personnel recognize this distinction.

Finally, the real irony, despite legal criticism by the Defendants, is they probably know exactly what happened but are not required to disclose the information. Regardless, the critical information cannot be used solely as a shield if a trial is to be about the search for the truth.

A significant issue, particularly as argued by Deaconess, is whether the monitor was cleared to default settings after a particular surgery, or whether the monitor was reconfigured to the settings previously saved?

Candidly, the answer to this question is not entirely clear and would be a greater area of focus at retrial knowing a spoliation instruction

¹³ Testimony of Dr. James King, RP 119-120.

might hang in the balance.

At trial, Plaintiffs introduced testimony by a biomedical engineer, Alan Lipschultz. Portions of his testimony are attached hereto as Appendix C, and the answer to the question whether a reconfigured monitor is set to default settings or simply previous settings is not entirely clear. More to the point, Deaconess had the opportunity to address this question at trial and did not do so: Instead, Deaconess chose to rely upon the testimony of Greg Repetti, the Chief Operating Officer of Deaconess, who admittedly had no biomechanical training; Deaconess called none of their biomedical staff to clarify this question at the time of trial. At this point, it is improper and incorrect for Deaconess or either Defendant to categorically state, as they so claim, the monitor's memory was absolutely wiped out in preparation for a following surgery when at least Dr. James King has testified he configured the monitor on prior occasions.

The trial testimony of Alan Lipschultz has been incorporated as a portion of the clerks papers in this case. The testimony of Mr. Lipschultz has been attached as Appendix C.¹⁴

¹⁴ See Testimony of Alan Lipschultz, CP 338-390, but pertinent portions are highlighted in response to the defense arguments:

(1) . . . The manual says that the data capability would have been turned off in terms of periodic events when it came, but any operator at any time – could change that configuration because it did not require a password. (Testimony of Lipschultz at CP 351.)

(2) Q. In what information does that tell you generally in terms of the ability to retain at least one of the monitor's utilized by Deaconess Medical Center and this anesthesia group at the time this event occurred?

A. That at the least the monitor that Dr. King referred to, and he didn't specific [sic] the number or how often he had done that, is at least the monitor's that he was referring to were capable and configured to retain that data.

Q. . . . And would that elimination of this particular monitor system as a practical matter prevent any ability on your part, or an expert similar to you, of going back and reconstructing what data was capable of being retained on any monitor at any given time?

A. Regardless, the monitors were capable of retaining the data. The question is were they configured. If I had the ability to examine the monitors, then we would be able to see how the monitors were actually configured to retain that data. (Lipschultz at CP 353.)

Q. Regardless of the particular brand of monitor, do you have an opinion as to whether it is standard treatment (practice) at most hospitals to utilize the retention capability of anesthesia monitors.

A. In my experience, it common for hospitals to be able to utilize that feature to record the – to retain the – to record that data at intervals so it can be interrogated at a later. That is why the manufacturer designed it into the monitor.

...

Q. From a clinical engineering standpoint, if one of the issues involved in this case was whether the patient developed hypoxia and at what time, is it likely, in your opinion, that this MindRay Datascope, had the data been available to access at a later [sic], would have been addressed that question?

A. Yes.

... Q. . . . We don't know what retention capabilities the monitor was – was utilized for?

A. That is correct. But in addition to that, we don't know that anyone actually tried to retrieve the data. There is no indication that anybody did try and retrieve the data, regardless of the configuration. Because even with no configuration, the monitor always retains what are the alarm settings, and what is the interval for the trend settings, and some

Finally, the real irony, despite legal criticism by both Defendants concerning the adequacy of evidence, is they probably know exactly what happened but are not required to disclose the information. Regardless, the Defendants claim that information would allegedly be insufficient, but the Defendants cannot use it solely as a shield if a trial is to be about a search for the truth.

Deaconess and Dr. Chen were required by law to provide a privileged Root Cause Analysis.¹⁵ It is a privilege Deaconess could waive if the information was in the least helpful. Per their exhibits, Deaconess submitted a photograph of **the** anesthesia monitor at the time of events in

other setup questions for the monitor. (Lipschultz Testimony at CP 360.)

. . . (Q By Mr. Rekofke) And the default setting for this retention of data is – is off. In other words, the – the default position for this machine is not to retain any data. Correct?

A. The default, meaning the way it was configured when it arrived from the factory. But given that this monitor was in use for several years, we don't know what it actually was as the default on the day of the event. (Lipschultz Testimony at CP 374.)

. . . (Q By Mr. Rekofke) . . . The trend data is the data concerning the heart rate and those other things, other parameters that we talked about. Correct?

A. That's correct. Now I would also find it strange after an untoward event of any kind to then deliberately go in and deliberately say to erase the data. I could understand perhaps that an oversight, not thinking about it, but it would seem rather strange to deliberately go in and erase the data at that point. (Lipschultz Testimony at CP 377.)

15 See Plaintiffs' Brief, RCW 70.56.*et seq.*

issue, and has not claimed otherwise in their submission to this Court, despite the fact Plaintiffs called into question this factual conflict. If Deaconess knows for a fact the monitor in issue did not contain useful information they should advise the court. On the other hand, if Deaconess is aware this privileged information would implicate their client, they cannot have it both ways – claiming the evidence is insufficient, but refusing to disclose the same evidence.

This privilege is a two-way street: While the Plaintiffs theoretically cannot utilize or access the RCA to prove fault, the Defendants cannot refuse to provide the information, but at the same time claim the evidence against them is somehow lacking when indeed it exists on a privileged level. This is the point of spoliated evidence; no one knows what it may have contained.

At a new trial, armed with an appropriate spoliation instruction, there will doubtless be greater inquiry and interrogation of bioengineering staff, together with information which was or was not obtainable, regardless of the contents of that information. At this point, for the Defendants to claim any evidence is somehow lacking, when it is unknown otherwise or already exists on a privileged level, is simply not candid.

An appropriate inquiry at the time of argument would at least be an

inquiry whether the Defendants are willing to disclose this privileged information, and if so, what would it be? The refusal of the Defendants to acknowledge this information should dispose of any claim the Plaintiffs' evidence is too speculative when the Defendants otherwise choose to remain mute. The information appears to be in place – the only issue being whether the Defendants are willing to disclose it when they are apparently aware of the sequence of events.

III. CONCLUSION

There remains a basic legal issue to be decided by this Court: Can there be negligent spoliation of evidence when a medical provider breached a duty to preserve the same evidence? Must there always be intentional misconduct the Plaintiff must prove, or can a culpability requirement be satisfied by demonstrating separate breach of duty to preserve a record by the health care provider?

The Plaintiffs submit the answer has been well established elsewhere and should be affirmed by this Court: The negligent breach of duty to preserve medical records merits a spoliation instruction.

The jury's determination was improperly constrained absent a spoliation instruction. A new trial should be ordered, including such instruction.

Respectfully submitted this 4 day of February, 2014.

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Counsel for Appellants

PROOF OF SERVICE

I, the undersigned, certify that on the 5th day of February, 2014,

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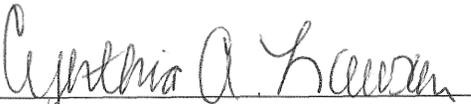
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SUPERIOR COURT OF WASHINGTON
COUNTY OF SPOKANE

FILED

JUN 25 2013

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and as Personal Representative :
of the ESTATE OF GLEN CLONINGER:
Plaintiffs, :

v. : C.A. No. 11-2-04888-2

KIM CHEN, DO and JANE DOE CHEN, : NOTICE OF VIDEO
husband and wife, ANESTHESIA : PERPETUATION DEPOSITION
ASSOCIATES OF SPOKANE, P.S.; : OF ALAN LIPSCHULTZ
and DEACONESS MEDICAL CENTER, :
Defendants. :

June 6, 2013

Videotaped oral deposition of ALAN
LIPSCHULTZ taken pursuant to notice in the offices of
Corbett Reporting - Veritext, 300 Delaware Avenue, Suite
815, Wilmington, Delaware, commencing at approximately
1:08 p.m., before Gloria M. D'Amore, Registered
Professional Reporter and Notary Public.

6-17-13
Video depo
KATHLEEN M. O'CONNOR

VERITEXT NATIONAL COURT REPORTING COMPANY
MID-ATLANTIC REGION
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Wilmington, DE 19801

Denise Hoover
Deputy Clerk

SPOKANE CO. NO.# 11-2-04888-2
CLONINGER VS CHEN, ET AL.
EXHIBIT NO. # P-
DISPOSITION _____

VERITEX
215-241-1

COMPANY
02-803-8830

APPENDIX C

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Armando Forte, Videographer

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(No exhibits were marked at this time.)

1 VIDEOGRAPHER: We're on the record.

2 The following is a videotape deposition.

3 My name is Armando Forte representing Veritext
4 Mid-Atlantic Region.

5 Today's date is June 6, 2013. The time
6 approximately 12:08 p.m. This deposition is being held
7 at the offices of Veritext, that's 300 Delaware Avenue,
8 Wilmington, Delaware 19801.

9 Caption of the case is as follows:

10 Pamela Cloninger, individually and as
11 personal representative of the estate of Glen Cloninger
12 versus Kim Chen and Jane Doe Chen, husband and wife,
13 Anesthesia Associates of Spokane, and Deaconess Medical
14 Center.

15 Present today is the witness, Alan
16 Lipschultz.

17 At this time will attorneys please
18 identify themselves and the parties they represent.

19 MR. HASKELL: Stephen Haskell, Counsel
20 on behalf of the plaintiffs.

21 MR. REKOFKE: Brian Rekofke on behalf of
22 defendant, Deaconess Medical Center.

23 MR. McMAHON: Michael McMahon for
24 Anesthesia Associates.

1 MR. KEEFE: Dan Keefe for Dr. Kim Chen.

2 VIDEOGRAPHER: Our court reporter for
3 today is Gloria D'Amore representing Veritext
4 Mid-Atlantic Region.

5 She will now swear in the witness, and
6 we will proceed.

7 COURT REPORTER: Sir, please raise your
8 right hand.

9 Do you swear that the testimony you're
10 about to give shall be the truth, the whole truth and
11 nothing but the truth.

12 THE WITNESS: I do.

13 COURT REPORTER: Thank you.

14 ALAN LIPSCHULTZ, having first been duly
15 sworn according to law, was examined and testified as
16 follows:

17 VIDEOGRAPHER: Please begin, Gentlemen.

18 MR. HASKELL: Thank you.

19 BY MR. HASKELL:

20 Q. Mr. Lipschultz, will you still -- will you,
21 please, state your full name and business address for the
22 record?

23 A. One -- I'm sorry. Alan, A-L-A-N, Lipschultz,
24 L-I-P-S-C-H-U-L-T-Z. Address is 116 Weldin, W-E-L-D-I-N,

1 Park Drive, Wilmington, Delaware 19803.

2 Q. And that's where you are today, correct,
3 Wilmington, Delaware?

4 A. I am in Wilmington, Delaware. Yes.

5 Q. In terms of background for the Jury, how --
6 how have you been professionally employed? What's your
7 job title?

8 A. I am currently the president of Health Care
9 Technology Consulting, LLC. It is a sole proprietorship.
10 And I have been in this business as a -- a consultant in
11 the field of health care technology since August of 2011.

12 Prior to that, I was employed as a
13 Director of Clinical Engineering for 22 years at
14 Christiana Care, a hospital system in Delaware.

15 And 15 years before that at Waterbury
16 Hospital Center in Waterbury, Connecticut in the same
17 capacity.

18 Q. I want to have you explain to the Jury what a
19 Clinical Engineer does.

20 But first of all, you're aware that this
21 Cloninger case is -- is going to trial next week.

22 Correct?

23 A. I'm aware of that.

24 Q. And because of travel plans that you had, you

1 will not be able to attend this trial.

2 Correct?

3 A. That's correct.

4 Q. You'll be out of the country?

5 A. Well, the plan is that I was going to be out
6 of the country. We had booked tickets to go to Central
7 Europe. They're under major flooding. And we just got
8 notice the day before yesterday that the trip is
9 cancelled. We're -- we may be in the country last
10 minute, but didn't know that.

11 Q. But in any event, at the time we planned
12 testimony your plan was not to be in the country.

13 Correct?

14 A. Absolutely.

15 Q. All right. Can you explain to the Jury what a
16 Clinical Engineer does within a hospital setting?

17 A. Certainly. A Clinical Engineer is someone
18 responsible for managing all of the health care
19 technology in all its various forms in a health care
20 organization. And as such, I had a crew of -- of folks
21 about 25 folks who reported to me who were responsible
22 for calibrating and repairing all of the equipment that
23 was in there. And my job was to manage the overall
24 program of what they were doing, decide how often

1 equipment was checked, and by what means it was going to
2 be checked. And to be the one who sat on the Patient
3 Safety Committee, Environmental Care Committee and
4 various other committees to make sure that overall that
5 the health care technology was being managed properly.

6 Q. And did that include management of anesthesia
7 monitors from time to time?

8 A. More than from time to time. I had management
9 responsibility for that both at Waterbury Hospital and at
10 Christiana Care for the entire time, but didn't deal with
11 it on a day-to-day basis because, for the most part, it
12 was handled by the folks that reported to me.

13 Q. Are you familiar with the make and model of
14 the anesthesia monitor utilized in the care and treatment
15 of Mr. Cloninger during his adverse event, as I'll call
16 it?

17 A. I'm aware by virtue of reviewing in detail the
18 instructions for use put out by the manufacturer. On a
19 hands-on basis, I did not deal with that while at
20 Christiana since we had a different brand of monitors
21 used for anesthesia monitoring.

22 And while at Waterbury, we used the
23 Datascope product, but an earlier generation of that
24 product.

1 Q. What I would like you to do is explain to the
2 Jury the make and model of the anesthesia monitor
3 utilized in this case and give them some them idea
4 whether you're familiar with the parameters of this
5 machine?

6 A. So, it is a Datascope Spectrum OR machine that
7 the company that manufactured a Datascope has -- has
8 since been purchased by Mindray, that's one word, Mindray
9 from China.

10 And the capabilities, did you say?

11 Q. Yes.

12 A. The capabilities were that it could monitor
13 multiple physiologic monitors, such as EKG, pulse
14 oximetry, End Tidal CO2, that's End Tidal, T-I-D-A-L,
15 CO2. And it could also monitor different anesthesia
16 gasses and level of consciousness.

17 And I'm sorry. It could also monitor
18 blood pressure, either invasively or non-invasively.

19 Q. And we -- we will get to that in a moment.

20 But in terms of your own background,
21 have you been involved in retention issues of medical
22 equipment on a national basis?

23 A. I have been involved in the policies about how
24 to deal with this type of situation at the national

1 level. But personally, I have only dealt with it while
2 in my capacity at Christiana Care and through one other
3 legal case that I'm presently involved in.

4 Q. As part of a -- your job as a Clinical
5 Engineer, have you dealt with what are called adverse or
6 sentinel events before?

7 A. Yes. On multiple occasions.

8 Q. And have you written about the role of
9 Clinical Engineering as it pertains to an adverse or a
10 sentinel event?

11 A. Yes. I had an article that was published in
12 March/April edition of -- of Biochemical Instrumentation
13 and Technology called BI&T. And that was specifically
14 dealing with adverse med -- adverse medical events
15 involving medical devices.

16 Q. Would that have included anesthesia of
17 monitors as a medical device?

18 A. It was a generic article referring to all
19 medical devices. It did not mention anesthesia monitors
20 at all. Because no specific types were mentioned in the
21 article.

22 Q. Are you familiar with the parameters of the
23 medical information this Mindray Datascope was capable of
24 retaining at the time Mr. Cloninger was treated?

1 A. Yes.

2 Q. Have you been trained, sir, to access the data
3 this monitor was capable of retaining?

4 A. I have not been trained specifically in this
5 particular model. The -- the instructions for the unit
6 did not require a particular technical skill. It just
7 showed that the data could be saved to a PC, MIA card, a
8 small memory card that could be put in the machine either
9 in advance or later on to take the data out, or the data
10 could be printed to a piece of paper.

11 Q. Let me try and ask the question an easier way.
12 Are clinical engineers trained to access
13 the data available on this type of monitor?

14 A. Clinical Engineers are generally not trained
15 to access the data, other than by reading the
16 manufacturer's manual, which is what I did in this case.

17 So, I'm not sure -- there's not specific
18 training, other than read the operator's manual. The
19 operator's manual doesn't even assume technical training.
20 So, anyone -- anyone who read the manual --

21 Q. To make it even simpler.

22 If you read -- if you read the
23 operator's manual, were you able -- would you have been
24 capable of accessing any retained data in this monitor?

1 A. Yes.

2 Q. All right. Now, I want you to describe for
3 the Jury in this case the ability of this monitor to
4 retain data.

5 Can you do that in a broad form, first
6 of all?

7 A. I can do it in a broad form. The monitor is
8 capable of storing some 200 data elements. And it all
9 depends on the interval at which the -- the data is
10 selected.

11 The -- the interval can be one minute,
12 two minutes, two -- every one minute, every two minutes,
13 every two-and-a-half minutes, every five minutes, every
14 ten minutes, every 15 minutes, every 20 minutes, every
15 30 minutes, once an hour, or once every two hours. Or it
16 can be -- the -- the interval can be set in the off mode,
17 meaning no data would be collected on a routine basis.

18 So --

19 Q. Mr. Lipschultz, I'm trying to -- did I
20 interrupt you? I'm sorry. Sometimes with this video
21 conferencing --

22 A. Some --

23 Q. -- we overlap sometimes.

24 A. I see that there's a delay there in terms of

1 when we're speaking.

2 So, could you ask the question again to
3 make sure I address it properly?

4 Q. Yes. I'm trying to ask it in a simpler way
5 than even you were attempting to answer it.

6 Is this anesthesia monitor capable of
7 retaining up to two hours of data?

8 A. Yes. Actually, more than two hours worth of
9 data, depending on what the interval is.

10 Q. Does it depend on how the monitor is
11 configured?

12 A. It does depend on how the monitor is
13 configured.

14 Q. And -- and what I would like you to do, we're
15 going to switch gears just a little bit, Deaconess had
16 monitors that were capable of retaining anesthesia data
17 for up to two hours or more.

18 Correct?

19 A. Correct.

20 Q. Is -- how would you compare the system
21 utilized by Deaconess at this time with retention systems
22 generally available in other medical centers?

23 A. It's better than some that I've seen and not
24 as capable of the modern ones that are on the market.

1 So, it's kind of mid line. There are some data
2 capability in there, but not a lot.

3 Q. Is -- is the trend, so to speak, to retain
4 data in a hard drive centralized in the hospital
5 information system?

6 A. That is the trend. But it's certainly not
7 something that is universal. More and more --

8 Q. That's the direction?

9 A. That is the direction that the industry is
10 going. But especially at the time of this event, it
11 would not be standard of care in my view.

12 Q. All right. Then, Doctor -- or Mr. Lipschultz,
13 I want to clarify, I'm not asking you standard of care
14 questions.

15 Understood by you?

16 A. I understand.

17 Q. All right. Now, in this particular case, do
18 you know how these Mindray Datascope Monitors came to the
19 hospital configured from the factory?

20 A. The -- the manual says that the data
21 capability would have been turned off in terms of
22 periodic events when it came. But any operator at any
23 time could -- could change that configuration because it
24 does not require a password.

1 Q. And could it have been changed or modified to
2 retain up to two hours of data that we've talked about?

3 A. Yes.

4 Q. And you had the opportunity to read the
5 deposition testimony of another anesthesiologist in this
6 case by the name of Dr. James King?

7 A. I did.

8 Q. And are you aware of whether Dr. King was able
9 to modify the retention abilities of this monitor when he
10 was using one?

11 A. My recollection of his testimony was not that
12 he actually did the modification. But he did say that he
13 did retain data, which implied that either he modified
14 that monitor or that someone else had done it. I don't
15 believe he made that distinction.

16 Q. And what information does that tell you
17 generally in terms of the ability to retain at least one
18 of the monitors utilized by Deaconess Medical Center and
19 this anesthesia group at the time this event occurred?

20 A. That at least the monitor that Dr. King
21 referred to, and he didn't specific the number or how
22 often he had done that, is that at least the monitors
23 that he was referring to were capable and configured to
24 retain that data.

1 Q. Have I advised you of the testimony of a
2 hospital administrator by the name Greg Repetti regarding
3 the ultimate fate of these monitors?

4 A. You have. And my understanding, the ultimate
5 fate of those monitors, they're no longer at Deaconess.
6 That there is no material saved from them. So,
7 therefore, they are not available for examination.

8 Q. And to cut to the chase, I have advised you,
9 have I not, that the Mindray Datascope Monitors some time
10 after this event were disposed of or replaced by a
11 different monitoring system.

12 Is that correct?

13 A. That is correct.

14 Q. And would that elimination of this particular
15 monitor system as a practical matter prevent any ability,
16 on your part, or an expert similar to you, of going back
17 and reconstructing what data was capable of being
18 retained on any monitor at any given time?

19 A. Regardless, the monitors were capable of
20 retaining the data. The question is were they
21 configured. If I had the ability to examine the
22 monitors, then we would be able to see how the monitors
23 were actually configured to retain that data.

24 Q. And given the fact that the monitors are no

1 longer available at Deaconess, did you have the ability
2 to examine the monitors and ascertain how they were
3 configured?

4 A. I did not.

5 Q. And would not at this point.

6 Correct?

7 A. I would not.

8 Q. All right.

9 A. I can also add that the monitors were capable,
10 if nothing else, even if the interval was set to the off
11 position of downloading the configuration that would tell
12 us how the alarm, or how the monitor was configured, what
13 the interval was and what the alarm values were.

14 Q. Regardless of the particular brand of monitor,
15 do you have an opinion as to whether it is standard
16 testament practice at most hospitals to utilize the
17 retention capability of anesthesia monitors.

18

19

20 THE WITNESS: In my experience, it is
21 common for hospitals to be able to utilize that feature
22 to record the -- to retain the -- to record that data at
23 intervals so it can be interrogated at a later. That is
24 why the manufacturer designed it into the monitor.

1 BY MR. HASKELL:

2 Q. And in your role as a Clinical Engineer at a
3 hospital, have you been asked to obtain or reconstruct
4 retained data from an anesthesia monitor on prior
5 occasions?

6 A. From patient monitors, I don't recall having
7 to retain one from an anesthesia monitor. But in the
8 institution where I worked, it was the same monitor used
9 in the ICUs as in anesthesia. There is no distinction.

10 So, I recall it for the ICU situation.
11 I do not recall it from the anesthesia situation, which
12 doesn't mean it occurred or didn't occur. It just means,
13 I don't recall it.

14 Q. So, I take it your answer is, yes, you've
15 retained -- you've obtained data from monitors, but you
16 in the ICU situation?

17 A. I have obtained and analyzed data from the
18 monitors. I only specifically recall it from the ICU
19 situation.

20 Q. What I want you to explain to the Jury, sir,
21 is the parameters and information or data that could have
22 been retained on this monitor.

23 And I'm showing you for the camera's
24 sake, I believe all Counsel have it, this is marked as

1 Exhibit 13, Plaintiff's Exhibit 13 for trial. It's two
2 pages. And using my terminology, it shows a printout of
3 the information available on an anesthesia monitor
4 Mindray Datascope.

5 Have you seen this information before?

6 A. Yes. I took that picture from the Mindray
7 Datascope Manual and added the labels onto one set of it.

8 Q. Is Exhibit No. 13, from your standpoint, an
9 accurate portrayal of the information customarily
10 demonstrated on this Mindray Datascope Monitor?

11 A. Yes.

12 Q. And can you tell the Jury the parameters of
13 the data that are displayed and capable of being
14 retained?

15 A. Certainly. Let me see if I have the actual
16 page here.

17 Heart rate in beats per minute. SPO2,
18 which is for -- in -- in a percentage, and that is the
19 percentage of oxygen take up for the blood, respiration
20 rate and respirations per minute.

21 The oxygen percentage being administered
22 to the patient in percent. The agent percent used for
23 anesthesiology. Nitrous oxide. And the tidal volume,
24 the amount of breath going in and out at each particular

1 time. And those are the parameters displayed on the
2 example listed in the instructions manual.

3 There are invasive pressure values that
4 can also be added. And some ventilatory -- ventilatory
5 values in addition. And I can go through all of those
6 parameters, if need be. But nevertheless, it depends
7 what was being used at that -- on that -- on that day
8 beyond what the monitor is capable of.

9 But in other words, what could have been
10 on the trend was everything that was being monitored that
11 day.

12 Q. Let me phrase the question with respect to the
13 circumstances of this particular case.

14 Would the monitor have portrayed or
15 demonstrated the patient's heart rate?

16 A. Yes.

17 Q. Blood pressure?

18 A. Yes.

19 Q. O2 saturation rates, which is oxygen sat --
20 sat -- sat -- saturation rates?

21 A. So, there's, actually, the SPO2, which is not
22 quite the same as oxygen saturation. But in -- for most
23 patients, it correlates well enough that people do refer
24 to it as oxygen saturation.

1 Q. Would it have demonstrated the patient's
2 cardiac output?

3 A. If that was being monitored that day, and I
4 don't recall from the record if it was. It wouldn't.

5 Q. Let me ask you this question.

6 From a Clinical Engineering standpoint,
7 if one of the issues involved in this case was whether
8 the patient developed hypoxia and at what time, is it
9 likely, in your opinion, that these Mindray Datascope,
10 had the data been available to access at a later, would
11 have been addressed that question?

12 A. Yes.

13

14

15 BY MR. HASKELL:

16 Q. The answer is yes?

17 A. The answer is yes.

18 Q. And if -- if another question in this case is
19 whether the patient had developed PEA at a later time,
20 would the monitor likely have demonstrated the onset and
21 event of PEA?

22

23

24

1 A. From what I understand, a PEA, yes, it would
2 have been able to show that by virtue of monitoring the
3 respiratory status.

4 Q. And PEA is a terminology that lawyers are --
5 have been accustomed to using only because of this case,
6 but it's not a term that we hear all of the time.

7 What does PEA mean from a Clinical
8 Engineering standpoint?

9 A. It's Pulseless Electrical Activity. And it's,
10 basically, saying that the EKG may appear normal, namely
11 that there's electrical activity. But the respiratory
12 status and also the blood pressure, which I didn't
13 mention before would be showing abnormalities, even
14 though the electrical system would -- in the heart was
15 working properly.

16 Q. Would these issues of hypoxia and PEA, or
17 would the data relevant to issues of hypoxia and PEA have
18 been capable of being retained with this monitor system?

19 A. You were breaking up a little bit.

20 Could you repeat the question?

21 Q. Okay. Would -- would the -- the issues of
22 hypoxia and development of PEA have been capable of being
23 retained, the data pertaining to those events, have been
24 retained with this monitor system possibly?

1 A. In my opinion, yes.

2 Q. All right. Would -- if -- if -- if one of the
3 issues in this case was the patient's airway management
4 and the course of the patient's airway management, would
5 the data that the monitor reflects have been capable of
6 addressing that issue?

7 A. It would have.

8 Q. And do you know if it was in this case?

9 A. Please clarify the question.

10 Q. Do you know if any data was retained from
11 anesthesia monitor in this case?

12 A. I have no evidence that any data was retained.

13 Q. And that is because, I'm -- I'm paraphrasing
14 your terms -- we don't know what retention capabilities
15 the monitor was -- was utilized for?

16 A. That is correct. But in addition to that, we
17 don't know that anyone actually tried to retrieve the
18 data. There's no indication that anybody did try and
19 retrieve the data, regardless of the configuration.
20 Because even with no configuration, the monitor always
21 retains what are the alarm settings, and what is the
22 interval for the trend settings, and some other setup
23 questions for the monitor.

24 Q. Would the monitor data that we've been talking

1 about be capable, had it been retained, of -- of -- of
2 getting input as to what period of time hypoxia or PEA
3 developed over with this patient?

4 MR. REKOFKE: Objection. Speculation.
5 Go ahead and answer.

6 THE WITNESS: It does depend on the
7 interval setting.

8 As I mentioned earlier, the interval
9 setting could be set as -- as infrequently as once an
10 hour or once ever two hours. And had that been the case,
11 then it is possible that there might not be a sample
12 point during the key period, or the monitors, or the
13 interval setting could have been off so that there was no
14 data being captured. It all depends on what those
15 settings were. It all depends on what those settings
16 were. And that would have been, or we wouldn't have been
17 able to determine that had anyone tried to access the
18 data out of the monitor.

19 BY MR. HASKELL:

20 Q. So, these questions that you just posed could
21 have been answered if some attempt had been made to
22 access the monitor data?

23

24 THE WITNESS: That is correct. If the

1 data had been accessed, then at least we would have known
2 what was the interval set at and what the alarm values
3 were set at, if nothing else.

4 BY MR. HASKELL:

5 Q. And would we have known what data was, or was
6 not available regarding the vital signs we just reviewed
7 with the Jury?

8 A. The actual vital signs would have also
9 depended on when -- how long after the event the -- the
10 data was accessed.

11 Q. In this -- in this case, sir, I want to ask
12 you to assume based -- I think you've read this in the
13 hospital records -- but I want you to assume that Mr.
14 Cloninger was extubated from surgery at 9:25 in the
15 morning.

16 Do you have that in mind?

17 A. Yes. That is correct.

18 Q. I want you to assume that a code was called at
19 9:37 in the morning.

20 Correct?

21 A. Okay. Yes. That is correct.

22 Q. Do you have that in mind?

23 A. Yes.

24 Q. And I want you to assume that the code ended

1 and the patient was transferred to ICU at 11:20 in the
2 morning utilizing a different transport monitor.

3 Do you have that in mind?

4 A. Yes.

5 Q. At 11:20 when the patient was transferred
6 utilizing a different monitor, was the anesthesia monitor
7 that had been utilized with Mr. Cloninger capable of
8 having retained data for the two hours prior?

9 A. Yes.

10 Q. And would that have included the 12-minute
11 time frame from 0925 to 0937?

12 A. Yes.

13 Q. And would that have included information on
14 hypoxia?

15 A. Yes.

16 Q. And the timing of the development of hypoxia?

17 A. Yes.

18 Q. And would it have included information on
19 development of PEA?

20 A. Yes.

21 Q. And the timing of PEA?

22 A. Yes.

23 Q. There's no way of knowing in this particular
24 case, however, whether that data was available.

1 Correct?

2 A. That is correct. Because nobody tried.

3 Q. I'll ask you to assume, sir, that
4 approximately 40 minutes after Mr. Cloninger was
5 transferred from the operating room to ICU that the room
6 was cleaned and the -- the monitor recycled and cleared.

7 Do you have that in mind?

8 A. Yes.

9 Q. At some time in that 40-minute time frame
10 between the time the patient was transferred to ICU and
11 the time the monitor was recycled or cleared, was there
12 the capability of preserving whatever data may have
13 existed on that anesthesia monitor machine?

14 A. Yes. And even beyond that point because the
15 data is stored in non-volatile memories. Turning the
16 machine off would not have made a difference.

17 Q. If the machine was turned off, as we
18 understand, would the data have been there in a -- in
19 what you call non-volatile form?

20 A. That is correct. So, when the monitor was
21 powered back on, it would still be possible to access the
22 data.

23 Q. For lay people, like myself and the Jury, does
24 a non-volatile form mean that the data remains in the

1 hard drive of the monitor to be accessed at a later time?

2 A. This monitor didn't have a hard drive. It is
3 retained in memory, similar to your Cell phone, which
4 does not have a hard drive. When you turn it on, it
5 remembers your phone number. It remembers the settings
6 of your monitor and what wallpaper you like to use on it.
7 All that is stored in non-volatile memory.

8 Q. Well, let me go back to the circumstances of
9 this case and ask it in, perhaps, an easier way.

10 At some point later down the road if the
11 monitor had been left unplugged, could the data to the
12 extent it was available had been accessed?

13 A. Yes.

14 Q. Was any attempt made to do that, according to
15 your information?

16 A. I have not received any information that any
17 -- that any attempt was made to access it.

18 Q. Is -- is this the kind of event that you have
19 been asked to participate in as a Clinical Engineer on
20 prior occasions?

21 A. Yes.

22 Q. Do you know if any attempt or request was made
23 to the hospital's Clinical Engineering Department to
24 attempt to access the data in this anesthesia monitor

1 machine?

2 A. I'm not aware of any attempt to ask them to
3 try and access it.

4 Q. I want to ask you, sir, a couple of questions
5 about the term sentinel event. That's a term of art used
6 in hospitals.

7 Correct?

8 A. There was -- I missed one word in what you're
9 saying. Something in hospitals.

10 Q. A sentinel event is a term of art used in
11 hospitals; is it not?

12 A. Again, it was a little difficult to hear you.

13 A sentinel event is a term used by the
14 Joint Commission to indicate a -- an adverse event that
15 is life threatening or could have caused or caused
16 serious injury or the risk thereof. So, in other words,
17 it could be a potential event that was a near miss.

18 Q. And whether you could hear all of what I said
19 or not, you are familiar with the term sentinel event;
20 are you not?

21 A. Very familiar with it. Yes.

22 Q. And in your role as a Clinical Engineer, have
23 you been involved in attempting to retain or reconstruct
24 data from medical equipment when a sentinel event has

1 occurred?

2 A. Yes, I have.

3 Q. In this particular case, I've asked you to
4 look at the Deaconess Medical Center Policy, which is
5 marked as Plaintiff's Exhibit 9; have you not?

6 A. You have.

7 Q. And if we go to Page 4, and I'll simply point
8 it out for you to speed this up, a sentinel event is
9 defined to include an event that has resulted in an
10 unanticipated death or permanent loss of function not
11 related to the nature, to the natural course of the
12 patient's illness or underlying condition.

13 Correct?

14 A. Correct.

15 Q. Do you have an opinion -- do you have an
16 opinion, sir, given your knowledge of this case and what
17 transpired with the patient as to whether a sentinel
18 event took place?

19 A. Based on my review of the record and what
20 happened, the institutions that I have been involved in
21 would have labeled this as a sentinel event.

22 Q. And from a Clinical Engineering or
23 administrative standpoint, as -- as you have told us that
24 you've been involved in, would this also be looked upon

1 as a sentinel event?

2 A. It would.

3 Q. And would this be -- and would this kind of
4 sentinel event be something that you, as a Clinical
5 Engineer, could be asked to be involved in in terms of
6 attempting to reconstruct or retain data from anesthesia
7 monitor machine?

8 A. Yes.

9 Q. Do you know if any attempt was made by
10 Deaconess to either preserve, sequester, or otherwise
11 leave for some other time the ability to access any data
12 in this anesthesia monitor machine?

13 A. I'm not aware of any attempt.

14 Q. In your opinion, should there have been such
15 an attempt?

16

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23 BY MR. HASKELL:

24 Q. And let me rephrase the question so we're all

1 on the same page, hopefully.

2 From a Clinical Engineering standpoint,
3 sir, should some attempt have been made within the
4 hospital to retain or reconstruct or otherwise later
5 access the data available in the anesthesia monitor
6 utilized for this patient?

7
8
9 THE WITNESS: The answer is, yes. And
10 that the first step would have been to gather the data to
11 investigate secondarily to the data being presented, then
12 there might be a determination as to whether the event
13 was a sentinel event or not. But even before it was
14 identified as a sentinel event, then there would have
15 been a -- an immediacy to try and retain the data because
16 you wouldn't close out options by erasing the data.

17 BY MR. HASKELL:

18 Q. Assuming that the data in this particular case
19 was erased on an anesthesia monitor, are you aware of any
20 objective data other than the monitor data that survived
21 this event?

22 A. Other than the memory of the people involved,
23 I'm not aware of any evidence.

24 Q. Are you aware of any objective realtime data

1 using later, putting later memory aside, are you aware of
2 any objective realtime data aside from this anesthesia
3 monitor information that survived this event?

4 A. I am not aware of any other data.
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15 BY MR. HASKELL:

16 Q. There are -- are, however, looking at
17 Exhibit 13, which is the printout that you've given me of
18 the monitor information with various buttons involved?

19 A. Yes.

20 Q. Do you have that in mind?

21 A. Yes.

22 Q. Is it possible to -- in -- in addition to
23 simply sequestering the monitor, is it possible to
24 utilize any of these buttons in terms of trends or the

1 trend data to preserve the type of data that we've been
2 talking about?

3 A. Yes. There is a trend button on the monitor
4 that if had been pushed would have called up a display on
5 the screen. And while that would not have been able to
6 have been saved directly other than by photography,
7 photography would have been a legitimate way to retain
8 the data on a personal basis.

9 Q. And has this trend aspect in your experience
10 been utilized to preserve anesthesia monitor data on
11 prior occasions?

12 A. Yes.

13 Q. Was it in this case?

14 A. Not to my knowledge. No.

15 MR. HASKELL: Mr. Lipschultz, I believe
16 that's all the questions I have. Thank you.

17 THE WITNESS: Thank you.

18 MR. HASKELL: Mr. Rekofke has some
19 questions for you.

20 BY MR. REKOFKE:

21 Q. Mr. Lipschultz. Brian Rekofke, I met you when
22 I took your deposition a few months ago.

23 Good morning, or good afternoon in
24 Delaware.

1 A. Good afternoon.

2 Q. I have a few follow-up questions, and I'll try
3 not to talk over you, and if you can do likewise, we'll
4 get through this.

5 First of all, this Mindray Datascope,
6 sir, is called a Physiologic Monitor.

7 Correct?

8 A. That is correct. That's the generic name.

9 Q. And its -- its function is to provide realtime
10 data, in this case, on -- on six different body
11 functions.

12 Correct?

13 A. I would say that is the primary function.
14 Yes.

15 Q. Okay. And included in -- in that realtime
16 data is heart rate, blood pressure, pulse oximetry?

17 A. Correct.

18 Q. And the Mindray Datascope has default
19 settings.

20 Correct?

21 A. It does.

22 Q. And the Datascope can be figured or customized
23 for each individual patient.

24 Correct?

1 A. It can be configured in general for the
2 institution so that every time the monitor is turned on,
3 it will have one configuration. And it can be configured
4 individually for the patient. Both.

5 Q. Okay. And there's a memory capacity for the
6 Datascope?

7 A. That's correct.

8 Q. And up to two hours of information can be
9 retained?

10 A. It is actually -- a certain number of data
11 points and the time interval -- and the overall time
12 interval is the number of data points multiplied by the
13 interval.

14 Q. But in response to Mr. Haskell's questions, I
15 understood you to agree that the monitor we're talking
16 about in this case had the capability of two-hours of
17 data retention?

18 A. That is correct.

19 Q. And then, whether it retains data is dependent
20 on a couple of things. First, whether it's being asked
21 to retain any data at all. And second, what time
22 interval it's asked to retain data.

23 Correct?

24 A. That is correct.

1 Q. And the default setting for this retention of
2 data is -- is off. In other words, the -- the default
3 position for this machine is to not retain any data.

4 Correct?

5 A. The default, meaning the way it was configured
6 when it arrived from the factory. But given that this
7 monitor was in use for several years, we don't know what
8 it actually was as the default on the day of the event.

9 Q. Okay. Well, you read the owner's manual.

10 Correct?

11 A. Yes.

12 Q. Or the operator's manual.

13 And we agree that when the machine
14 comes, it has certain default settings, and those are all
15 listed in the -- the operator's manual.

16 Correct?

17 A. They are all -- they are all listed in the
18 operator's manual. That is correct.

19 Q. Okay. And the default position for this
20 monitor is to not retain any data.

21 Correct?

22 A. With the exception of blood pressure, the
23 blood pressure is not put in the off position in the off
24 mode. The default for blood pressure is in the on mode.

1 It can be turned off, but out of the box it is on the on
2 mode.

3 Q. Okay. You reviewed the deposition of a
4 gentleman by the name of Greg Repetti?

5 A. I did. I did review the -- a review of his
6 testimony supplied to me by my attorney, or by the
7 attorney.

8 Q. Okay. Did you -- did you understand through
9 the information that Mr. Haskell gave you that Mr.
10 Repetti was the Chief Operating Officer at Deaconess at
11 the time in question?

12 A. I'm aware of that. Yes.

13 Q. And he was acting in this case as the
14 corporate spokesman for Deaconess Medical Center
15 concerning the Datascope?

16 A. Yes.

17 Q. And do you recall that Mr. Repetti confirmed
18 in his deposition that the maximum memory of -- of -- of
19 generic Datascope at Deaconess was 120 minutes?

20 A. That's what he testified. That is correct.

21 Q. And the Datascope had to be programmed to
22 retain data?

23 A. That's what he testified. I do remember that.

24 Q. And the standard procedure at Deaconess was

1 that the monitors were cleared to the default setting
2 after each case?

3 A. I do not recall that. That would require
4 manual intervention. But I cannot recall that statement.

5 Q. Okay. And you recall from reading the
6 operator's manual that -- that data on a particular
7 patient is erased when the discharge button or the
8 discharge function is employed.

9 Correct?

10 A. This is in Mr. Repetti's testimony?

11 Q. No. This is in the owner's manual.

12 A. I'm not sure where -- which page you're
13 referring to.

14 Q. I'm referring to Page 2-9.

15 A. Let me just look at that to refresh myself.
16 Hang on a second while I look that up. I have it on my I
17 pad. I'm on 2-9. Where are you referring to on 2-9?

18 Q. On the bottom of the page it says, Discharging
19 a patient?

20 A. Yes.

21 Q. It says, Discharging a patient from the
22 monitor causes the following to occur. And then it list
23 a number of things that occur?

24 A. Yes.

1 Q. And it indicates that all patient trend data
2 is cleared?

3 A. It does say that.

4 Q. And let me ask you this, sir.

5 The -- going back to Mr. Repetti's
6 deposition, do you recall that he testified that
7 depending on the surgery schedule, that the standard
8 clearing of the Datascope may occur as little as
9 15 minutes?

10 A. I don't recall that from Mr. Repetti's
11 testimony. I do know that the monitor, regardless, would
12 retain the -- the configuration data, namely how often
13 the data is -- is -- is sampled and what the alarm values
14 were, regardless if the trend data was cleared.

15 Q. Understood. The -- the trend data is the data
16 concerning the heart rate and those other things, other
17 parameters that we talked about.

18 Correct?

19 A. That's correct. Now, I would also find it
20 strange after an untoward event of any kind to then
21 deliberately go in and deliberately say to erase the
22 data. I could understand, perhaps, that an oversight,
23 not thinking about it, but it would seem rather strange
24 to deliberately go in and erase the data at that point.

1 Q. You're answering a question that I did not
2 ask, and I move to strike that response.

3 The question was, when the patient is
4 discharged, certain data is erased or eliminated.

5 Correct?

6 A. According to the manual, yes, that data is
7 erased when discharged.

8 Q. And let me ask you this now concerning the --
9 the Datascope that was used in Mr. Cloninger's case.

10 The Cloninger Datascope used for Mr.
11 Cloninger was working properly during the procedure.

12 Correct?

13 A. There's no indication it was not. That is
14 correct.

15 Q. In other words, there's no indication it
16 malfunctioned?

17 A. That is correct.

18 Q. And so, it did provide the realtime data that
19 -- that could be used during the procedure?

20 A. Correct.

21 Q. And you don't know how the Datascope was
22 configured for Mr. Cloninger?

23 A. I do not know.

24 Q. If it was at a default setting, no data would

1 be collected or retained?

2 A. If it was at the default setting, no trend
3 data would have been retained with the exception of blood
4 pressure values. Because that is -- the default for
5 blood pressure is on position -- is on -- collected.

6 Q. Therefore, based upon what you know, you can't
7 state more likely than not that any data, other than the
8 blood pressure, was retained during Mr. Cloninger's
9 procedure?

10 A. I cannot state categorically, other than the
11 blood pressure about other -- other parameters, that is
12 correct.

13 Q. Mr. Lipschultz, let me ask you some questions
14 about the sentinel event issue.

15 Your current job is as a consultant in
16 cases involving medical devices that -- that malfunction
17 or reportedly malfunction?

18 A. That is one aspect of my consulting. I'm also
19 doing work for hospital systems and for manufacturing --
20 manufacturers.

21 Q. And would this all be in terms of health care
22 technology; in other words, machines -- machines related
23 to health care?

24 A. Devices related to health care. Some of them

1 are not machines.

2 Q. And based on your experience, you would agree
3 with me, sir, that not every bad -- bad outcome in a case
4 is a sentinel event?

5 A. I would agree with that.

6 Q. And not every unusual occurrence is a -- is a
7 sentinel event?

8 A. I agree.

9 Q. A decision has to be made whether a particular
10 event is a sentinel event?

11 A. I agree.

12 Q. And that decision is typically made at an
13 administrative level?

14 A. I agree.

15 Q. And when you were working in the hospital
16 systems, I think you told me at your deposition, you had
17 never been a decision maker regarding whether an unusual
18 occurrence was a sentinel event?

19 A. That is correct. I was one of the ones who
20 would gather the data to present to the decision makers
21 so that they can make a determination whether it was
22 sentinel.

23 Q. The point is that you were not -- in terms of
24 the sentinel event declaration -- you wouldn't make that

1 decision?

2 A. Correct.

3 MR. REKOFKE: That's all the questions I
4 have, sir. Well, maybe -- I take -- I take that back.

5 We just had a little blurb on the
6 speakerphone here. So, let me start again.

7 BY MR. REKOFKE:

8 Q. So, it's clear, Mr. Lipschultz, you are
9 unaware of the standard of care in the State of
10 Washington as to the issues in this case?

11

12 THE WITNESS: I am not qualified to
13 judge the standard of care in the State of Washington.

14 MR. REKOFKE: That's all the questions I
15 have. Thank you.

16 BY MR. McMAHON:

17 Q. Mr. Lipschultz, Mike McMahon for Anesthesia
18 Associates off camera here.

19 I -- did Mr. Haskell share with you the
20 depositions of Dr. Hagberg and Dr. Cooper?

21 A. No.

22 Q. So, you do not know what the opinions of Dr.
23 Cooper and Dr. Hagberg, who are the plaintiffs' medical
24 experts are in this case with respect to the Datascope?

1 A. No.

2 MR. McMAHON: That's all I have. Thank
3 you, sir.

4 MR. KEEFE: It's Dan -- Dan Keefe for
5 Dr. Chen. I have no questions for this witness.

6 BY MR. HASKELL:

7 Q. Mr. Lipschultz, I have a couple of follow-up
8 questions. Steve Haskell again.

9 You were asked questions about the
10 standard procedure would be to clear the data from this
11 monitor, correct? Do you recall being asked those
12 questions?

13 A. I do.

14 Q. If a staff member, such as a nurse or the
15 surgeon perceives that a potential sentinel event has
16 occurred, per the way we defined it earlier, would that,
17 in your opinion, alter the standard approach of clearing
18 the monitor?

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THE WITNESS: Assuming that the
clinician, the person that had been educated as to what
the Deaconess policy was regarding adverse or sentinel

1 events because the policy covers both, then it would be
2 logical, I would think to say that we need to figure out
3 what happened in order to improve patient safety.

4 BY MR. HASKELL:

5 Q. In the real world, sir, understanding that the
6 ultimate answer to a sentinel event has to go through
7 administrative channels, is data subject to loss or to
8 change over a relatively short period of time customarily
9 retained, and then the answer whether it falls within the
10 sentinel event reached at another time.

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THE WITNESS: So, the answer is that
from administrators that I have dealt with who are
involved in deal deciding whether an event is a sentinel
event or not a sentinel event, any and all data that they
can use to help in that determination is extremely useful
and they were very grateful any time I was able to
provide any today hard data directly out of a medical
device that might have been involved in an -- in an event
-- whether or not it was sentinel.

BY MR. HASKELL:

Q. And would that include in this particular case

1 providing to administration any anesthesia monitor data
2 that was available in the context of this particular
3 patient's care?

4 A. Since the anesthesia monitor was directly
5 involved in a -- a -- the case, A and B, since it did
6 include data than, then, yes, it would have been
7 something that folks making the decision would have been
8 very interested in assessing as much data as they could
9 from this monitor.

10 Q. It has been pointed out by Counsel that you
11 cannot categorically tell the Jury whether there was any
12 data available to retain or retrieve on this particular
13 monitor.

14 Correct?

15 A. That is correct. I cannot categorically state
16 that. However, if you don't look for the data, you don't
17 know whether you're going to get any data. And I don't
18 know that anybody will be able to determine what were the
19 settings of that monitor on that day.

20 Q. Well, that assumes my next question.

21 Can you also categorically state, sir,
22 that no attempt was made to access this data?

23 A. I can categorically state that there -- that I
24 have received no information that there was any attempt

1 to try and retrieve this information.

2 Q. And again, if we go back to the -- the picture
3 for the Jury in this case, which is, I believe, the
4 12 minutes between 9:25 and 9:37, is there any objective
5 data, sir, that you're aware of that survived this
6 12-minute period?

7 A. I'm not aware of any data from that time
8 period, especially objective data.

9 MR. HASKELL: All right. Thank you.

10 BY MR. REKOFKE:

11 Q. Just -- just a couple of follows up, Mr.
12 Lipschultz. This is Brian Rekofke again. Let me follow
13 up with the last comment first.

14 In terms of objective data, you are
15 aware an anesthetic record was maintained in this case.

16 Correct?

17 A. I'm aware of that.

18 Q. And that would be objective data; wouldn't it?

19 A. It would be data, but not -- and I would
20 consider it to be objective data -- not the same level as
21 something that was being automatically recorded. Because
22 one never knows in an handwritten system as to whether or
23 not what was the gap between when the data was collected
24 and when it was documented.

1 Q. Well, there's no gap. In other words, if data
2 is collected in realtime, that's fairly reliable; is it
3 not?

4 A. I would say it's fairly reliable.

5 Q. Were you provided, sir, the deposition of a
6 Deaconess employee by the name of Colleen Dugger?
7 D-U-G-G-E-R.

8 A. No. I was not.

9 Q. I'll ask you to assume that Ms. Dugger has
10 been an anesthesia tech at Deaconess for 30 years and
11 that she is in charge of setting up the operating room
12 including setting up the Datascope.

13 A. Okay.

14 Q. Armed with that -- armed with that assumption,
15 sir, she testified at her deposition that each morning
16 when she sets up the operating room, the Datascope is set
17 to the default position.

18 Would that position then be, as far as
19 you know, a position that there would be no data
20 retained?

21 A. Without knowing the details of what she
22 actually did, it's hard for me to know whether she really
23 would have gone in and changed all of the settings back
24 to the factory default, when if someone had said that

1 this monitor is going to retrieve data every one minute,
2 that would stick from case to case unless someone
3 deliberately went in and set up it back to off.

4 Q. Understood, sir.

5 The default position for this monitor is
6 not to retain any data. That's what you told me at your
7 deposition.

8 Correct?

9 A. That is correct.

10 Q. And you don't know how Mr. Cloninger's
11 Datascope was configured on the day of his unfortunate
12 event; do you?

13 A. That is correct.

14 MR. REKOFKE: That's all the questions I
15 have. Thank you. Oh, one more question. I'm sorry.

16 BY MR. REKOFKE:

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Q. What I'm saying is that all of the clinical
events that occurred prior to any issue about data

1 retrieval, we can agree is a factual matter on that?

2 A. We can agree that the data was collected. Any
3 data that was collected because it was displayed during
4 the case, through the transition to PEA and after, the
5 only issue is what was retained. But it was on the
6 screen, and, therefore, was collected by the machine.

7 Q. The realtime data worked just fine in this
8 case?

9 A. Every indication is yes. So, therefore, my
10 only point is, it was collected by the device and
11 displayed on the screen. So, it was there.

12 Q. Correct. And able to be used by the personnel
13 attending to Mr. Cloninger?

14 A. Correct.

15 MR. REKOFKE: No further questions.

16 MR. McMAHON: Nothing further.

17 MR. KEEFE: Dan Keefe. No questions.

18 BY MR. HASKELL:

19 Q. And I apologize. The judge may not like this,
20 but I need to clarify one question that Counsel just
21 asked, which is about the graphic anesthesia record of
22 Dr. Chen.

23 You have had an opportunity, sir, to
24 review the deposition testimony of Dr. Chen; have you

1 not?

2 A. Yes. That's correct.

3 Q. And with regard to the critical time frame
4 that we believe is an issue in this case, in other words,
5 0925 to 0937, do you understand whether that charting in
6 the graphic anesthesia chart was done in realtime or was
7 it reconstructed at a later time?

8 A. I was not able to determine that.

9 Q. Are you aware of whether any objective data
10 the graphic anesthesia chart included survived this
11 12-minute time frame in realtime?

12 A. Not that I am aware of.

13 MR. HASKELL: Okay. Thank you.

14 MR. REKOFKE: Nothing further.

15 MR. McMAHON: I have nothing further
16 because there is no surrebuttal permitted.

17 MR. HASKELL: We're done. Thank you.

18 VIDEOGRAPHER: Sir, this then concludes
19 the deposition. The time 1:08 p.m.

20 (The videotaped deposition was concluded
21 at, approximately, 1:08 p.m.)

22 (Presentation, reading and signing of
23 the deposition were waived.)

24

