ORIGINAL

HONORABLE JAY B. ROOF
Hearing Date: February 5, 2013
Hearing Time: 9:00 a.m.

IN THE SUPERIOR COURT OF THE STATE OF WASHINGTON
IN AND FOR THE COUNTY OF KITSAP

JOSETTE TAYLOR as Personal Representative of the Estate of FRED E. TAYLOR, deceased; and on behalf of the Estate of FRED E. TAYLOR; and JOSETTE TAYLOR, Individually,

Plaintiffs

v.

SCOTT BILDSTEN, D.O., individually, JOHN C. HEDGES, M.D., individually, KITSAP UROLOGY ASSOCIATES, P.C., a Washington active, for profit corporation, and INTUITIVE SURGICAL, INC., a foreign corporation doing business in Washington,

Defendants.

NO. 09-2-03136-5

PLAINTIFF'S OPPOSITION TO INTUITIVE'S MOTION FOR SUMMARY JUDGMENT ON ALL CLAIMS

I. CASE OVERVIEW

Fred Taylor was severely injured during an operation to remove his prostate gland. This operation is called a prostatectomy. Fred Taylor's operation was the first time his surgeon, Scott Bildsten, had used the da Vinci robotic system, unsupervised, to effectuate a prostatectomy. The robotic system was manufactured by ISI; Dr. Bildsten was trained in its use by ISI.

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Like all tort cases, this one involves questions of duty, breach, causation and damages. Because Mrs. Taylor can show genuine issues of material fact as to each element of her claims, ISI's motion for summary judgment should be denied.

A. Duty

A defendant's duty can arise from multiple sources, including statutes and the common law. Here, there is no dispute that the Washington Product Liability Act ("WPLA") imposes certain duties on ISI, as the manufacturer of a product, as a matter of law. *See* RCW 7.72.030.

There is a fact question as to whether ISI voluntarily assumed additional duties, beyond the scope of the WPLA, by creating a training program which surgeons could pay to attend whether or not they or their institution had purchased a *da Vinci* robot. Washington law recognizes that a defendant can voluntarily assume duties, beyond those that would otherwise be imposed by law. *E.g. Meneely v. S.R. Smith, Inc.*, 101 Wn.App. 845, 856; 5 P.3d 49, 55 (2000) (trade association that voluntarily undertook to issue safety standards for the protection of pool users, assumed the duty to act with reasonable care); Restatement (Second) of Torts, Section 324A.

ISI says it did not assume a duty to train doctors. Yet, it admits that it provides each urologist it trains[1] with a document entitled: "The Clinical Pathway and Training Protocol for da Vinci Prostatectomy."[2] Dr. Bildsten was given such a document before he ever operated on a live patient.[3] The document describes a detailed training program, telling Dr. Bildsten:

> The following clinical pathway has been put in place ***to ensure success in becoming a proficient robotic surgeon.***

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[1] Exhibit A to Mullenix Declaration (Daniels Deposition) at 231:23-25 ("Q. Were there ever times when you didn't go over the clinical pathway with a surgeon? A. No.").

[2] PT-42, Ex. A.

[3] Exhibit PT-42, at 2.

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(emphasis added).

After describing a detailed training regime, designed, operated and controlled by ISI, the document then requires signature from the doctor, committing to the ISI training "pathway," in order to "***ensure*** early success for Robotic Prostatectomy."[4] Damon Daniels, the ISI sales rep who gave Dr. Bildsten the Clinical Pathway, admitted that he would tell the surgeons, and wanted those surgeons to believe, that the Clinical Pathway would ensure the surgeon's success in becoming a proficient robotic surgeon.[5]

When training its salespeople, ISI defines this Clinical Pathway document as a "[p]rescribed, stepwise approach for surgeons and OR staff to develop knowledge and skills using the da Vinci Surgical System *in clinical applications*."[6] In fact, the "Clinical Sales Representatives" (CSRs) understood that an ISI certification meant the surgeons had successfully completed "the protocol for their specialty" and were able to apply surgical skills "to procedural applications."[7] CSRs were explicitly told: "All necessary training for surgeons and nurses is built into the clinical plan."[8] In documents it gave to Harrison, ISI urged surgeons to "Follow the Prescribed Clinical Pathway."[9]

As outlined in following sections of this brief, there are a great many additional facts showing ISI's assumption of the duty to train Dr. Bildsten. But the facts recited above are sufficient to defeat ISI's summary judgment motion. By "prescribing" and providing a

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[4] Exhibit PT-42, at 6 (emphasis added).
[5] Exhibit A to Mullenix Declaration (Daniels Deposition) at 268:22-269:5.
[6] PT 212 (emphasis added); Exhibit A to Mullenix Declaration (Daniels Deposition) at 258:10-22; 211:17-18 ("I told [surgeons] ... here's our clinical pathway document, you know, you should abide by this").
[7] Exhibit A to Mullenix Declaration (Daniels Deposition) at 266:1-8.
[8] PT-30 at 10878; Exhibit B to Mullenix Declaration (Nagel Deposition) at 59:10-11.
[9] PT-72 at 1.

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detailed training program for surgeons that ISI said would "ensure early success for Robotic Prostatectomy," ISI assumed a duty beyond those imposed by statute upon manufacturers: ***it assumed a duty to train with reasonable care.*** ISI's disclaimers to the contrary do nothing more than create a genuine factual dispute as to the assumption of the duty and its scope.

B. Breach

The declaration of William Scott Helton, M.D. states that the ISI training program applied to Dr. Bildsten was

> incomplete and potentially unsafe... Further, to suggest that any surgeon could be adequately trained to perform any type of major surgery using the da Vinci surgical system after only the level of training proposed is unfounded and unsupported by any data, a leap of faith, potentially unsafe, and irresponsible."[10]

While more facts showing ISI's breach of its assumed duty to train are outlined in later sections of this brief, this declaration, standing alone, is sufficient to defeat ISI's motion with respect to breach of the duty to train.

Under the WPLA, ISI had the same duties all manufacturers do; it can be held liable if it provided a product that was "not reasonably safe because adequate warnings or instructions were not provided." RCW 7.72.030(1). For example,

> A product is not reasonably safe because adequate warnings or instructions were not provided after the product was manufactured where a manufacturer learned or where a reasonably prudent manufacturer should have learned about a danger connected with the product after it was manufactured. In such a case, the manufacturer is under a duty to act with regard to issuing warnings or instructions concerning the danger in the manner that a reasonably prudent manufacturer would act in the same or similar circumstances. This duty is satisfied if the manufacturer exercises reasonable care to inform product users.

RCW 7.72.030(1)(c); *see also* RCW 7.72.030(1)(b) (describing duty of manufacturers to

[10] Helton Declaration at ¶ 7.

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provide adequate warnings and instructions with product).

In his declaration, Dr. Helton addresses the fact that ISI knew or should have known that Dr. Bildsten would not be in a position to safely perform robotic prostatectomies until he had far more than the 2 proctored surgeries laid out for him by ISI in his Clinical Pathway. He then states:

> 15. For these reasons, ISI had an ethical responsibility to inform Dr. Bildsten that it would likely take him 20 to 40 procedures before he could safely perform unsupervised da Vinci prostatectomy on the average patient, and 50 procedures before he could safely perform unsupervised da Vinci prostatectomy on a patient like Fred Taylor who was not an ideal robotic surgical candidate, especially for a novice surgeon on the robot. ISI *should* have given these warnings to Dr. Bildsten well before they convinced him to "commit" to their "Clinical Pathway." (These learning curve expectations should have been incorporated into the "Clinical Pathway" drafted by ISI for Dr. Bildsten.) ISI should also have given warnings of this nature to Harrison Medical Center.
>
> 16. Based on the clinical pathway document that ISI provided to Dr. Bildsten (PT-42), ISI suggested to Dr. Bildsten that he would be safe to operate on patients without supervision after only two proctored surgeries. Rather than telling him that the median time for even high-volume surgeons was 20 to 40 procedures for basic proficiency, ISI merely told Dr. Bildsten that he might not "reach a level of comfort" until "around 20" (106-107) procedures. If indeed he was told that, such a statement would be misleading in light of the literature cited above, about which ISI, as a reasonably prudent medical device manufacturer knew or should have known.[11]

Dr. Helton concludes his declaration:

> 20. In light of the facts outlined above, a reasonable and responsible company in ISI's *position* would have informed Dr. Bildsten and Harrison Hospital of the variable and unknown learning curve for robotic prostatectomies for any given urologist. It would not have encouraged Harrison and Dr. Bildsten to believe that Dr. Bildsten could safely operate unsupervised after having only completed its simplified training program (unapproved by the FDA) and two proctored surgeries. ISI's actions in this regard were irresponsible and reckless.[12]

While there are many more facts recited below that demonstrate ISI's breach of its duties under

[11] Helton Declaration, at ¶¶ 15-16.
[12] Helton Declaration, at ¶ 20.

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the WPLA to provide adequate warnings and instructions, Dr. Helton's declaration, standing alone, is sufficient to defeat summary judgment.

C. Causation

As recounted by Joseph D. Schmidt, M.D., Dr. Bildsten made numerous mistakes during the Taylor surgery. According to Schmidt, it was a mistake for Bildsten to use the da Vinci at all on Mr. Taylor.[13] Schmidt also testified that Bildsten fell below the standard of care in failing to create a watertight anastomosis (seal) between the bladder and the urethra, once the prostate was removed.[14] Inflating Mr. Taylor's abdomen with carbon dioxide pressure ("insufflation") at 20 mm for the length of time Dr. Bildsten did also fell below the standard of care.[15]

S. Adam Ramin, M.D. is a robotic surgeon who testified that Dr. Bildsten fell below the standard of care in various ways, including poor patient selection, improper insufflation, and failing to even try to obtain a water-tight anastomosis.[16] He testified that it is more likely than not that Mr. Taylor's outcome would have been different if the anastomosis had been water-tight.[17] Among other things, he more likely than not would not have had a breakdown of the rectal repair performed as a result of Dr. Bildsten cutting Mr. Taylor's rectum.[18]

Dr. Schmidt testified that Mr. Taylor suffered injury from the high-pressure insufflation—including encephalopathy and stroke.[19] Dr. Ramin testified that high-pressure insufflation can cause renal failure, decreased cardiac output, acidosis, and increased "end title CO2."[20] As Dr.

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[13] Exhibit C to Mullenix Declaration (Schmidt Deposition) at 47-48.
[14] Exhibit C to Mullenix Declaration (Schmidt Deposition) at 49 - 52.
[15] Exhibit C to Mullenix Declaration (Schmidt Deposition) at 49-50, 53.
[16] Exhibit D to Mullenix Declaration (Ramin Deposition) at 102-05.
[17] Exhibit D to Mullenix Declaration (Ramin Deposition) at 105.
[18] Exhibit D to Mullenix Declaration (Ramin Deposition) at 105-06.
[19] Exhibit C to Mullenix Declaration (Schmidt Deposition) at 54-55.
[20] Exhibit D to Mullenix Declaration (Ramin Deposition) at 108-109.

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Ramin testified: "These are some of the problems that this patient developed," and "the scenario here points to the intra-abdominal pressure being the main cause."[21] The presence of these pressures for a very long time, as was the case in the Taylor surgery, significantly increase the chance of developing respiratory and renal complications, which Mr. Taylor suffered.[22]

These doctors and others have more to say about Dr. Bildsten's mistakes causing injury to Mr. Taylor, but these citations are enough to establish there are genuine issues of fact in that regard.

Prior to this surgery, Dr. Bildsten had performed over 100 prostatectomies using the traditional "open" procedure, without a single complication.[23] A jury could reasonably conclude that the mistakes he made in this robotic procedure were a result of the poor training and lack of warnings he received from ISI. Indeed, that is the conclusion Dr. Bildsten has reached:

> 4. ... I was led to believe that ISI training and two proctored surgeries was sufficient to achieve basic competency and safely perform unsupervised robotic surgeries. I was not told by ISI representatives that paid expert consultants to ISI (as well as other researchers) were reporting that basic competency or proficiency were not being obtained until twenty or more operations were complete.
>
> 5. I relied upon ISI's representatives to give me a fair and accurate picture of ISI's training program and the learning curve.
>
> 6. Having learned information in FDA documents about the training program, and from other documents about research on the learning curve to obtain basic competency which I did not know at the time I became involved with ISI, I believe I likely would not have agreed to begin training on the robot had I been given this information.
>
> ....
>
> 8. At the time I committed to receiving one of Harrison Medical Center's free training slots, and thus to begin performing robotic prostatectomies, I was led to believe I would be able to provide equal or better results to my prostatectomy

[21] Exhibit D to Mullenix Declaration (Ramin Deposition) at 108.
[22] Exhibit D to Mullenix Declaration (Ramin Deposition) at 109.
[23] Exhibit Q to Mullenix Declaration (Bildsten Deposition) at 42:21-43:13.

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patients with the daVinci machine. I was not told by ISI that, especially for surgeons with no prior laparoscopic experience doing prostatectomies, this was very unlikely until I accomplished 100 or more robotic surgeries. Had I been informed of that fact, I would not have performed da Vinci surgery on Fred Taylor.

9. ***During my robotic surgery training by ISI, I was not informed of the need to ensure a watertight urethral anastomosis. Likewise, I was not informed by ISI of the dangers of insufflating patients during long surgeries at levels over 15 millimeters of mercury. Had I been so informed, I would have conducted the Taylor surgery differently, in a way that would have reduced the risk of harm to Mr. Taylor.***[24]

More facts are recited below to establish genuine issues of material fact as to whether ISI's poor training of, and lack of warnings to Dr. Bildsten was a substantial factor in causing Mr. Taylor's injuries; but the facts cited above are independently sufficient to justify denial of ISI's motion.

D. Damages

There is no factual dispute that Mr. Taylor suffered injuries and damages during his operation. The nature and extent of the injuries is in dispute, but is not put in issue by ISI's motion. The portions of the record cited above establish not only causation, but many of the injuries.

Because ISI has made such an effort to convince the Court that the rectal injury did not occur during the robotic portion of the operation, plaintiff cites the court to the testimony of Dr. Ramin, which clearly refutes defendant's position:

Q Is it your opinion that it [the rectal injury] occurred during the da Vinci portion of the procedure before opening?

A Yes.

Q How did that happen?

A This is a portion where they were trying to again develop the

[24] Declaration of Dr. Scott Bildsten, at paragraphs 4-6, 8-9 (emphasis added).

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> Denonvillier's fascia. And based on his operative report he said after several hours of trying to develop this area, they decided to convert to open surgery. This is an area which has a high risk of cutting into the rectum and not recognizing it. The rectum is only a few millimeters away from the Denonvilliers' fascia in this particular area. And if you have more visualization, if there is blood coming into the field and bowel is coming into the field, add it to physician's fatigue, add it to a certain level of frustration, and add it to a patient not being in a correct position, it's very hard to tell whether you're properly -- you are in the proper space or not. Very high chance that the rectum is injured at that point.[25]

There are genuine issues of material fact about the damages Mr. Taylor received during surgery, and ISI cannot credibly argue otherwise.

E. Summary

The facts and law reviewed thus far are sufficient to justify denial of ISI's motion in all respects. If plaintiff was to end the brief here, however, the Court would lack context for ruling on the evidentiary motions that will shortly follow. Rather than force the Court to learn the case in a piece-meal fashion, plaintiff has elected to provide a thorough (though not complete) discussion of how the facts relate to her legal claims. It is hoped that in the long run, this will make the Court's job easier. The expanded legal arguments below should also make the Court's job easier as it considers evidentiary motions and jury instructions.

II. STATEMENT OF FACTS

A. ISI is founded to pursue military-developed robotic surgery technology.

In 1994, Dr. Fred Moll learned of a robotic "tele-surgery" system developed at Stanford Research Institute in California and funded by the army.[26] The original goal of the project was

[25] Exhibit D to Mullenix Declaration (Ramin Deposition) at 79:10-80:3.
[26] PT-240 ("Has the Real MIS Revolution Finally Arrived") at 2235.

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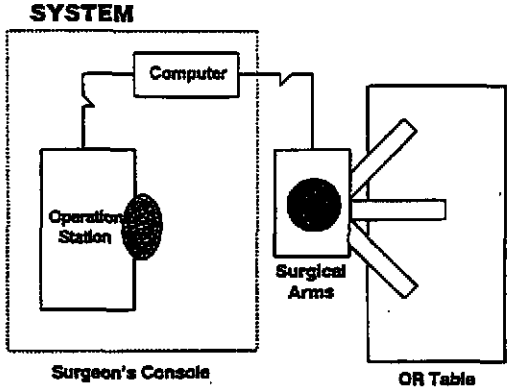
to make it possible for surgeons to operate on wounded soldiers from secure locations.[27] Moll bought a license for the technology and founded Intuitive Surgical, Inc. ("ISI"), in 1995.[28] ISI's only corporate offices in the United States are in Sunnyvale, California.[29] ISI also manufactures its robots in Sunnyvale.[30]

The ISI robot allows a surgeon working through a console to use to use remote-controlled instruments inside the body, as shown in the following schematic:[31]

SCHEMATIC OF INTUITIVE SURGICAL SYSTEM



[32]

Moll described this system in 1997 as "a new approach to minimally invasive surgery."[33]

B. In response to specific and explicit concern from the Food and Drug Administration, ISI promises to provide comprehensive training, objective assessment, and certification for would-be robotic surgical teams.

The novelty of ISI's surgical approach posed a hurdle in that the robot could not even be legally *advertised* in the United States when ISI began. ISI first sought permission to

[27] PT-240 ("Has the Real MIS Revolution Finally Arrived") at 2235.
[28] PT-240 ("Has the Real MIS Revolution Finally Arrived") at 2233 (founded ISI in 1995), 2235 (licensed technology).
[29] Exhibit B to Mullenix Declaration (Nagel Deposition) at 15:23-16:2. ISI's original offices were in Mountain View, California. It now also maintains an office in Switzerland.
[30] Mullenix Declaration at ¶ 4 (Ryan Rhodes testified that robots manufactured in California).
[31] PT-240 ("Has the Real MIS Revolution Finally Arrived") at 2236.
[32] PT-240 ("Has the Real MIS Revolution Finally Arrived") at 2237.
[33] PT-240 ("Has the Real MIS Revolution Finally Arrived") at 2233 (1997); 2236 ("new approach").

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advertise from the FDA in 1996.[34] The initial request sought permission only to market the device "to perform blunt dissection and to manipulate tissue, but nothing beyond that."[35] In other words, ISI's first request "included only instruments providing surgical assistance *i.e.,* retractors and graspers, rather than tools to perform surgical tasks, *i.e.,* scissors and cautery."[36] However, even for these basic functions, ISI assured the FDA that it would provide *training* for surgeons who would use the device.[37] The draft labeling that ISI provided to the FDA stated explicitly: "Appropriate training and instructions will be provided to ensure that the surgeon is sufficiently familiar with operation of the System to be able to effectively perform the desired surgical procedures."[38] The device was cleared for this limited purpose, with this understanding of "appropriate training," on July 31, 1997.

Even so, by January 1999,[39] ISI had still not sold a single robot[40] or trained a single surgeon in the US.[41] Accordingly, ISI sought to drastically expand the manner in which it could permissibly market its robot. In pursuit of this goal, ISI filed a new application with the FDA seeking clearance to market its robot for certain kinds of laparoscopic surgical procedures: "cholecystectomy" and "Nissen fundoplication."[42]

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[34] PT-242 (K965001 Cover Sheet) at 25599.
[35] Exhibit E to Mullenix Declaration (Kreaden Transcript) at 14:9-11.
[36] PT-145 at 31447; *see also* PT-253(Indications for Use Statement for K965001) at 3167 with PT-235 (Indications for Use Statement for K990144) at 27474.
[37] PT-59 at 3137 (providing revised labeling to the FDA "to clarify our intent regarding training").
[38] PT-59 at 3140.
[39] PT-241 (ISI Internal Timeline) at 27458, PT-231 (510(k) Summary) at 2706-2708.
[40] Exhibit E to Mullenix Declaration (Kreaden Deposition) at 72:13-17.
[41] Exhibit E to Mullenix Declaration (Kreaden Deposition) at 72:21-25.
[42] PT-231 (510(k) Summary) at 2706-2708, 2713. A cholecystectomy is a gall bladder removal procedure, while a Nissen fundoplication is a surgical procedure to address gastroesophageal reflux, or GERD.

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ISI filed this new request under the "Premarket Notification"[43] regulatory regime, rather than the more burdensome and rigorous "Premarket Approval"[44] regulatory regime. Although there are numerous differences between these two regimes, the primary difference is that the manufacturer need demonstrate only "substantial equivalence" to a predicate device under the Premarket Notification regime, whereas the manufacturer must show "safety and efficacy" when seeking PMA Approval.[45] While the manufacturer makes the initial election between these regimes, the FDA can unilaterally reclassify a proposed technology into the appropriate category once it begins to review the application.

On May 19, 1999, the FDA did just that, reclassifying ISI's device as a "Class III" device, meaning ISI would be required to undergo the more rigorous "PMA" process and receive "approval" for "safety and efficacy."[46] On June 16, 1999, ISI presented data in support of its now-PMA application to the Medical Devices Advisory Committee of the FDA's General and Plastic Surgery Devices Panel.[47] ISI's founder, Dr. Fred Moll, personally presented information to the Panel, which asked numerous questions about the learning curve and training plan for surgeons who would use the robot. Dr. Moll assured the Panel that ISI had specific, concrete plans for training on the device:

> I think in one sense surgeons never have enough training but, clearly, training is a very important part of this story and will be a very important part of how this system is introduced. There is no surgical device that is introduced and is

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[43] PreMarket Notification is also sometimes referred to as the "510(k)" process, which refers to § 510(k) of the federal Food, Drug and Cosmetic Act, which is now codified at 21 C.F.R. § 807.81-807.100.

[44] "PreMarket Approval" refers to § 515 of the federal Food, Drug and Cosmetic Act, which is now codified at 21 C.F.R. § 814.1-814.126.

[45] Exhibit E to Mullenix Declaration (Kreaden Deposition) at 46:19-47:2, 49:8-18.

[46] PT-236 at 2699; PT-55 (Panel Meeting Transcript) at 34 ("We submitted a 510(k) in January of this year and last month FDA made the decision to convert that 510(k) to a PMA.").

[47] *See* PT-55.

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> immediately picked up by the surgeon and used properly without training. I won't go into specific plans about how the system, if sold in the United States, will be trained. I am probably not the right person to do that, but it is at the top of our mind and we will have very clear plans for introducing a training protocol together with the sale of this device.[48]

Dr. Moll later added that ISI took training "very seriously," and even regarded training as "one of the keys to both clinical and commercial success."[49] The Panel advised that the robot was "approvable with conditions."[50] One of the conditions was training: "The sponsor needs to provide a comprehensive training program for the users of this device."[51] FDA notified ISI of the requirement on September 2, 1999.[52]

On November 26, 1999, ISI filed its proposed labeling and training program with the FDA.[53] The ISI employees who handled ISI's communications with and submissions to the FDA regarding training each worked out of ISI's California office,[54] and the majority of ISI's correspondence with the FDA in general "originated in California."[55]

In the November 1999 submission, ISI modified its earlier "indications for use" to indicate that the device was "intended for use by *trained* physicians."[56] The training program that ISI described to the FDA was intense, objective, and marked by constant "expert"[57] assessment.[58] ISI stated that "consistent assessment" was one of the "key components" of its training program, a lesson purportedly learned from "the pitfalls" of the "laparoscopic boom of

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[48] PT-55 at 78-79.
[49] PT-55 at 184.
[50] PT-100 at 26886-26887.
[51] PT-100 at 26886-26887.
[52] PT-100 at 26886-26887.
[53] PT-6.
[54] Exhibit E to Mullenix Declaration (Kreaden Deposition) at 34:23-35:5.
[55] Exhibit E to Mullenix Declaration (Kreaden Deposition) at 38:20-24.
[56] PT-6 at 799 (emphasis added).
[57] PT-6 at 815 ("Expert assessment" for Phases Two and Three).
[58] *See* PT-6 at 815.

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the late 1980's and early 1990's."[59] This assessment would apply to "both cognitive and motor skills competency," and it would occur "throughout the program."[60] It also meant ISI would "develop and document metrics."[61] ISI proposed that the training would occur "in phases," and would include "training centers."[62] The training centers would be required to "utilize standard performance assessment for each phase *prior to moving the learner to the next phase*."[63] ISI touted the effectiveness of its "phases" approach in its FDA submissions:

> Each phase accomplished will build the knowledge and skills necessary to prepare the learner to successfully perform his or her role in the recommended operation of the System. Additionally, each phase will allow the instructor and learner to assess knowledge and skills *prior to moving to the next module*. This will provide for the feedback and remediation that are so important in learning new knowledge and skills. [[64]]

The first phase would be a "distance learning program"[65] that would "mimic the cognitive activity required during actual performance."[66] The program would provide the knowledge "necessary to perform pre-operative System preparations, intra-operative use and preliminary troubleshooting, and post-operative care of the System."[67] It would also provide "a basic understanding of computer-assisted surgery and the System."[68] ISI proposed to asses performance with a "70-item, multiple-choice instrument" based on "curriculum learning objectives."[69] The entire "surgical team" would be required to pass this test.[70] By the end of

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[59] PT-6 at 814.
[60] PT-6.
[61] PT-6.
[62] PT-6.
[63] PT-6 (emphasis added).
[64] PT-6 at 815 (emphasis added).
[65] PT-6 at 814.
[66] PT-6 at 817.
[67] PT-6 at 814.
[68] PT-6.
[69] PT-6.
[70] PT-6.

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Phase One, ISI promised, among other things, that all surgical team members would be able to "Describe patient positioning and preparation"[71] and all physicians would be able to "Meet team objectives" and "Identify and describe System-specific surgical skills."[72]

The second phase was to be a "three-day, hands on program" at an "approved training center."[73] Whereas the first phase was to provide knowledge, the second phase was to provide "the practical skills necessary" for pre-operative preparations, intra-operative use, troubleshooting, and post-operative care of the System.[74] Because the entire team would attend, the "team" would also "gain a basic understanding of team dynamics necessary for successful use of the System."[75] ISI promised that "[p]erformance evaluation will be ongoing within the hands-on training throughout the course,[76] which would include "constructive simulation of procedures."[77] Moreover: "*Expert* evaluation … will determine mastery."[78]

Phase Three would occur "during installation at the site of the installed System."[79] The third phase would use an "installation/in-service training curriculum" to provide each of the above-numerated skills, teach more advanced troubleshooting skills,[80] and further guarantee that the team gained "a basic understanding of the team dynamics necessary for successful use."[81] Also, during this phase, both the "console" and "patient-side" surgeons would

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[71] PT-6 at 816.
[72] PT-6.
[73] PT-6 at 815.
[74] PT-6.
[75] PT-6.
[76] PT-6.
[77] PT-6 at 819.
[78] PT-6 at (emphasis added).
[79] PT-6 at 815.
[80] PT-6 at 815.
[81] PT-6 at 815.

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"advance their surgical skills" through "intense practice on surgical models."[82] ISI would also "introduce problem-solving activities during a surgical procedure."[83] Again, ISI promised that "Metrics" would be developed to "certify mastery, including time and accuracy."[84] Again, ISI promised that, with respect to the entire team: "Expert evaluation ... will determine mastery."[85]

Phase Four was to be conducted by the team itself as a "self-directed" curriculum. Though this portion was self-directed, ISI still promised that trainee surgeons would "*practice specific procedures* on surgical models, including cadaveric models[.]"[86] Doing so would "result in demonstrated mastery of competence in applying surgical skills to procedural applications."[87] This would occur "prior to application of the System to patients[.]"[88] And ISI promised to monitor the surgeons' performance during this phase: "Monitoring of performance within the Surgeon Skills Practice to Competence phase training will be ongoing throughout the phase."[89] By the end of Phase Four, ISI stated, all physicians would be able to "[d]emonstrate specific surgical skills applied to specific procedures" and even "[d]emonstrate to the Chief of Surgery the necessary competence for credentialing."[90] This would be determined by "[e]xpert and peer evaluation" and "successful completion of surgical procedures."[91]

ISI also promised, with respect to Phase Four, that that the company would provide the

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[82] PT-6 at 815.
[83] PT-6 at 821.
[84] PT-6 at 815.
[85] PT-6 at 815.
[86] PT-6 at 815 (emphasis added).
[87] PT-6 at 815.
[88] PT-6 at 815.
[89] PT-6 at 823.
[90] PT-6 at 822.
[91] PT-6 at 823.

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names of "experienced preceptors and proctors" that the hospital may access if it is necessary to the credentialing process.[92] ISI would also provide to hospitals "a training curriculum that can be used for training" for operating room staff and surgeons.[93]

To lend credibility to the training program it proposed, ISI stated that it was partnering with an outside firm to audit and improve its training program:

> Intuitive Surgical, Inc. is partnering with Medical Education Training Associates (META) to assess learning needs and develop and refine the curriculum in the pilot process. Additionally, META will assess the pilot program's success and design the curriculum, instructional design, and instructional delivery system for both training centers and installation sites. The META organization includes M.Ed. and Ed.D. level personnel who have had extensive experience in instructional design, simulation training, and industry sponsored device training.[94]

ISI included in its materials the curriculum vitae "of the principals" from META whom it proposed to work with.[95]

After reviewing ISI's proposed training program, the FDA responded on February 2, 2000, with a "Deficiency" letter.[96] With respect to the training program, the FDA mandated language changes, asked for definitions of terms used, and demanded that ISI provide the "tool of evaluation and criteria of success" for "each phase of the training."[97] The FDA also demanded that ISI produce a copy of the "70-item multiple choice instrument" it intended to use.[98] The FDA required ISI to provide "additional detail" and discussion about the training

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[92] PT-6 at 815.
[93] PT-6 at 815.
[94] PT-6 at 815.
[95] PT-6 at 815.
[96] PT-7 at 765.
[97] PT-7 at 765.
[98] PT-7 at 765.

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and criteria for success in Phases Three and Four.[99]

ISI produced its response on February 22, 2000.[100] With respect to Phase One (the distance learning program), ISI assured that a "da Vinci™ System trainer" would perform the evaluation of trainees, and even "provide[] feedback to the surgical team."[101] Likewise, a da Vinci System trainer would perform evaluations for Phases Two, Three, and Four. For Phase Three, ISI promised to "make the assessment data available to each team and the hospital official in charge of the da Vinci™ system training."[102] For Phase Four, ISI promised that its trainers' evaluations would be measured "against the [hospital] directed objectives for simulated intra-operative tasks."[103] In addition to those hospital-directed objectives, the Phase Four criteria for success would be measured with "the same instruments and evaluation as Phase III training,"[104] "based on the surgical team's use of the da Vinci™ surgical system as applied during targeted procedure(s)."[105] The evaluations in Phases Two, Three, and Four, would be "quantitatively assessed ... using a Likert-type scale of one to five (1=poor and 5=excellent)."[106]

On May 17, 2000, FDA sent *another* deficiency letter to ISI. This time, the FDA sought copies of the actual "distance learning materials" and "questionnaires" that ISI intended to use.[107] ISI responded the next day by producing its 64-page "comprehensive Training

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[99] PT-7 at 765.
[100] PT-8 at 2211-2212; PT-246 at 761 (providing date).
[101] PT-8 at 2211.
[102] PT-8 at 2214.
[103] PT-8
[104] PT-8 at 2215.
[105] PT-8 at 2215.
[106] PT-8 at 2211-2212.
[107] PT-10 at 27497.

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Package."[108] This training package confirmed that ISI's "Surgical Training Personnel" would be responsible for "instructional materials and facilitation" of the da Vinci training, meaning they would "Organize and facilitate" the training phases, "Assess performance" of the "da Vinci™ Surgical System gross tasks during training," "Coordinate proctor(s) as requested," and "Provide post training support as requested."[109]

ISI also provided more detailed information regarding each proposed phase of its training program. For instance, ISI actually provided the 70-item test it would use to assess Phase One performance.[110] For Phase Two, ISI listed out 23 different goals and objectives, promising to train on 22 of those goals during the three-day off-site training.[111] Relevant to this case, that training was to include: (a) "Patient Positioning and Preparation,"[112] which would require the trainee to "Describe and demonstrate patient position on table matching OR procedure;"[113](b) "Secondary troubleshooting,"[114] which addressed "Insufflator device operation and settings"[115] and required trainees to recognize when the "Position of Position of patient on [the] table [was] incorrect for da Vinci Surgical System procedure;"[116] (c) "Surgical skills", which required the surgeon to "Identify, perform, and evaluate the specific surgical

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[108] PT-10 at 27548-27614; PT-10 at 27497 ("comprehensive Training Package").
[109] PT-10 at 27549.
[110] PT-10 at 27554-27569.
[111] PT-10 at 27572 (day one), 27574 (day two), 27580 (day three). "Anesthesia considerations" was the only goal that ISI did not explicitly promise to train upon in Phase Two. As noted below, ISI did promise to train on anesthesia considerations in Phase Three. PT-10 at 27591.
[112] PT-10
[113] PT-10 at 27605.
[114] PT-10 at 27574.
[115] PT-10 at 27609.
[116] PT-10 at 27609.

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skills utilized during surgery using the da Vinci Surgical System and a training model,"[117] (d) "Interference of Arms, instruments, scopes, masters, and patient anatomy," which would address "body positioning (patient and table)"[118] with the surgeon; and (e) "Team Dynamics," which would require the entire team to be able to "Describe roles and responsibilities of individual team members, pre-procedure, intraoperatively, and post-procedure."[119] Each of these skills would be rated, from 1-5 (1 = Beginner, 5 = Expert), by the trainer.[120]

ISI also provided a 13-page agenda that would be used for the training.[121] Among the agenda items relevant to this case:

- A Day 2 lunchtime review of a "Pre-test."
- 3 tasks related to Patient Positioning and Preparation, including: "Describe and demonstrate patient position on table *matching sample OR procedure*."
- A two hour and 45 minute session for the entire surgical team in the "Cadaver or Animal Lab" for "LAP CHOLE AND/OR NISSEN". This includes a section called "Lap Chole or Lap Nissen Procedure," which included: "Identify, demonstrate and evaluate Surgical Skills." The lab session was followed by a 45 minute "SURGEON'S Review" session. That review session included a "Surgeon's Self Assessment of Surgical Skills."[122]
- Day 3 included, for the entire team, a one hour and 15 minute "Dry Lab" session plus four more hours in the "Animal or Cadaver Lab." That session would include more drilling on patient positioning and preparation and, among other things, another "Lap Chole or Lap Nissen."[123] The lab session was to be followed by another 45 minute Surgeon's Review, and another "Self Assessment

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[117] PT-10 at 27612-27613. These skills included: "Dissection – blunt/sharp; Tissue handling; Ligating; Holding/passing needles; Suturing skills - large and fine; Knot tying - tensioning large and fine' Ambidexterity; Vision - Anatomy identification within field of view/focal length. Identify skill performance differences with 2-D vs. 3-D. Perform and demonstrate non-dominate [sic] hand skills." *Id.*

[118] PT-10 at 27614.

[119] PT-10 at 27614.

[120] PT-10 at 27572 (day one), 27574 (day two), 27580 (day three).

[121] PT-10 at 27572-27585.

[122] PT-10 at 27579.

[123] PT-10 at 27583.

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of Surgical Skills."[124]

Finally, during the lunch break on the third day of the offsite training, the surgical team and expert trainers would "Create On-Site Plan/Agenda for Installation (Phase 3)."[125] At the end of that day, ISI assured, the entire surgical team would review its "Workshop Assessment and recommendations for On-Site training."[126]

In supplementing Phase Three, ISI explained that Phase Three would be the implementation of the On-Site Plan created as a result of the training and assessment done during Phase Two.[127] The Phase Three training agenda is similar to, but more detailed, than the Phase Two agenda. Again, ISI would train on the same list of 23 Goals and Objectives. Again, ISI would "Rate Team's Proficiency" from 1-5 (1 = Beginner, 5 = Expert).[128] ISI also provided a seven page list of specific tasks, correlated to the list of goals, that the trainees would be required to perform in order to earn their rating. For instance, the table that corresponds with Goal #5 (Patient Positioning and Preparation) requires the nurses and surgeons to "Describe and demonstrate patient position on table matching sample O.R. Procedure."[129]

Unlike the Phase Two agenda, the Phase Three agenda also included a section on "Anesthesia Considerations."[130] This portion of the Phase Three curriculum would require

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[124] PT-10 at 27585.
[125] PT-10 at 27585.
[126] PT-10 at 27585.
[127] PT-10 at 27588 ("This On-Site/Installation Plan is customized for each institution. It is derived from Instructor Assessments of the surgical team at the end of Phase 2 and from a needs assessment identified by the surgical team and Project Manager.").
[128] PT-10 at 27589.
[129] PT-10 at 27591.
[130] PT-10 at 27589.

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participation by the anesthesiologist, nurses, clinical technician, and surgeons.[131] It would require each of these participants to, in various ways: "Explain importance of patient positioning."[132] Also unlike Phase Two, Phase Three included a "Dry Run of Procedure with Training Model."[133] The dry run would include a section on the "Interference of ... Patient Anatomy," which includes demonstration of "Body positioning (patient and table)."[134]

Finally, ISI provided further detail on Phase Four, which it described again as "Surgeon Directed Training."[135] ISI explained that Phase Four would address "basic and advanced minimally invasive skills applied to the da Vinci™ Surgical System."[136] The surgeon, ISI assured, would "identify, perform, and evaluate the specific surgical skills utilized during surgery using the da Vinci™ Surgical System and a training model."[137] The surgeon would have "sufficient information to objectively assess and document the results" of this further training due to the "Didactic and practical experiences" conducted during Phase Two.[138] Moreover, ISI promised, the surgeons would complete a "self assessment ... at the completion of Phase Two and/or Phase Three."[139]

ISI even provided the forms that it would use for this self-assessment.[140] These forms required assessment of the "surgical skills used during surgery with the da Vinci Surgical System." This included assessment of the surgeon's mastery of the "Principles of

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[131] PT-10 at 27591.
[132] PT-10 at 27591.
[133] PT-10 at 27593-27594.
[134] PT-10 at 27593-27594.
[135] PT-10 at 27597-27960.
[136] PT-10 at 27597.
[137] PT-10 at 27597.
[138] PT-10 at 27597.
[139] PT-10 at 27597.
[140] PT-10 at 27599-27600.

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insufflation." The forms also required assessment of the surgeons' ability to perform the procedures themselves: i.e., the surgeon would be asked to rate whether they were "able to perform and demonstrate understanding of ... Minimally Invasive Cholycystectomy using the da Vinci™ Surgical System."[141] Likewise, a surgeon receiving training on Nissen Fundoplication would rate, after Phase Two and/or Phase Three, the surgeon's ability "to perform ... Minimally Invasive Nissen Fundoplication" with the da Vinci Surgical System.[142]

In summary, ISI promised the FDA a "comprehensive"[143] training program marked by "consistent"[144] assessment performed by "experts" using documented and specifically developed "metrics."[145] Phase One would be distance education followed by a 70-question[146] exam, specific "feedback"[147] from an "instructor,"[148] and "remediation."[149] Phase Two would be a three-day,[150] whole team,[151] hands-on[152] training course that would teach the trainees specific patient and table positions for specific procedures,[153] address insufflator settings,[154] and require the surgeons to perform the specific surgical skills[155] for a given surgery. 22 of 23 skillsets[156] would be taught, and each of those skillsets would be assessed with a Likert

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[141] PT-10 at 27599.
[142] PT-10 at 27600.
[143] PT-10 at 27497.
[144] PT-6 at 814.
[145] PT-6 at 814, 815.
[146] PT-6 at 814; PT-10 at 27554-27569.
[147] PT-6 at 815.
[148] PT-6 at 815.
[149] PT-6 at 815.
[150] PT-6 at 815.
[151] PT-6 at 815.
[152] PT-6 at 815.
[153] PT-10 at 27605, 27609.
[154] PT-10 at 27609.
[155] PT-10 at 27612-27613.
[156] PT-10 at 27572 (day one), 27574 (day two), 27580 (day three).

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rating.[157] This practical experience would also be sufficient[158] to allow for the surgeon to self-assess,[159] at that time, his or her ability to perform the given procedures[160] on humans with the da Vinci robot. The entire surgical team would then work with the expert trainers to create a plan[161] for the next phase: implementation. Phase Three implementation would require the console and patient-side surgeons to advance their surgical skills through "intense practice"[162] on "specific procedures"[163] using "cadaveric models."[164] Their performance would be compared by ISI against objective metrics and certified for mastery.[165] ISI would also make this assessment data available to the team and the hospital.[166] Phase Three would also require the surgical team to *incorporate* and educate an anesthesiologist[167] before conducting a "dry run."[168] Phase Four would ensure the surgeon had "sufficient information to objectively assess"[169] his or her readiness to perform actual, specific procedures: cholecystectomy and Nissen Fundoplication. And ISI promised to "partner"[170] with META to take advantage of META's "M.Ed. and Ed.D. level personnel"[171] as ISI and META further developed and assessed "the curriculum, instructional design, and instructional delivery system for both

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[157] PT-8 at 2211-2212.
[158] PT-10 at 27597.
[159] PT-10 at 27599-27600.
[160] PT-10 at 27599 (cholycystectomy), 27600 (Nissen fundoplication).
[161] PT-10 at 27588.
[162] PT-6 at 815.
[163] PT-6 at 815.
[164] PT-6 at 815.
[165] PT-6 at 815.
[166] PT-8 at 2214.
[167] PT-10 at 27591.
[168] PT-10 at 27593-27594.
[169] PT-10 at 27597.
[170] PT-6 at 815.
[171] PT-6 at 815.

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training centers and installation sites."[172] All of this was designed to ensure "demonstrated mastery of competence in applying surgical skills to procedural applications"[173] ***before*** surgeons operated unsupervised on live human beings.

C. Having received assurances regarding the proposed training, the FDA reclassifies and clears ISI's device for marketing of specific procedures.

Shortly after receiving ISI's "comprehensive Training Package," the FDA again reclassified ISI's application, switching back to the less rigorous Premarket Notification process.[174] Importantly, this regulatory change from Premarket Approval to Premarket Notification did not modify the application so far as it concerned ISI's promises regarding training of surgical teams. ISI thus admits that "the material that had been submitted prior to clearance, even if it was under a PMA designation," remained "part of the ... file."[175] As explained by Suzanne Parisian, M.D. – a former FDA Medical Officer and instructor at the FDA's "staff college" – ISI was *required* to provide no less than the rigorous training program described in its submissions:

> [I]t's their responsibility, introducing a new technology, to ensure that the physicians who are using it have adequate training and experience and knowledge before you allow them just to go off with a new device. And they took it upon themselves when they got the 510(k) clearance . . . . The company agreed voluntarily that they were going to do this, that it was a commitment.[176]

In fact, Parisian explained, the only way a product like da Vinci *could* have been cleared via Premarket Notification was with a commitment for "adequate physician training."[177]

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[172] PT-6 at 815.
[173] PT-6 at 815.
[174] PT-135 at 31448.
[175] Exhibit E to Mullenix Declaration (Kreaden Deposition) at 75:25-76:6.
[176] Exhibit F to Mullenix Declaration (Parisian Deposition) at 25:15-25.
[177] Exhibit F to Mullenix Declaration (Parisian Deposition) at 25:25-26:11 ("to make it equivalent, they have to make sure the physicians are trained to be able to use the product.").

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In its Supplemental Brief, ISI asserts that "the FDA did not impose a training requirement on Intuitive" before Intuitive was permitted to market the da Vinci Surgical System.[178] But even ISI's Chief Medical Officer, Dr. Curet, a CR 30(b)(6) designee, recognized the absurdity of the notion that *no* training was required by the FDA:

> if the FDA came and asked, we'd be required to prove to them that [ISI's training program] was adequate. So I think it's -- we can't just make a decision because it's easy for us, right? We have to make a decision that would satisfy that the FDA would agree that it was training them -- training the user safely on it.[[179]]

Indeed, Dr. Curet has gone further, having published an article stating that ISI's training program was ***mandated*** by the FDA.[180]

Ultimately, on July 11, 2000, the FDA cleared the device for marketing of the two laparoscopic procedures, laparoscopic Cholecystectomy and Nissen Fundoplication, *in the* United States.[181] In an application filed the next month,[182] ISI also sought clearance to advertise its robot for "general non-cardiovascular thoracoscopic procedures such as internal mammary artery mobilization."[183] ISI's application materials for thoracoscopic procedures contained a materially identical training proposal.[184] The FDA cleared that device for

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[178] Defendant Intuitive Surgical, Inc.'s Supplemental Brief in Support of Its Motion for Summary Judgment on All Claims and for Partial Summary Judgment on Plaintiffs' Claim for Punitive Damages, at 2. The parties' dispute regarding whether the FDA mandated training is not essential to resolution of this motion. The important point about ISI's extensive representations to the FDA about the type of training it would provide is that they represents ISI's own description of what it considered an appropriate training program, which contrasts starkly with the training it later provided.

[179] Exhibit G to Mullenix Declaration (Curet Deposition) at 47:13-18.

[180] *See* PT-68 at ¶ (I)

[181] PT-235 (July 11, 2000, clearance letter) at 27472-27474.

[182] *See* http://www.accessdata.fda.gov/cdrh_docs/pdf/k002489.pdf (accessed Jan. 3, 2013) (stating application for K002489 was prepared August 8, 2000).

[183] PT-239 (Clearance Letter for K002489) at 12314-12315.

[184] PT-11 at 10056-10103.

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marketing, via the Pre-Market Notification process, on March 2, 2001.[185]

At this point, however, ISI was still not allowed to market its robot in the United States for laparoscopic radical prostatectomy, the procedure Fred Taylor ultimately underwent in September 2008. Rather, as an ISI CR 30(b)(6) designee testified, ISI was required to submit a new pre-market notification to the FDA "every time [ISI] want[ed] to market a procedure in a new surgical specialty for which it doesn't already have clearance."[186]

D. ISI is caught by the FDA improperly marketing its device for prostatectomy.

Although it had not received clearance to market its robot for laparoscopic radical prostatectomy or cardiac procedures, ISI began to do so illegally in early 2001.[187] On February 20, 2011,[188] and again on and April 12, 2001,[189] the FDA sent "Warning" letters to ISI about its illegal "off-label" advertising. Specifically, the FDA informed ISI that its "promotion of the device for off-label uses such as prostatectomies and cardiac procedures misbrands and adulterates the da Vinci™ system," and ordered ISI to take "prompt action to correct these violations."[190]

E. ISI seeks FDA approval for prostatectomy, claiming "substantial equivalence" with its own prior FDA submissions, which included detailed training programs.

In response to these letters, ISI submitted a Pre-Market Notification application for clearance to advertise for laparoscopic prostatectomy.[191] ISI claimed "substantial equivalence"

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[185] *See* http://www.accessdata.fda.gov/cdrh_docs/pdf/k002489.pdf (accessed Jan. 3, 2013) (stating decision of substantial equivalency made March 2, 2001).
[186] Exhibit E to Mullenix Declaration (Kreaden Deposition) at 89:4-6.
[187] PT-136.
[188] PT-136.
[189] PT-27 at 1.
[190] PT-27 at 3.
[191] PT-92.

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with the three indications the FDA had earlier cleared: blunt dissection (K965001), laparoscopic cholecystectomy and Nissen fundoplication (K990144), and internal mammary artery mobilization (K002489).[192] ISI's robotic prostatectomy application did not indicate that it intended to modify the earlier, cleared iterations of its training programs. Rather, it submitted an indication that stated, like the earlier indications, that its robot was "intended to be used by trained physicians in an operating room environment."[193] ISI's Vice President of Clinical, Regulatory, and Quality Affairs certified to the FDA that "no material fact has been omitted" from the "data and information submitted in this pre-market notification."[194]

F. ISI's Gene Nagel drastically reduces the rigor of the training and assessment program under the guise of making the program more "efficient."

In November 2000, only four months after receiving its first surgical clearance, ISI hired Gene Nagel to take over (among other things) its surgeon training program. Nagel was not a physician or an educator. His college degree was in marketing and operations management.[195] After college, he had spent thirteen years as a salesman, first on behalf of two wineries, and then at a medical device company.[196] He then spent two years as a manager at the device company, "teaching the salespeople how to sell."[197] When he joined ISI in 2000, he had never had any higher education in the fields of education[198] or "medical related subjects."[199]

Despite his lack of relevant experience or education, in July 2001, ISI put Nagel in

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[192] PT-92.
[193] PT-92.
[194] PT-92 at 3247.
[195] Exhibit B to Mullenix Declaration (Nagel Deposition) at 10:1-11:1; 22:10-18.
[196] Exhibit B to Mullenix Declaration (Nagel Deposition) at 10:1-11:1; 22:10-18.
[197] Exhibit B to Mullenix Declaration (Nagel Deposition) at 11:2-10; 11:15-17.
[198] *See* Exhibit B to Mullenix Declaration (Nagel Deposition) at 10:5-6.
[199] Exhibit B to Mullenix Declaration (Nagel Deposition) at 19:12-15.

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charge of its ***surgeon*** training program.[200] Moreover, ISI allowed Nagel to make substantial changes to the surgeon training program without approval from anyone else at ISI.[201] ISI likewise chose not to partner with META to guide Nagel, despite its promise to the FDA to partner with META "to assess learning needs and develop and refine the curriculum" for the promised surgeon training. Nor did META "assess the pilot program's success and design the curriculum, instructional design, and instructional delivery system for both training centers and installation sites,"[202] as ISI had said it would. Rather, ISI's only contract with META concerned the training of ISI's *sales force* in how to best sell ISI's robot.[203]

Without META's guidance, and under Nagel's unqualified and unchecked direction, ISI drastically reduced the rigor and quality of the training program it had promised the FDA. Nagel testified that he did so because the existing training program was being done "inefficiently in terms of down time."[204] Specifically, the post-Nagel training program was not "comprehensive," was not marked by "consistent" assessments, was not conducted by "experts," and was not conducted using developed "metrics."[205] In fact, ISI never required that

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[200] Exhibit B to Mullenix Declaration (Nagel Deposition) at 8:15 ("customer training"); 18:11-23 (took over customer training in approximately July 2001).

[201] Exhibit B to Mullenix Declaration (Nagel Deposition) at 92:6-10.

[202] PT-6 at 815. ISI's failure to work, as promised, with META, is particularly dumbfounding given that Nagel had actually worked with Nagel at the device company he left to join ISI. Exhibit B to Mullenix Declaration (Nagel Deposition) at 117:11-15.

[203] PT-244 (META Letter) at 31583-31584.

[204] Exhibit B to Mullenix Declaration (Nagel Deposition) at 81:4; *see generally* Exhibit B to Mullenix Declaration (Nagel Deposition) at 79:24-85:7. In retrospect, it makes sense that Mr. Nagel cared so much about making the surgeon training program as short as possible. Damon Daniels, the ISI salesman who convinced Dr. Bildsten to "commit" to robotic surgery, testified that the "most common" objection he encountered from surgeons he sought to train was "time." Exhibit A to Mullenix Declaration (Daniels Deposition) at 272:11-17. Specifically, surgeons would say: "I don't have time to take away from my practice, I don't have time to train, I don't have time to come and spend time with you at the console and practice, time, period." *Id.*

[205] Exhibit H to Mullenix Declaration (Lederer Deposition) at 77:24-78:2.

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its "expert" trainers have any prior education in medicine or teaching.[206]

With respect to Phase One, ISI did not, under Nagel, provide a 70-question exam followed by specific "feedback" and remediation from an "instructor." Rather, the entirety of Phase One, which was developed and revised in California,[207] was simply a video that was less than one hour long and a ten question quiz.[208] Moreover, this quiz was impossible to fail because, when a trainee selected an incorrect answer, the online program would simply prompt the trainee to choose a different answer.[209] When the trainee finally selected the correct answer, only that correct answer would be recorded in the test taker's final score.[210] For this reason, *every test-taker receives a perfect score at the end of the exam.*[211] ISI had promised a distance learning program that would "mimic the cognitive activity required during actual performance" and ensure that all trainee surgeons could "[i]dentify and describe System-specific surgical skills." The program Nagel actually delivered for this phase was, in his words, a "very cursory basic overview of the system."[212]

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[206] Exhibit H to Mullenix Declaration (Lederer Deposition) at 16:19-17:3, 51:10-14; Exhibit B to Mullenix Declaration (Nagel Deposition) at 94:12-15.

[207] Exhibit B to Mullenix Declaration (Nagel Deposition) at 65:12-15.

[208] PT-5A at 31309-31321; Exhibit B to Mullenix Declaration (Nagel Deposition) at 87:9-11 ("I'm the one who -- who made the decision to convert it to an online module with a ten-question test.").

[209] *See*, PT-5A at 31309 ("Incorrect – Please Try Again"); PT-5 at 40:00-42:43 ("Your Score: 100; Max Score: 100"); Exhibit B to Mullenix Declaration (Nagel Deposition) at 63:5-15, 64:18-21 ("Q. But in this phase, there's no way to fail this test, is there, unless you have a heart attack in the middle or something? A. I don't know.").

[210] *See*, PT-5A at 31309 ("Incorrect – Please Try Again"); PT-5 at 40:00-42:43 ("Your Score: 100; Max Score: 100"); Exhibit B to Mullenix Declaration (Nagel Deposition) at 63:5-15, 64:18-21 ("Q. But in this phase, there's no way to fail this test, is there, unless you have a heart attack in the middle or something? A. I don't know.").

[211] *See* Exhibit B to Mullenix Declaration (Nagel Deposition) at 65:9-10 ("Q. Are you aware of anybody ever failing this test? A. I'm not.").

[212] Exhibit B to Mullenix Declaration (Nagel Deposition) at 64:4.

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Nagel reduced Phase Two from the promised three days down to one.[213] He also eliminated participation of the whole team as promised, limiting Phase Two just to the surgeons.[214] Phase two also did not include the promised training on insufflator settings[215] or require the surgeons to perform the specific surgical skills for a given surgery.[216] In fact, at the relevant time, only pigs (not cadavers) were used to train the surgeons trying to learn da Vinci prostatectomy,[217] and pigs do not even have prostates.[218] This revised Phase Two was finalized in California.[219]

Likewise, and contrary to ISI's promises, no Likert ratings were used in Nagel's Phase Two. In fact, no written forms are used at all.[220] Surgeons were not asked to self-assess, let alone given sufficient information to rate their own performance on a specific procedure.[221] In fact, the trainers would often be training two surgeons at the same time, meaning the trainers could watch only *half* of the activities they were supposedly assessing and correcting.[222]

At the end of Phase Two, there was no implementation plan created through the joint work of expert trainers and the entire surgical team so as to address specific skills or knowledge deficiencies. (In fact, there were no "expert" trainers.) Thus, that plan did not

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[213] Exhibit B to Mullenix Declaration (Nagel Deposition) at 88:13-89:7, 90:16-90:21; 99:7-8.
[214] Exhibit B to Mullenix Declaration (Nagel Deposition) at 100:6-100:23.
[215] PT-10 at 27609; Exhibit B to Mullenix Declaration (Nagel Deposition) at 47:14-15.
[216] Exhibit H to Mullenix Declaration (Lederer Deposition) at 45:5-10 ("As it relates to urology is nonspecific."); Exhibit G to Mullenix Declaration (Curet Deposition) at 63:16-19 ("Q. As I am understanding what you're saying, you're saying ISI does not train on how to do procedures, including robotic prostatectomy. A. That's correct."); at 76:14-15 ("We aren't in the position to teach somebody how to do a procedure.").
[217] Exhibit H to Mullenix Declaration (Lederer Deposition) at 81:18-20.
[218] PT-243 (Liberman Article Excerpt) at 18 ("pigs have no fat or prostate gland").
[219] Exhibit B to Mullenix Declaration (Nagel Deposition) at 67:18-67:6.
[220] Exhibit H to Mullenix Declaration (Lederer Deposition) at 77:24-78:2.
[221] Exhibit G to Mullenix Declaration (Curet Deposition) at 100:2-101:1.
[222] Exhibit H to Mullenix Declaration (Lederer Deposition) at 40:1-7.

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serve as a basis for any Phase Three work. In fact, there was no "standard performance assessment" for *any* phase.[223] Nagel decided to stop conducting performance assessments and self-assessments in approximately 2002.[224]

Likewise, Nagel's Phase Three did not require that surgeons advance their surgical skills through "intense practice" on "specific procedures" using "cadaveric models."[225] Rather, ISI's actual Phase Three consisted of a 45 minute "dry run" procedure that took place, without an anesthesiologist, the night before the first surgery on a live human.[226] ISI thus did not compare that performance against objective metrics or certify the surgeons for mastery.[227] Nor could ISI make any such assessment data available to the team or hospital.

Phase Four under Nagel was essentially non-existent. ISI does offer to find proctors for trainee surgeons and hospitals, for a fee,[228] but it refused to vouch for the experience of those proctors.[229] As noted for Phase Two, ISI did not ensure the surgeon had "sufficient information to objectively assess" his or her readiness to perform actual, specific procedures. In the absence of those assessments and remediation, Phase Four now consists solely of

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[223] Exhibit B to Mullenix Declaration (Nagel Deposition) at 76:24-77:1.
[224] Exhibit B to Mullenix Declaration (Nagel Deposition) at 79:21-23, 81:8-18.
[225] *See* Exhibit I to Mullenix Declaration (O'Connor Deposition) at 53:23-54:9, 54:11-12.
[226] Exhibit I to Mullenix Declaration (O'Connor Deposition) at 54:11-12 (training between offsite training and first cases consists of 45 minute dry run the night before the first case); Exhibit B to Mullenix Declaration (Nagel Deposition) at 74:4-5.
[227] Exhibit I to Mullenix Declaration (O'Connor Deposition) at 56:2-10 (no written evaluations or testing after Phase Two training).
[228] Exhibit J to Mullenix Declaration (Lohrasbi Deposition) at 54:22-55:1 (ISI told proctors how much to charge); 59:2-60:4 (ISI charged hospitals $3,000 for proctoring, $2,000 of which would go to the proctor, and $1,000 of which would go to ISI to reimburse proctor for travel expenses; ISI would reimburse surgeon only for travel expenses incurred, keeping the remainder).
[229] PT-256 at 25 ("Intuitive does not express or imply that a given proctor on the list satisfies any credentialing requirement of the User.... all Proctors listed or referred by Intuitive are independent contractors.").

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"advanced training and case observation."[230] And as later illustrated by Dr. Bildsten's experience, the "advanced training" that ISI offered to surgeons would *not* be provided the surgeons *before* their first live patient.[231] "Advanced training" was offered only to surgeons who had already "done an initial series of cases"[232] on live human beings.

A description of the training process to a surgeon by ISI in July 2008 shows the truly abbreviated nature of the surgeon training program implemented under Nagel. That description describes an "online orientation module" that the surgeon could expect to take "1 hour," an "onsite inservice" that the surgeon could expect to take "4 hours," offsite training on the "porcine model" in California (seven hours), and a "dry run first case" a "day or two prior to first case."[233]

To summarize, even as ISI sought clearance from the FDA to market for prostatectomy, Nagel was reducing ISI's surgeon training program without review by any medically trained person. ISI did this notwithstanding its claim that its prostatectomy submission was "substantially equivalent" to the two prior premarket notifications, each of which documented a rigorous training program. Moreover, ISI has never notified the FDA of any "changes that were made to that training protocol.[234] In the words of ISI's former director of clinical and regulatory affairs: "we did not believe it was necessary to inform FDA with every little change that was made to a training program."[235]

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[230] Exhibit B to Mullenix Declaration (Nagel Deposition) at 75:9-13.
[231] Exhibit B to Mullenix Declaration (Daniels Deposition) at 250:3-25.
[232] Exhibit B to Mullenix Declaration (Daniels Deposition) at 250:3-25.
[233] PT-238 (Carson Email of July 1, 2008) at 32425.
[234] Exhibit E to Mullenix Declaration (Kreaden Deposition) at 42:2-4, 66:21-67:5.
[235] Exhibit E to Mullenix Declaration (Kreaden Deposition) at 58:10-12.

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G. While the training program that ISI promised the FDA was arguably reasonable, the training program ISI has actually implemented is unreasonable.

Notably, no urologist has ever failed ISI's "certification" course.[236] Nor is there any indication that any other surgeon has failed any of the other phases of ISI's training program.[237] At trial, the plaintiff will present the testimony of William Helton, M.D. with respect to the reasonableness of the various iterations of ISI's surgeon training programs. Dr. Helton was one of the first general surgeons in America to use ISI's robot, and he also led one of the largest clinical and robotic surgery training programs in America in the early 2000s.[238] Dr. Helton has analyzed the material ISI presented to the FDA[239] and the evidence showing the actual training program ISI provided to surgeons when it trained and certified Dr. Bildsten.[240]

Dr. Helton concludes that ISI's initially proposed training program "could have been," with certain caveats,[241] "a reasonable introductory training regime for training surgeons on the use of the da Vinci system in surgery."[242] However, especially after the Nagel changes, that training program was unreasonably unsafe:

> 7. The actual training program, in use at the time of Dr. Bilstein's training, described by Nagel and Lederer lacks depth and breadth, is incomplete, and is potentially unsafe. There was no logical reason or rationale to scale back the

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[236] Exhibit H to Mullenix Declaration (Lederer Deposition) at 51:21-24.

[237] Exhibit I to Mullenix Declaration (O'Connor Deposition) at 111:6-14 ("Has any surgeon ever failed the online training? A. Not to my knowledge. Q. To your knowledge, has any surgeon ever failed the on-site training? A. Not to my knowledge. Q. To your knowledge, has any surgeon ever failed the off-site training? A. No.").

[238] Helton Declaration at ¶3.

[239] Helton Declaration at ¶4.

[240] Helton Declaration at ¶6.

[241] Helton Declaration at ¶5. Dr. Helton notes that even ISI's initially promised training regime would be insufficient if, as in the program ISI actually put in place, (1) the "expert" evaluators had no medical training and no educational training, and (2) ISI gave inaccurate representations during training about the learning curve for robotic surgery.

[242] Helton Declaration at ¶5.

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> program from the originally proposed training paradigm that was submitted to the FDA and it was inexcusable to do so for the reasons they state. Further, to suggest that any surgeon could be adequately trained to perform any type of major surgery using the da Vinci surgical system after only the level of training proposed is unfounded and unsupported by any data, a leap of faith, potentially unsafe, and irresponsible.
>
> 8. … It was ***not*** reasonable to reduce or scale back that training program as ISI did. Such a reduction in training could put patients at risk; the reasons stated by ISI for reducing that training do not justify that risk. The training program ultimately adopted by ISI and applied to Dr. Bildsten was inadequate and unreasonable to ensure patient safety.[243]

Moreover, Dr. Helton opines that, by the time of the Taylor surgery, ISI should have known (and warned) about the true nature of the learning curve for robotic surgery.[244] This knowledge was readily available from a host of published literature, much of which was authored by ISI's "own paid consultants[.]"[245] In fact, ISI's most prominent consultant, Dr. Vipul Patel, stated recently (after reviewing literature available in 2008) that the learning curve "to achieve ***basic competency*** for robotic radical prostatectomy" has been estimated to be between 20 and 25 cases.[246] In fact, when training its sales persons, ISI tells those sales persons that a surgeon's 11th through 20th procedures are the "Competence Development" stage.[247]

Dr. Helton, based on his review of the literature available to ISI in September 2008, concludes that ISI acted unethically in failing to fully disclose the nature of the learning curve:

> ISI had an ethical responsibility to inform Dr. Bildsten that it would likely take him 20 to 40 procedures before he could safely perform unsupervised da Vinci

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[243] Helton Declaration at ¶¶7-8.
[244] Helton Declaration at ¶¶9-13.
[245] Helton Declaration at ¶11.
[246] PT-232 (Patel et. al, Difficult Conditions in Laparoscopic Urologic Surgery (ISBN 978-1-84882-104-0), Chapter 16: "Difficulties in Robotic Radical Prostatectomy") at 209 (emphasis added).
[247] PT-73; Exhibit A to Mullenix Declaration (Daniels Deposition) at 194:8-196:3 (PT-73 accurately reflects the clinical sales process while Damon Daniels was at ISI.)

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> prostatectomy on the average patient, and 50 procedures before he could safely perform unsupervised da Vinci prostatectomy on a patient like Fred Taylor who was not an ideal robotic surgical candidate, especially for a novice surgeon on the robot. [248]

According to Helton, ISI "should also have given warnings of this nature to Harrison Medical Center."[249] As Helton notes, ISI had "numerous"[250] opportunities to provide this information to Harrison and Dr. Bildsten, and its decision not to do so was "irresponsible and reckless."[251]

H. ISI's business model.

When ISI formed, there was no market for robotic surgery devices. ISI recognized even in the late 1990s that one of its "big issues" was the surgeons' perception of "how user friendly or patient specific" its robot was.[252] It also recognized that it would have to sell initially only to "large, high-volume tertiary care centers who can make the huge capital investment."[253] It recognized that creating a demand for its "high cost"[254] product would depend using patients to create financial pressures on surgeons: "The last thing a surgeon wants is to have a patient walk in and talk about a friend who had a procedure done minimally invasively and have to say, 'I can't do that,' because he knows the patient will look for another doctor."[255] But even in the 1990s, ISI's goal was to drive the demand for its robot to such an extent that even small hospitals would be forced to purchase the robot: "Ten years from now, will we find these systems in 50-bed hospitals? ... I think it's a real possibility."[256]

ISI's method of achieving that reality is summed up in its sales motto: "Driving the

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[248] Helton Declaration at ¶15.
[249] Helton Declaration at ¶15.
[250] Helton Declaration at ¶18.
[251] Helton Declaration at ¶19.
[252] PT-240 ("Has the Real MIS Revolution Finally Arrived") at 2239.
[253] PT-240 ("Has the Real MIS Revolution Finally Arrived") at 2243.
[254] PT-240 ("Has the Real MIS Revolution Finally Arrived") at 2238.
[255] PT-240 ("Has the Real MIS Revolution Finally Arrived").
[256] PT-240 ("Has the Real MIS Revolution Finally Arrived") at 2243.

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Curve."[257] The "curve" *in* question is the "adoption curve" for robotic surgery,[258] i.e., the extent to which surgeons are performing given surgeries with the da Vinci robot as opposed to with open procedures or even non-robotic laparoscopy. ISI's express goal was to make the use of its robot the "Standard of Care"[259] for surgeons. And its sales documents from 2007 show that ISI was, at that time, intensely focused on "da Vinci Prostatectomy" ("dVP"): "2007 Marketing Strategy: dVP in <u>every</u> account![260] ... Drive incremental dVP growth at <u>all</u> hospitals!"[261] Pushing "dVP" in 2007 was labeled, to ISI's sales trainees, as ISI's "***Highest Priority***".[262]

ISI's efforts were remarkably successful. By the end of 2007, according to ISI, more than 60 percent of all prostatectomies nationally were being performed with the da Vinci robot.[263] Locally, by 2008, ISI had already sold (multimillion dollar) robots to eight Seattle- and Tacoma-area hospitals.[264] Swedish Medical Center had already purchased a *second* robot.[265]

By July 2008, ISI's procedure goals for dVP had grown even more ambitious. ISI's July 2008 Sales and Marketing Plan demanded that that its sales force "[d]rive dVP to standard-of-care in every market by achieving a minimum of 20 dVPs in every [hospital], in every quarter."[266] Higher level salespersons were responsible for a "minimum" of six

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[257] *See, e.g.*, PT-29 at 414.
[258] Exhibit B to Mullenix Declaration (Nagel Deposition) at 188:22-23.
[259] PT-29 at 409.
[260] By "account," ISI was referring to hospitals that had purchased robots.
[261] PT-29 at 412.
[262] PT-29 at 404.
[263] PT-1 at 1016.
[264] PT-1 at 1019.
[265] PT-1 at 1019.
[266] PT-149 at 31894.

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"greenfield" sales in 2008.[267] "Greenfields" were hospitals buying a robot for the first time, with no prior surgical robotics programs. Thus, those salespersons were each required to sell robots to six *new* hospitals in a single year. Because major hospitals had each already purchased systems by that time, ISI's sales force understood that *smaller* hospitals must be their focus. In the words of one of ISI's local salesmen: "Hospitals like Harrison are our future."[268]

Other high level ISI sales persons were required to make at least three "second system" sales in 2008.[269] To do so, those sales persons were required to "Create demand for additional da Vinci System acquisitions" by driving "procedure growth"[270] at hospitals that had already bought robots. By driving procedure growth, i.e., increasing the number of procedures at a given hospital that were performed with the robot, ISI could create "capacity and scheduling constraints" that would lead to "additional system sales."[271]

To drive procedure growth, ISI trained a large section of its sales force in "clinical" sales. These "Clinical Sales Representatives" ("CSRs") were judged and paid not on selling robots, but rather on the extent to which they were able to convince surgeons to *use* robots: i.e., to "maximize the utilization of installed do Vinci Surgical Systems."[272] ISI provided "case volume goals" to these CSRs, and it considered those goals "the only measure of success."[273]

For this reason, ISI actually paid its CSRs through a quota system based on *how many procedures were performed in the hospitals to which the CSR's were assigned.* For instance, in

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[267] PT-149 at 31894.
[268] PT-188.
[269] PT-227 (Drive the Curves 2008) at 31895.
[270] PT-227 (Drive the Curves 2008) at 31895.
[271] PT-227 (Drive the Curves 2008) at 31895.
[272] PT-80; Exhibit A to Mullenix Declaration (Daniels Deposition) at 189:19-90:10.
[273] PT-192.

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2008, the CSR assigned to Harrison Medical Center (Damon Daniels) was promised a $65,000 base salary.[274] However, if the surgeons to whom Daniels was assigned performed the required number ("quota") of surgeries, Daniels would receive $120,000 *more* per year plus a likely $15,420 in commissions for additional instrument sales.[275] If Daniels's surgeons performed more than 10 percent above quota, he received an automatic *additional* 15 percent bonus, making his total bonus $138,000. Consequences for failure were similarly stark: failing to hit at least 90 percent of the quota would mean a 75 percent reduction in procedure-based bonuses for Daniels in 2008.[276] As Daniels's manager (Sean O'Connor) warned him one month before the Taylor surgery: "Missing quota by one case is a significant financial hit."[277]

To enable its CSRs to convince surgeons to use its robot, ISI made a massive investment in *clinical* training of its sales staff. In contrast with its one-day surgeon training program, ISI's sales training was ***nine*** weeks long.[278] It consisted of a three-week distance education course, four[279] to six[280] weeks of intensive residential "Clinical and Sales Training" ("CAST") and then two more weeks of "field training" with an experienced CSR known as a "Field Trainer,"[281] followed by another week of "advanced CAST" in California.[282] One of the purposes of this training was to develop the CSRs' "Equal Clinical Stature skillsets,"[283] *i.e.*, to develop the CSRs' understanding of anatomy and medical terminology so that they have

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[274] PT-172 at 34222.
[275] PT-172 at 34222.
[276] PT-172 at 34222.
[277] PT-197.
[278] Exhibit A to Mullenix Declaration (Daniels Deposition) at 168:14-19; *see also* Exhibit B to Mullenix Declaration (Nagel Deposition) at 50:16-17.
[279] Exhibit A to Mullenix Declaration (Daniels Deposition) at 168:14-16.
[280] Exhibit K to Mullenix Declaration (Carson Deposition) at 47:17-22.
[281] Exhibit A to Mullenix Declaration (Daniels Deposition) at 168:14-19.
[282] Exhibit B to Mullenix Declaration (Nagel Deposition) at 159:20-22.
[283] PT-70.

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credibility when "talking about clinical benefits" with surgeons.[284] All CAST training was held at ISI headquarters in California.[285]

Once the CSRs emerged from CAST and field training, ISI provided each CSR with a "Clinical Sales Manager." The job of the CSM was to constantly monitor the CSR's progress. The CSM would hold weekly meetings with a small group of CSRs to motivate the CSRs and refine their sales techniques. These CSMs even required the CSRs to read new sales books each quarter.[286] The book for the fiscal quarter in which Fred Taylor's surgery occurred was called "Hardball Selling."[287]

In addition to this constant monitoring, all of ISI's sales force would meet annually for a week at a time at ISI's "World Wide Sales Meetings." At these meetings, ISI would continue the training by, for instance, teaching the CSRs how to persuade urologists that da Vinci Prostatectomy was a better option than brachytherapy, or external beam radiation therapy.[288] They would also further develop the CSRs' "equal clinical stature" skillsets by providing scripts to be memorized in how to "handle objections" from surgeons about the limitations or difficulty of using of ISI's robot.[289]

As a result of these trainings, ISI held high expectations for its CSRs. ISI's CSRs were expected to "[b]ecome a clinical expert across all primary OR procedures" in which the robot could be used.[290] One of a CSR's "core activities" was to "Develop surgeon competence."[291]

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[284] Exhibit P to Mullenix Declaration (Thompson Deposition) at 24:22-25:8.
[285] Exhibit K to Mullenix Declaration (Carson Deposition) at 48:14-22; Exhibit B to Mullenix Declaration (Nagel Deposition) at 136:7-9.
[286] PT-199; Exhibit I to Mullenix Declaration (O'Connor Deposition) at 189:1-8.
[287] PT-199; Exhibit I to Mullenix Declaration (O'Connor Deposition) at 189:1-8.
[288] PT-31.
[289] PT-102.
[290] PT-80; Exhibit A to Mullenix Declaration (Daniels Deposition) at 189:19-190:10.

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ISI expected CSRs to position themselves "as a partner in the development of surgical teams," and even "[d]evelop a clinical plan for each surgical team to insure they are capable of using the system independently within reasonable time frame."[292] And ISI expected CSRs to "[d]rive utilization of the da Vinci" by "partnering with surgical teams to ***review and select appropriate cases*** and insure consistent usage of the da Vinci."[293]

Importantly, other than the training they received at ISI, these CSRs had no medical or educational training. Damon Daniels, the CSR who worked with Dr. Bildsten, for example, had a 1995 business degree.[294] Nor has any other member of ISI's sales force yet deposed in this case had any prior medical or educational training.[295] Nonetheless, ISI expected these CSRs to be able to successfully challenge reluctant surgeons to convert previously scheduled open surgeries into robotic surgeries.[296] As one ISI Clinical Sales Director put it to a group of CSRs over whom he had direct authority:

> We've all invested a lot of energy into developing our Equal Clinical Stature skill sets. It is now a matter of putting all of that practice to action. Be proactive in finding cases to convert. Be prepared to challenge each trained surgeon every time you see a lap or open case. Be unsatisfied with the thought of ending a day without a converted case.[297]

"Converting," in this context, means finding a scheduled operation that a surgeon has decided to do without a robot, and convincing him against his initial judgment, to operate with the da Vinci.

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[291] Exhibit A to Mullenix Declaration (Daniels Deposition) at 193:21-194:4; PT-57.
[292] PT-80; Exhibit A to Mullenix Declaration (Daniels Deposition) at 189:19-190:10.
[293] PT-80 (emphasis added); Exhibit A to Mullenix Declaration (Daniels Deposition) at 189:19-190:10.
[294] PT-33.
[295] Paragraph 6 of Mullenix Declaration.
[296] See, e.g., PT-70.
[297] PT-70; *see also* Exhibit L to Mullenix Declaration (Ziegler Deposition) at 13:4-7 (ISI sales policies do not differ in significant ways between different geographical areas).

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ISI knew that its sales force would not be effective at challenging the clinical judgments of trained surgeons unless the sales persons believed fully in the value of da Vinci surgery. Accordingly, ISI chose not to teach its sales persons that new robotic surgeons might be dangerous to their patients,[298] that new robotic surgeons would have higher complication rates,[299] or "anything" that would make a CSR "question the value of da Vinci® surgery."[300]

Instead, ISI actually minimized the danger that new robotic surgeons posed to patients by teaching its CSRs to pressure hospitals to adopt only minimal credentialing and privileging requirements. The primary credentialing protections that hospitals would adopt for patients of new robotic surgeons were (1) completion of ISI's training program and (2) "proctoring," i.e., the personal supervision of a new robotic surgeon's procedures by an experienced robotic surgeon for some number of cases. Proctoring, stood in the way of ISI's goal of "driving" the adoption curve, however, because the higher a hospital's proctored procedure requirement, the less likely a surgeon would be to incorporate the robot into the practice, for two main reasons. First, the proctor surgeon would have to be paid $2,000-$3,000 per procedure by either the hospital or the surgeon, which made it more difficult for the CSR to convince new surgeons to perform procedures with the robot.[301] Second, the proctor surgeon's availability would limit the trainee surgeon's ability to book cases, meaning the surgeons would be unable to perform as many procedures as they could otherwise perform.[302]

ISI was able to combat this proctoring problem by having its sales persons closely

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[298] Exhibit A to Mullenix Declaration (Daniels Deposition) at 169:16-19.
[299] Exhibit A to Mullenix Declaration (Daniels Deposition) at 169:20-24.
[300] Exhibit A to Mullenix Declaration (Daniels Deposition) at 169:25-170:5.
[301] Exhibit A to Mullenix Declaration (Daniels Deposition) at 245:4-246:2.
[302] *See* PT-215 ("I have challenged him to get at least one more case on by the end of the month so that he can have the freedom to book his cases at his convenience, without having to worry about the logistics of a proctor.").

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associate themselves with the robotics steering and credentialing committees at the "Greenfield" hospitals.[303] These Greenfield hospitals relied so heavily on ISI's expertise that ISI would sometimes even set the agendas for the steering committee meetings.[304] Credentialing boards in such situations would look to ISI for guidance in adopting credentialing criteria.[305] ISI's non-medically trained sales persons would then respond by either (1) providing credentialing examples from other hospitals that had adopted only minimal requirements (and not providing those examples of hospitals that had adopted difficult requirements), or (2) outright telling the hospitals that their proposed credentialing requirements were too high, even if that proposed requirement was as low as five proctored surgeries.[306]

ISI's efforts to "drive the curve" have worked. According to its website, 2,462 da Vinci systems have been installed in over 1,936 hospitals worldwide.[307] As explained below, the CSR whose conduct is primarily at issue in this case (Damon Daniels), also achieved great success as a result of ISI's training. In fact, he was the top CSR in the entire world for the year of the Taylor surgery.[308] For context, ISI had 700 sales employees at the end of 2010.[309] Daniels was even promoted by ISI in 2009.[310]

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[303] "Greenfield" was the term ISI uses to describe hospitals without a da Vinci.
[304] PT-192.
[305] *See* Exhibit A to Mullenix Declaration (Daniels Deposition) at 202:15-23; 203:23-204:3; 205:3-9; 225:3-7; 225:13-16; Exhibit I to Mullenix Declaration (O'Connor Deposition) at 140:18-141:5; 141:13-23; Exhibit M to Mullenix Declaration (Gillam Deposition) at 14:1-19; PT-137; Exhibit N to Mullenix Declaration (Sanders Deposition) at 26:20-25.
[306] *See* PT-137
[307] http://www.intuitivesurgical.com/products/products_faq.html#19 (available: online; accessed Jan. 17, 2013).
[308] Exhibit A to Mullenix Declaration (Daniels Deposition) at 66:18-20; PT-33.
[309] PT-257 (2011 ISRG Annual Report) at 10.
[310] PT-33.

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I. The ISI "Recommendations," "Clinical Pathway," and "Partnership."

Although ISI denies in this litigation that it is willing or able to teach surgeons how to perform robotic procedures,[311] it admits that it provides each urologist it trains,[312] before the Sunnyvale training, with a document entitled: "The Clinical Pathway and Training Protocol for da Vinci Prostatectomy."[313] When training its salespeople, ISI defines this Clinical Pathway document as a "[p]rescribed, stepwise approach for surgeons and OR staff to develop knowledge and skills using the da Vinci Surgical System *in clinical applications*."[314] In fact, the CSRs understood that an ISI certification meant the surgeons had successfully completed "the protocol for their specialty" and were able to apply surgical skills "to procedural applications."[315] CSRs were explicitly told: "All necessary training for surgeons and nurses is built into the clinical plan."[316]

These representations about the comprehensive nature of ISI's training program were consistent with those ISI made to hospitals and the medical community at large. For instance, in 2007, ISI's California-based[317] marketing department authored a chapter in a "Robotic Urology"[318] textbook. The chapter stated without qualification that: "Intuitive Surgical's ***Comprehensive*** Clinical Training Continuum helps ***ensure*** optimal safety, efficacy, and

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[311] Exhibit G to Mullenix Declaration (Curet Deposition) at 76:14-15 ("We aren't in the position to teach somebody how to do a procedure.")

[312] Exhibit A to Mullenix Declaration (Daniels Deposition) at 231:23-25 ("Q. Were there ever times when you didn't go over the clinical pathway with a surgeon? A. No.").

[313] PT-42, Ex. A.

[314] PT 212 (emphasis added); Exhibit A to Mullenix Declaration (Daniels Deposition) at 258:10-22; 211:17-18 ("I told [surgeons] ... here's our clinical pathway document, you know, you should abide by this").

[315] Exhibit A to Mullenix Declaration (Daniels Deposition) at 266:1-8.

[316] PT-30 at 10878; Exhibit B to Mullenix Declaration (Nagel Deposition) at 59:10-11.

[317] PT-104 at XXII.

[318] PT-104.

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utilization of each Da Vinci system."[319] ISI also provided Greenfield hospitals (including Harrison)[320] with a document, on ISI letterhead, that is entitled: "Recommendations for Building a da Vinci Robotic Surgery Program."[321] That document recommends as a "fundamental best practice"[322] that surgeons "Follow the Prescribed Clinical Pathway,"[323] which "Your Intuitive Surgical Clinical Sales Manager (CSM) will establish … with you."[324] When presenting that document to Harrison during early sales meetings, ISI likewise told Harrison it was a "Best Practice" for "surgeons and staff" to "Follow Intuitive's prescribed training pathway."[325] Similarly, ISI told Harrison that "[p]artnership with Intuitive Surgical" was a "Best Practice" because ISI had "experience from 600 other launches".[326] As part of that process, ISI even promised the trainee surgeons and new hospitals: "Your Clinical Sales Representative will help measure your progress against state-of-the-art technique."[327] (ISI makes this representation to hospitals like Harrison even though its Chief Medical Officer claims ISI "is not in a position to measure a surgeon's performance against state of the art technique.")[328] This is all part of ISI's overarching assurance that it will play an active role in ensuring the success of the program: "The success of your implementation is a direct reflection of our effectiveness and our support."[329] These educational and marketing materials all

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[319] PT-104 at 259 (emphasis added).
[320] Exhibit K to Mullenix Declaration (Carson Deposition) at 32:19-33:2.
[321] PT-72.
[322] PT-72 at 1.
[323] PT-72 at 1.
[324] PT-72 at 6.
[325] PT-1 at 1026.
[326] PT-1 at 1026.
[327] PT-72 at 6.
[328] Exhibit G to Mullenix Declaration (Curet Deposition) at 99:23-100:1.
[329] PT-72 at 8.

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originate from California.[330]

ISI's "Recommendations for Building a da Vinci Robotic Surgery Program" document is also important in that it runs wholly counter to ISI's central theme in its summary judgment brief: that ISI training pertains to nothing but "the use of the da Vinci System" and specifically *does not* pertain to "a specific medical procedure."[331] In fact, ISI has a da Vinci Prostatectomy Procedure Guide that takes a urologist through every step of a robotic prostatectomy.[332] In the "Recommendations for Building a da Vinci Robotic Surgery Program," surgeons are instructed that as part of their training, they are to "[l]earn the procedure guide."[333] This is recommended by ISI as a "fundamental best practice."[334]

Likewise, the Clinical Pathway document also states that it is a "Training Protocol" for a specific kind of *procedure:* "da Vinci Prostatectomy." The Clinical Pathway states that it has been put "in place" to "ensure success in becoming a proficient robotic surgeon."[335] And the Clinical Pathway also states that it represents the "best practices around the country[.]"[336]

Among these purported "best practices" was a requirement that "2 cases must be booked" before offsite training would even be allowed by ISI.[337] In other words, ISI required the surgeons to book patients for robotic surgery *before those surgeons had received any robotic training.* ISI even threatened: "Training will be cancelled if cases are not booked."[338] With respect to proctoring, ISI recommended as a "best practice" that each trainee surgeon

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[330] Exhibit B to Mullenix Declaration (Nagel Deposition) at 24:18-24. PT-104 at XXII.
[331] *See, e.g.,* ISI MSJ at 12.
[332] PT-13.
[333] PT-73 at 6.
[334] PT-73 at 1.
[335] PT-42, Ex. A.
[336] PT-42, Ex. A.
[337] PT-42, Ex. A at HEDGES 0041.
[338] PT-42, Ex. A at HEDGES 0041.

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have only two proctored cases before beginning to work unsupervised.

Perhaps the most striking aspect of Pathway, however, is its intense focus on commitment to robotic surgery. The Pathway states in its first paragraph that becoming "a skilled robotic surgeon" takes "a high level of commitment early in the case series[.]"[339] ISI's sales persons even treat these Clinical Pathway documents as "contracts."[340] The CSRs ask the surgeons to *sign* the "contracts."[341] They do so for the express purpose of "gain[ing] commitment" from the trainee surgeon.[342] The CSRs then keep and maintain copies of those signed contracts,[343] telling the doctors that the CSRs will "help them maintain their commitment to robotic surgery" and "hold them accountable."[344]

In gaining this commitment, the CSRs would position themselves so that the surgeons viewed them "as a partner."[345] ISI even taught CSRs to portray themselves as "a strong partner" with the hospital.[346] As ISI put it, in the Recommendations document given to Greenfields: "Behind every successful robotic surgery program is not only a great deal of effort, but also a strong partnership with Intuitive Surgical. . . . With this in mind, we would like to be closely involved in the development and execution of your program."[347]

Despite their portrayal as "partners," the CSRs were by no means fully forthcoming

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[339] PT-42, Ex. A.
[340] Exhibit A to Mullenix Declaration (Daniels Deposition) at 230:1-6, 231:9-10.
[341] Exhibit A to Mullenix Declaration (Daniels Deposition) at 259:13-16.
[342] Exhibit A to Mullenix Declaration (Daniels Deposition) at 259:17-23.
[343] Exhibit A to Mullenix Declaration (Daniels Deposition) at 231:9-11.
[344] Exhibit A to Mullenix Declaration (Daniels Deposition) at 212:1-6.
[345] Exhibit A to Mullenix Declaration (Daniels Deposition) at 212:14.
[346] Exhibit A to Mullenix Declaration (Daniels Deposition) at 197:5-17.
[347] PT-72 at 1; see also PT-53 at 4143 ("Behind every successful da Vinci Surgery program is a strong partnership with Intuitive Surgical. Through the implementation of more than 930 da Vinci Surgery programs around the world, Intuitive Surgical has acquired the expertise and experience to facilitate development of a successful da Vinci program.").

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with the partner surgeons or hospitals. For instance, the CSRs would "never" tell the surgeons that the CSRs had a financial incentive to make sure that the surgeons actually performed procedures on humans with the robot.[348] Likewise, the CSRs would not tell the hospital steering committees that the CSRs "would be compensated based on the number of procedures done with the robot."[349] Rather, ISI's sales force learn to portray itself as entirely altruistic: "Everything we do is for the benefit of the patient."[350]

J. ISI approaches Harrison in April 2008.

In April 2008,[351] Dave Carson, an ISI "Area Sales Manager," began the process of convincing Harrison Medical Center to spend nearly $1.8 million on a surgical robot that no Harrison surgeon knew how to use. Intuitive had trained Carson that, to make such a sale, it was important to "[f]oster a competitive landscape between hospitals and surgeons."[352]

In doing so, Carson first recognized that, at that time, Harrison was "being challenged" by a new Gig Harbor hospital scheduled to open in 2009: Saint Anthony's.[353] Carson knew that the urologists who were performing surgeries at Harrison were "in discussions with Fransicans to move their practice to Gig Harbor."[354] Thus, to increase the pressure on Harrison to buy a robot, Carson began meeting with several Kitsap Peninsula surgeons, including the surgeons of Kitsap Colorectal, Kitsap Obstetrics and Gynecology, and Dr. Bildsten's clinic: Kitsap Urology.[355] He convinced each of these groups to send letters to the executives at

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[348] Exhibit A to Mullenix Declaration (Daniels Deposition) at 274:18-21.
[349] Exhibit A to Mullenix Declaration (Daniels Deposition) at 275:10-13.
[350] Exhibit L to Mullenix Declaration (Ziegler Deposition) at 42:25-43:1.
[351] PT-105.
[352] PT-254 at 4100.
[353] PT-105.
[354] PT-105.
[355] *See* PT-251; Exhibit K to Mullenix Declaration (Carson Deposition) at 141:6-25.

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Harrison, urging them to purchase a robot.[356]

At the same time, Carson began to exert pressure on Harrison by informing them that another of Harrison's "competitors," St. Joseph's Hospital in Tacoma (CHI), was in the process of buying its second robot.[357] Carson informed Harrison that "historically," CHI had requested "market protection" from ISI, i.e., that CHI would negotiate its purchase so that ISI would not sell robots to CHI's competitors in the same geographical area.[358] In other words, to create urgency for Harrison, ISI threatened to make an agreement with Harrison's competitor that would cause Harrison to lose patients. Internal ISI emails show that Carson and his Clinical Sales Manager worked together to convince Harrison that "market protection" was a real, potentially devastating, threat.[359]

While he applied all of this pressure, Carson also made numerous representations about the effectiveness of ISI's training program.[360]

> Intuitive Surgical would like to be an integral part of your *da Vinci* Surgery program. We can:
>
> - Take the lead in coordinating *da Vinci* System installation, on-site training, staff in-servicing and surgeon training
> - Be part of the robotics steering committee if the hospital decides it is necessary
>
> * * *
>
> - Work with surgeons to develop and execute their clinical paths
>
> * * *

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[356] *See* PT-251.
[357] Exhibit K to Mullenix Declaration (Carson Deposition) at 68:16-69:1.
[358] Exhibit K to Mullenix Declaration (Carson Deposition) at 73:1-7.
[359] Exhibit I to Mullenix Declaration (O'Connor Deposition) at 166:18-167:2; *see also* PT-258 (June 6, 2008, email) at 32713 ("How did you want me to fwd this [market protection request] on to you?"); PT-259 to Mullenix Declaration (June 9, 2008, email) at 32287 ("Please do not commit to any market protection requests from St. Joe's until I get back to you on Wednesday. I will bring this up to them in person tomorrow night.").
[360] PT-108 at 30611.

- Actively support cases in the OR; …
- Work with entire team to develop technical competency [361]

With respect to training, Carson told Harrison's purchasing staff that ISI's training programs were "designed to provide surgeons with the knowledge and skills necessary to utilize the da Vinci S Surgical System *for its intended use in a variety of endoscopic surgical procedures*."[362] He told Harrison the training would be performed by "Experienced faculty."[363] And he promised ISI would make "Surgeon led proctoring" available for $3,000.[364] And to help the Harrison executives justify the expense of the purchase, Carson even provided them with a draft "Business Plan for the da Vinci Robotic Surgery System At Harrison Medical Center."[365]

K. ISI illegally informs Harrison that its device has been "approved" by the FDA.

ISI's sales tactics included repeatedly suggesting to Harrison that the FDA had "approved" its device for certain surgical procedures. As even ISI's retained FDA expert (Phillip Phillips) will explain at trial, FDA regulations bar device companies from doing anything to suggest that the FDA has given official approval of a device unless the manufacturer has successfully put the device through the rigorous Premarket Approval process.[366] Nevertheless, ISI directed communications squarely at Harrison that stated that its system had been "approved" by the FDA. For instance, the "Business Plan" that ISI provided to Harrison to support the purchase stated – misleadingly – that da Vinci gynecologic surgery

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[361] PT-72 at 8.
[362] PT-108 at 30611 (emphasis added).
[363] PT-108 at 30611.
[364] PT-108 at 30611.
[365] PT-115.
[366] Exhibit O to Mullenix Declaration (Phillips Deposition) at 65:10-20 ("A. … there is a regulation that prohibits suggesting that anything cleared through 510(k) is an approval by FDA. Q. And that regulation goes on to say that suggesting that is considered misleading and misbranding; correct? A. That's correct. Q. And in fact, when a device is cleared under 510(k), it does not indicate approval of the device by FDA? A. That's correct.").

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was "FDA-approved" in May 2005.[367] Likewise, another sales communication with Harrison states ISI's robot "has been used in over 100 different types of surgical procedures."[368] After listing a "sampling" of some 44 different procedures, ISI then states to Harrison: "*Certain* clinical applications have not *yet* been approved in the US."[369] In reality, no procedure has ever been "approved" in the US.[370]

These communications to Harrison were not isolated incidents. In fact, one of ISI's own paid consultants stated in a published article that the FDA had approved some forms of da Vinci surgery, and ISI would regularly provide that article to surgeons and hospitals.[371] ISI's press release templates all stated, incorrectly, that the robot received "FDA approval ... in 2001."[372] Even ISI's chapter in the textbook, ***Robotic Urology*** stated that ISI had received "U.S. Food and Drug Administration approval in 2005."[373]

L. The Sale and Implementation at Harrison.

Not surprisingly, Harrison ultimately agreed to buy a robot. The sale was finalized on June 20, 2008.[374] For the robot, and a five year service plan, Harrison paid $1,754,500. With Harrison's instrumentation order, the total purchase price was $1,870,167.50.[375] Although

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[367] PT-115 at 30651.
[368] PT-108 at 30610.
[369] PT-108 at 30610 (emphasis added).
[370] *See* Parisian Report at 8 (citing 21 C.F.R. § 807.97 (1996)).
[371] *See, e.g.,* PT-122 at 30 ("The da Vinci robot ... remains the only Food and Drug Administration (FDA)- approved master–slave surgical system still in existence able to provide the benefits necessary for the facile performance of robotic surgery."); *id.* at 29 (stating Dr. Patel a "paid consultant" of ISI); Exhibit __ to Mullenix Declaration (Thompson Deposition) at 57:9-19 (stating that Thompson regularly provides PT-122 to customers).
[372] PT-229 (Press Release) at 31870; *see also* PT-260 (ISRG Q2 2012 Earnings Call Transcript) at 11 ("we are FDA approved in the US for chole").
[373] PT-104.
[374] PT-110 at 30631.
[375] PT-120.

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training of surgeons could be purchased separately from the robot, ISI included free training for six surgeons:

> Intuitive shall provide training in the use of the System to Purchaser's surgical personnel. As of the Effective Date of this Agreement the price for such Training shall be three thousand dollars ($3000) per surgeon or physician's assistant. Notwithstanding the above Intuitive agrees to provide training to six (6) surgeons as set forth above, at no charge, provided such training is completed within the first twelve (12) months of the Initial Term of this Agreement. [376]

Even before the sale was finalized, and as recommended by Carson, Harrison formed a "DaVinci Taskforce" (which was later renamed "Da Vinci Steering Committee").[377] On the Committee were several of the surgeons who had written letters in support of the robot at Carson's behest, including Dr. Bildsten.[378] These were also many of the surgeons who would receive Harrison's free training slots (including Dr. Bildsten).

ISI's Dave Carson, Sean O'Connor, and Damon Daniels attended the Task Force/Steering Committee.[379] All three salesmen were supervised by Glenn Vavoso, who worked out of ISI's headquarters in California.[380] And the Commission Plans of all three salesmen were, at ISI's demand, "governed by the laws of the State of California."[381]

After the first meeting, O'Connor privately "expressed some doubt about the potential quality" of Harrison's robotics program to Carson.[382] Carson reminded O'Connor "not to communicate any bias against Harrison" because "Hospitals like Harrison are our future."[383]

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[376] PT-110 at 30627.
[377] PT-82.
[378] PT-82.
[379] PT-82.
[380] Exhibit K to Mullenix Declaration (Carson Deposition) at 20:12-21:2; Exhibit B to Mullenix Declaration (Nagel Deposition) at 12:17-25.
[381] PT-221 at 34227; PT-210 at 34338; PT-261 at 34257.
[382] PT-188.
[383] PT-188.

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He warned O'Connor that his concerns "shouldn't extend beyond you and me."[384]

In the meantime, the Committee had to decide credentialing criteria for robotic surgery at Harrison. No one on the Committee had any experience as a robotic surgeon. As one of the non-physician members of the Committee, Mickey Sanders, put it: "we had nothing to start with, and so … we were looking to the reps … to tell us what is the community standard in the other hospitals[.]"[385] Sanders said that ISI's representatives first provided the Committee with the Clinical Pathway Document—the document that sets a standard of "2 Cases or Hospital Protocol." According to Sanders: "That was kind of … where we started[.]"[386] As Sanders continued to gather information on credentialing criteria, there continued to be "input from the da Vinci rep[.]"[387] According to the Steering Committee notes, this input included "samples of credentialing criteria" provided to Sanders by ISI's O'Connor or Carson.[388]

The following week, Sanders presented draft Credentialing Criteria to the Committee which, in every material respect, mirrored the ISI Clinical Pathway Document.[389] These criteria were later adopted.[390] Under the adopted criteria, Dr. Bildsten would not be allowed to perform robotic surgery until he had "documented successful completion of the hands-on

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[384] PT-188.
[385] Exhibit N to Mullenix Declaration (Sanders Deposition) at 26:20-25.
[386] Exhibit N to Mullenix Declaration (Sanders Deposition) at 28:19-21; 27:17-21.
[387] Exhibit N to Mullenix Declaration (Sanders Deposition) at 33:13-17; 40:23-41:3 ("Q. And there was an earlier minute that we looked at from one of the earlier meetings where Mr. Carson or one of the Intuitive reps was going to get you material on credentialing. Did they ultimately do that? A. They did, but could I -- I couldn't sit here and tell you in what form it was, was it conversation, documents.").
[388] PT-82.
[389] PT-83; PT-229 (Bildsten Credentialing Application) at BATES 50158-50159; compare with PT-42 (Clinical Pathway).
[390] *See* PT- 262 (Bildsten Credentialing Application).

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training ... required by the manufacturer."[391] This was the training that ISI offered him in Sunnyvale, California.[392]

Another issue confronting the Committee was whether to get a new operating table for urology procedures. The Committee had money in its budget for a new table if necessary, and wanted to assure that any table it bought "can better accommodate obese patients."[393] On June 20, 2008, Dave Carson emailed Harrison's Director of Surgical Services to confirm that "any table will work" with the robot.[394] Under this assurance, Harrison elected to not to buy a new table.

ISI also convinced Harrison through the Steering Committee process to make one of its staff members, Perla Lapidario, a dedicated da Vinci "robotics coordinator." ISI even brought Ms. Lapidario to California for training as robotics coordinator.[395]

By the July 1 Steering Committee meeting, Carson was ready to hand the Harrison Steering Committee over to the "clinical team" of Damon Daniels (the CSR who would work directly with Harrison's surgeons) and Sean O'Connor (Daniels's supervisor).[396] At that meeting, according to Carson, Daniels and O'Connor "really established themselves as experts."[397] They did so by again reinforcing the need for surgeons to "commit" to the Clinical Pathway.[398] They also did so by presenting ISI's "marketing toolkit," which ISI provided to hospitals as part of the sale. The toolkit included numerous marketing resources that would

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[391] Exhibit Q to Mullenix Declaration (Bildsten Deposition) at 53:25-54:8.
[392] Exhibit Q to Mullenix Declaration (Bildsten Deposition) at 54:6-8.
[393] PT-82 at 2.
[394] *See* PT-186, PT-187.
[395] Exhibit R to Mullenix Declaration (Lapidario Deposition) at 23:9-23.
[396] *See* PT-84; *see also* PT-191.
[397] PT-191.
[398] *See* PT-118 at 30808; PT-84.

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allow ISI to help the hospital market da Vinci surgery to nearby patients.[399] Included in these resources were ISI brochures designed to tell potential patients: "Your doctor is one of the growing number of surgeons worldwide who's been *successfully trained* in providing leading-edge treatments *such as da Vinci Prostatectomy*."[400]

Finally, at the July 1 meeting, ISI presented a three-page implementation timeline for the da Vinci program at Harrison.[401] The plan ISI presented included detailed entries, complete with dates and persons responsible, for every step ISI suggested Harrison take, including the date credentials should be decided, install dates for the robot, the date the proctor would be scheduled for the first case, the date a "Core Four" staff team would be selected, the dates the surgeons would discuss the Clinical Pathway, and numerous other scheduled events.

According to the implementation timeline, the conversation with Dr. Bildsten and Damon Daniels regarding the Clinical Pathway should have taken place on July 2, 2008.[402] If the conversation did take place that day, then Daniels should have learned by that day that it would be impossible, given the patient volume of Dr. Bildsten's urology practice, for Dr. Bildsten to meet the procedure volume requirements of the Clinical Pathway. For instance, Dr. Bildsten had completed only approximately 100 prostatectomy procedures in the 16 years since beginning his residency in 1992.[403] Thus, Dr. Bildsten could not be reasonably expected to be able to pick and choose "simple cases" with "Low BMI" if he was also to follow ISI's

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[399] PT-118 at 30820 ("Integrated Marketing Implementation Plan, Print Ad Samples & Templates, Website Samples & Templates, Television Ad B-Roll, Patient Education Videos, Patient Hospital Posters, Patient Education Brochures & Seminars, and Referring Physician Seminar" materials).

[400] PT-152 at 2 (emphasis added).

[401] PT-121.

[402] PT-121 at 30838.

[403] Exhibit Q to Mullenix Declaration (Bildsten Deposition) at 42:21-43:13.

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instruction to perform "one case per week in order to get through the learning curve as quickly as possible."[404] He simply did not have enough patients to be selective ***and*** follow the Pathway.

Even so, Dr. Bildsten committed to Daniels to follow the pathway.[405] Dr. Bildsten traveled to California for his one-day training at the porcine lab on July 17, 2008.[406] Damon Daniels traveled to California with Dr. Bildsten for training.[407] He did so to give Dr. Bildsten "a sense of comfort."[408]

Because of the changes Mr. Nagel had made years prior, Dr. Bildsten received almost none of the training or assessment ISI had first promised to the FDA.

It is unclear what Dr. Bildsten did in the way of further training between his Sunnyvale training and his first procedures, which took place on July 28-29, 2008. Damon Daniels testified that surgeons will generally do some practice with him in the week leading up to their first procedures, though he had no specific recollection of Dr. Bildsten engaging in such practice.[409] Daniels explained that surgeons get value from this practice because, despite the fact that they have already been "certified" by ISI at the Sunnyvale training, they still have many questions about how to work the robot. Regardless, Daniels testified that Dr. Bildsten never refused any request Daniels ever made of him regarding training.[410]

Dr. Bildsten's first two procedures were proctored by a doctor from Tennessee.[411] The

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[404] PT-42.
[405] Exhibit A to Mullenix Declaration (Daniels Deposition) at 259:13-18; 231:23-25.
[406] PT-41 at 319.
[407] Exhibit A to Mullenix Declaration (Daniels Deposition) at 39:15-40:2.
[408] Exhibit A to Mullenix Declaration (Daniels Deposition) at 40:5-9.
[409] Exhibit A to Mullenix Declaration (Daniels Deposition) at 180:20-181:7.
[410] Exhibit A to Mullenix Declaration (Daniels Deposition) at 214:21-24.
[411] PT-96, PT-94.

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proctor was arranged by Daniels through ISI's California-based Training Department,[412] and Dr. Bildsten had no choice in who would be his proctor.[413] (ISI required its proctors to agree that California law would govern any disputes between ISI and the proctors.[414]) Harrison paid a proctor fee to ISI, and the proctor was then paid by a check from ISI.[415] A traditional open prostatectomy in the hands of an experienced surgeon would take 2.5 hours.[416] ISI trained its sales persons to tell surgeons who were reluctant to adopt da Vinci that "most da Vinci surgeons today perform quality radical prostatectomy procedures in less than two hours." Dr. Bildsten's first two robotic procedures took 9.5 and 7.5 hours respectively,[417] despite the fact that both patients were relatively easy patients.[418]

ISI has produced no records to reflect any training or assessment of Dr. Bildsten's skills during or following those two proctored procedures. There is no evidence that Daniels suggested any "advanced" or additional training to Dr. Bildsten following these procedures. Dr. Bildsten did not have another opportunity to perform any prostatectomy, robotic or open, until Fred Taylor's surgery on September 9, 2008.[419]

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[412] Exhibit A to Mullenix Declaration (Daniels Deposition) at 49:7-50:2.
[413] Exhibit Q to Mullenix Declaration (Bildsten Deposition) at 157:11-13.
[414] Exhibit J to Mullenix Declaration (Lohrasbi Deposition) at 63:22-64:15.
[415] Exhibit J to Mullenix Declaration (Lohrasbi Deposition) at 30:19-25. The hospital would have to pay ISI $1,000 for the proctor's travel expenses, even if those travel expenses did not total $1,000. The proctor received reimbursement from ISI only for his actual travel expenses. *Id.* at 59:2-60:4.
[416] PT-93 at 3263.
[417] PT-94.
[418] Exhibit Q to Mullenix Declaration (Bildsten Deposition) at 139:25-140:15.
[419] PT-265 (Plaintiffs' Third Set of Interrogatories and Second Set of Requests for Production Propounded to Defendant Scott Bildsten, DO, with Responses) at RFP No. 39 (July 28, 2008-September 9, 2008).

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M. The Taylor Surgery: *Dr. Bildsten's first non-proctored procedure.*

Fred Taylor had a biopsy sample diagnosed with prostate cancer on August 16, 2008.[420] He was 67 years old, had undergone coronary artery bypass graft surgery six years prior, and had undergone an umbilical hernia repair with mesh before that.[421] He was obese, with a BMI of 39. Even so, he was in good general health and would fish, swim, and golf.[422]

Open prostatectomy, the type of surgery that Dr. Bildsten had performed his entire career, is "routinely performed for localized prostate cancer, with excellent results and minimal morbidity."[423] Dr. Bildsten had never had a complication during an open prostatectomy.[424] *da Vinci* Prostatectomy, on the other hand, is far more difficult for new robotic surgeons to safely perform. For instance, surgeons early in their da Vinci learning curve face the danger that the surgery will take a very long time.

ISI had trained Damon Daniels to believe that Bildsten had learned "all necessary skills" to perform da Vinci Prostatectomy. It had trained and authorized Daniels to "partner" with surgical teams "to review and select appropriate cases." It had financially incentivized Daniels to try to convince surgeons to perform *every* prostatectomy with the robot. It had not trained him to seek a proctor for particularly challenging cases,[425] and Daniels recognized that the necessity of a proctor (at $3,000 per surgery) can make it more difficult to convince surgeons to perform surgeries with the robot.[426] This problem is such an impediment to a

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[420] PT-263 at 100120 (9/5/2008 Surgical Note).
[421] PT-263 at 100120 (9/5/2008 Surgical Note).
[422] Exhibit S to Mullenix Declaration (Josette Taylor Deposition) at 55:10-56:7, 81:17-85:12, 85:14-90:3.
[423] PT-93 at 3262.
[424] Exhibit Q to Mullenix Declaration (Bildsten Deposition) at 134:20-22.
[425] Exhibit A to Mullenix Declaration (Daniels Deposition) at 283:1-12.
[426] Exhibit A to Mullenix Declaration (Daniels Deposition) at 245:17-246:4.

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CSR's ability to meet his procedure quota that one ISI manager even explicitly ordered his CSRs: "Don't let proctoring or credentialing get in our way."[427] Thus, Daniels never made any attempt to even suggest that Bildsten have a proctor for the Taylor surgery.[428] Rather, with Daniels as his "partner," Dr. Bildsten decided to use the robot for the Taylor surgery.

The Taylor surgery took place on September 9, 2008. Though no surgeon proctor was present, Damon Daniels *was* present in the operating room for the surgery. Daniels believed it was his "responsibility" to "be there to help" the surgeons in the operating room, and he told the doctors as much.[429] According to Daniels, the device is so complex that questions remain even after (1) physicians have been trained and certified by ISI, (2) the staff has gone through an in-service with the CSR, (3) hospital credentialing requirements have been satisfied, (4) the surgeons have had additional practice with the robot, (5) the surgical team has had a dry run of the procedure, and (6) the surgeon has successfully completed two proctored surgeries:

> It's a lot -- it's an intricate device. It is a lot of stuff. I mean, it's not just one instrument taken in and fire it, and then you're done. There's a lot of hand movements. There's a clutch. There's a camera. There's things to control that you need to be comfortable with, and it takes some time to do that. There's a lot of stuff to remember. And you know, after -- after those things you just mentioned, you know, it's not that easy to remember everything.[[430]]

One of ISI's proctors offered a similar assessment, testifying that the ISI representatives are present in the operating room "for the first couple hundred cases" because the robot is such a "complex machine."[431] In fact, when he was asked whether "it would be safe" for a surgeon to perform an unsupervised surgery without a proctor *or* a CSR there, the response by Daniels

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[427] PT-99.
[428] Exhibit A to Mullenix Declaration (Daniels Deposition) at 284:2-6.
[429] Exhibit A to Mullenix Declaration (Daniels Deposition) at 206:5-24.
[430] Exhibit A to Mullenix Declaration (Daniels Deposition) at 302:1-303:12.
[431] Exhibit J to Mullenix Declaration (Lohrasbi Deposition) at 78:20-21.

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was: "I would prefer to be there."[432]

With no proctor present, preventable errors were made from the start. First, Bildsten began the surgery by "insufflating" (inflating) Mr. Taylor's abdomen at "20mmHg pressure."[433] An unnecessarily high level of pressure exacerbates the harmful effects of a long surgery:

> Insufflation pressures as high as 20 can cause renal failure. They can cause decreased cardiac output. They can cause ventilatory profusion and ventilation mismatches in the lung. The increased intra-abdominal pressure can push CO2 into veins and cause an increase in end *title* CO2. They can cause acidosis.[434]

After Mr. Taylor was insufflated, it became clear that the operating table ISI had earlier recommended was actually unable to accommodate Fred Taylor, due to his size, in the proper "extreme Trendelenburg" position.[435] Daniels attempted to fix the problem by removing x-ray cassettes from the table to lower it, but even then the robot could not get over Mr. Taylor's abdomen.[436] As a result, Mr. Taylor "had to be flattened out to just only slight Trendelenburg" in order for the robot to "dock."[437]

"Ideal patient positioning" is necessary to prevent nerve damage during robotic prostatectomy due to "the potential for long operative times at the beginning of the learning curve[.]"[438] Use of the "slight Trendelenburg" position decreases visibility, further prolonging the surgery.[439] The longer the surgery, the greater the risk of rhabdomyolosis[440] and excessive

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[432] Exhibit A to Mullenix Declaration (Daniels Deposition) at 303:13-20.
[433] PT-252 (Operative Note).
[434] Exhibit D to Mullenix Declaration (Ramin Deposition) at 108:15-20.
[435] PT-252 (Operative Note).
[436] *Id.*
[437] *Id.*
[438] Exhibit J to Mullenix Declaration (Lohrasbi Deposition) at 101:18-102:1.
[439] Exhibit D to Mullenix Declaration (Ramin Deposition) at 122:4-8.
[440] Exhibit J to Mullenix Declaration (Lohrasbi Deposition) at 81:8-82:3; 85:22-25.

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blood loss.[441] Because Bildsten had not been trained about the dangers of proceeding without placing Mr. Taylor in steep Trendelenburg, and because Daniels did not warn Bildsten about those dangers,[442] the surgery continued.

At this point, Dr. Bildsten had not even gotten "on console," meaning he had not yet taken the controls of the robot, even though Mr. Taylor had already been in the operating room and under anesthesia for over two hours.[443] The trouble continued, however, as Dr. Bildsten quickly discovered "a moderate amount of intestines still covering the lower pelvis."[444] Dr. Bildsten did his best to proceed with the surgery robotically, but "it was difficult to maintain good vision for the posterior bladder neck dissection due to the intestinal contents continually getting into the visual field."[445] Dr. Bildsten continued for "several hours of trying to get better visualization,"[446] but eventually decided to abandon the use of the robot. After Mr. Taylor had been in the operating room for eight hours and fifty minutes, the robot was finally undocked.[447]

By the time Dr. Bildsten undocked the robot, Mr. Taylor had already lost almost 1800 milliliters (7.6 cups) of his blood.[448] And because Dr. Bildsten had already performed several of the procedural steps in the prostatectomy at that time, simply closing Mr. Taylor up at that point was *not* a safe option. He had to finish the prostatectomy, despite the fact that Mr. Taylor had already been under anesthesia for nine hours. This required a new, six inch incision, in

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[441] Exhibit J to Mullenix Declaration (Lohrasbi Deposition) at 106:7-18.
[442] PT-266 (ISI's Answers to Plaintiff's Second Requests for Production).
[443] PT-264 (Lapidario Timeline).
[444] PT-252 (Operative Note).
[445] PT-252 (Operative Note).
[446] PT-252 (Operative Note).
[447] PT-264 (Lapidario Timeline).
[448] PT-264 (Lapidario Timeline).

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addition to the five existing "port" holes in Mr. Taylor's abdomen.[449]

Unfortunately, another problem was soon discovered: a two centimeter "tear" in the lower rectum.[450] The tear was not discovered until Mr. Taylor had been in the operating room for ten hours and 36 minutes.[451] Dr. Bildsten, upon discovering the tear, obtained an "intraoperative consult" from general surgeon Greg Fleischhauer.[452] Dr. Fleischhauer worked to surgically repair the tear, further extending the length of the surgery.[453]

ISI takes the position in its summary judgment brief that this tear was actually caused by Dr. Bildsten's finger, during the open part of the procedure.[454] That position is directly contradicted by robotic urology expert Adam Ramin, M.D.:

> Q Is it your opinion that it occurred during the da Vinci portion of the procedure before opening?
>
> A Yes.
>
> Q How did that happen?
>
> A This is a portion where they were trying to again develop the Denonvillier's fascia. And based on his operative report he said after several hours of trying to develop this area, they decided to convert to open surgery. This is an area which has a high risk of cutting into the rectum and not recognizing it. The rectum is only a few millimeters away from the Denonvilliers' fascia in this particular area. And if you have more visualization, if there is blood coming into the field and bowel is coming into the field, add it to physician's fatigue, add it to a certain level of frustration, and add it to a patient not being in a correct position, it's very hard to tell whether you're properly -- you are in the proper space or not. Very high chance that the rectum is injured at

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[449] PT-252 (Operative Note).
[450] PT-252 (Operative Note).
[451] PT-264 (Lapidario Timeline).
[452] PT-252 (Operative Note).
[453] PT-252 (Operative Note).
[454] *See* ISI's Motion for Summary Judgment on All Claims at 11 (relying on Dr. Bildsten's deposition testimony to support its claim that "[t]he rectal injury occurred after the da Vinci system had already been turned off, disconnected from Mr. Taylor, removed from the surgical field, and was sitting unused in the operating room."); *see also* Exhibit Q to Mullenix Declaration (Bildsten Deposition) at 275:18-20 ("And I believe my finger slipped into -- you know, went into his rectum and caused the tear that was there.").

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that point.[455]

The general surgeon that Dr. Bildsten asked to repair the tear also casts significant doubt on ISI's "finger tear" theory. Dr. Fleischhauer testified at his deposition that the tear "looked clean," not "ragged."[456] He further testified that the tear looked like "it was a surgical instrument … that made the laceration."[457]

Regardless, after Dr. Fleischhauer repaired the tear, Dr. Bildsten still had to finish the procedure. Because it is necessary to slice through the urethra to remove the prostate (which surrounds the urethra like a donut), the final step of the surgery requires reconnecting the two sections. This process is called "anastomosis." "[W]atertight anastomosis is key to preventing urinary complications" in robotic surgery.[458] Watertight anastomosis is particularly important in robotic prostatectomy because, unlike in a traditional open procedure, robotic prostatectomy requires the arms of the robot to open the peritoneum.[459] Thus, in robotic prostatectomy: "The stakes are higher" with respect to achieving watertight anastomosis.[460] Dr. Bildsten, unfortunately, had not been trained by ISI to understand that opening of the peritoneum required watertight anastomosis, something not required in an open procedure, and he did not perform a watertight anastomosis on Mr. Taylor.[461] That failure directly contributed to several of Mr. Taylor's later complications.[462]

After 13 hours and 26 minutes, the surgery was finally considered "finished."[463] Even

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[455] Exhibit D to Mullenix Declaration (Ramin Deposition) at 79:10-80:3.
[456] Exhibit T to Mullenix Declaration (Fleischhauer Deposition) at 59:4-7.
[457] Exhibit T to Mullenix Declaration (Fleischhauer Deposition) at 59:8-19.
[458] Exhibit J to Mullenix Declaration (Lohrasbi Deposition) at 108:17-109:23.
[459] Exhibit D to Mullenix Declaration (Ramin Deposition) at 104:10-105:3.
[460] Exhibit D to Mullenix Declaration (Ramin Deposition) at 104:10-105:3.
[461] Exhibit Q to Mullenix Declaration (Bildsten Deposition) at 257:12-258:14.
[462] Exhibit D to Mullenix Declaration (Ramin Deposition) at 105:8-20.
[463] PT-264 (Lapidario Timeline).

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so, Fred Taylor remained in the operating room as his surgeons waited for an ambulance to arrive so he could be transported from Harrison's Silverdale facility to its Bremerton facility, which had an intensive care unit.[464] Nearly 15 hours after he first entered the operating room for his "minimally invasive surgery," he was intubated in an ambulance.

The weeks and months to come showed that the results of the surgery were devastating. ISI does not even dispute that, because of the surgery, Mr. Taylor lost 3500 cubic centimeters (almost 15 cups) of blood,[465] had to have 7500 cubic centimeter "volume replacement,"[466] and underwent a consequent hypovolemic shock.[467] Nor does ISI dispute that the effects of the extraordinarily long surgery also caused Mr. Taylor to suffer from acute renal failure (kidney failure),[468] encephalopathy (impaired brain function),[469] acute rhabdomyolosis (break down in muscle tissue),[470] critical illness myopathy (muscle disease),[471] urethral anastomotic leak (non-watertight urethra),[472] femoral nerve injury,[473] stroke,[474] acute respiratory failure,[475] metabolic acidosis (abnormally acidic body fluids),[476] severe urethral contracture (shortened urethra),[477] pleural effusions (fluid on the lungs),[478] and permanent incontinence.[479] He also suffered a one-

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[464] PT-264 (Lapidario Timeline).
[465] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 9.
[466] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 15.
[467] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 19.
[468] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 10.
[469] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 11.
[470] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 12.
[471] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 21.
[472] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 13.
[473] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 16.
[474] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 17.
[475] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 18.
[476] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 20.
[477] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 24.
[478] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 26.
[479] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 25.

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inch tear of his rectum during the surgery. ISI does not dispute that this tear caused him to further suffer a colourethral fistula (abnormal hole through his colon) and gram negative sepsis (bacterial infection).

Nine days after the robotic surgery, the repair of the rectal tear had broken down. The repair required another surgery and a diverting colostomy. He was not finally extubated until 17 days after the robotic surgery. *Five months after* the robotic surgery, he had another procedure to begin repairing urinary problems. Ten months after the robotic surgery, he had a surgical implantation of an "artificial urinary sphincter" because he was still "totally incontinent of urine." 11 months after the robotic surgery, he had another surgery to reverse the earlier colostomy. A year after the robotic surgery, he had another surgery to repair the artificial urinary implant. The stresses from these numerous injuries and procedures left Mr. Taylor largely sedentary, which further increased the stresses on his heart. He succumbed to heart failure and died on August 25, 2012. The pathologist who performed his autopsy concluded that "the enormous stress" placed on Mr. Taylor's already diseased heart by the 2008 da Vinci Prostatectomy placed "additional severe demands" on Mr. Taylor's heart.[487] For that reason, Mr. Taylor's death was "a direct and proximate result of the complications of his robotic surgery on September 9, 2008."[488]

N. Dr. Bildsten gives up on robotic surgery.

Dr. Bildsten has stopped using robots to perform surgery. Though ISI tried to convince him to continue as a robotic surgeon, even sending him again to California for additional

[487] Declaration of William J. Brady at 4:16, 4:24.
[488] *Id.* at 5:8-10.

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training,[489] he gave up robotics forever in early 2009.[490] Dr. Bildsten testified that robotic surgery was simply too difficult to learn to be worthwhile:

> I was under the initial impression you would get a level of comfort within a certain number of cases. And as the -- as it went along, it seemed it was going to be much longer than that. . . . And after speaking with some other urologists in a similar situation who attempted to use the robotic -- the da Vinci robot for prostatectomy, a lot of others have decided not to proceed, as well. They found the learning curve so steep and lengthy that the level of comfort just took too long and decided to quit. And I was one of those.[[491]]

Dr. Bildsten has also since explained that, when he first agreed to train with ISI, he believed that "the ISI training program had been approved by the FDA."[492] He also believed, based on his conversations with ISI representatives, "that ISI training and two proctored surgeries was sufficient to achieve basic competency and safely perform unsupervised robotic surgeries."[493] He explained at his deposition that, looking back, more proctored surgeries were necessary: "With the advantage of looking back, I would prefer to have more proctored cases . . . . a minimum of five, but possibly ten[.]"[494] Bildsten explained that having a proctor present not only provides the advantage of that proctor's experience and knowledge, it also reduces the pressure on the novice surgeon: "As you're doing the procedure and you realize that you're really the only one in the vicinity that's qualified to use the robot, you're sort of out there on an island a little bit."[495]

Dr. Bildsten believes he "likely would not have agreed to begin training on the robot" if he had been accurately informed about the amount of time to reach basic competency.[496] He believes if he had simply performed an open procedure on Mr. Taylor, "there may have been no

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[489] Exhibit Q to Mullenix Declaration (Bildsten Deposition) at 153:7-11.
[490] Exhibit Q to Mullenix Declaration (Bildsten Deposition) at 29:20-21.
[491] Exhibit Q to Mullenix Declaration (Bildsten Deposition) at 29:22-30:14.
[492] Bildsten Declaration at ¶3.
[493] Bildsten Declaration at ¶4.
[494] Exhibit Q to Mullenix Declaration (Bildsten Deposition) at 181:17-25.
[495] Exhibit Q to Mullenix Declaration (Bildsten Deposition) at 182:17-21.
[496] Bildsten Declaration at ¶6.

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complications" and Mr. Taylor's injuries, "if any, would have been significantly less."[497] Had he been informed about the dangers of insufflation "at levels over 15 millimeters of mercury," or of "the need to ensure a watertight urethral anastomosis," he would have "conducted the Taylor surgery differently, in a way that would have reduced the risk of harm to Mr. Taylor."[498]

III. STATEMENT OF ISSUES

1. Does the Washington Product Liability Act preempt negligence claims unrelated to the design, manufacture or distribution of a product?

2. Is there a genuine factual dispute about whether ISI undertook or assumed a duty to train Dr. Bildsten to perform robotic prostatectomies?

3. Is there a genuine factual dispute about whether ISI breached its assumed duty to train Dr. Bildsten with reasonable care?

4. Is there a genuine factual dispute as to whether ISI provided negligent warnings under the WPLA?

5. Is there a genuine factual dispute as to whether ISI's conduct was a substantial factor in causing Mr. Taylor's injuries?

IV. LEGAL AUTHORITY AND ARGUMENT IN OPPOSITION TO ISI'S MOTION FOR SUMMARY JUDGMENT

A. Summary Judgment Standard

Summary judgment is not appropriate unless "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." CR 56(c). ISI, as the moving party, "bears the initial burden of showing the

[497] Bildsten Declaration at ¶7.
[498] Bildsten Declaration at ¶9.

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absence of an issue of material fact." *Young v. Key Pharmaceuticals, Inc.*, 112 Wn.2d 216, 225, 770 P.2d 182, 187 (1989). If ISI carries this initial burden, Mrs. Taylor must make a sufficient showing to establish the existence of at least a factual issue regarding any challenged element of her claims. *Id.* In making her response, Mrs. Taylor "cannot rely on the allegations made in its pleadings" but must set forth by affidavits or otherwise, specific facts showing that there is a genuine issue for trial. *Id.*, at 225-26. "A material fact is one upon which the outcome of the litigation depends." *Clements v. Travelers Indem. Co.*, 121 Wn.2d 243, 249, 850 P.2d 1298, 1301 (1993). "All facts are considered in the light most favorable to the nonmoving party," here, Mrs. Taylor, and "summary judgment is granted only if, from all of the evidence, reasonable persons could reach but one conclusion." *Vallandigham v. Clover Park School Dist. No.400*, 154 Wn.2d 16, 26 109 P.3d 805, 810 (2005).

B. Mrs. Taylor Is No Longer Stating Claims for Design Defect, Manufacturing Defect, Breach of an Express or Implied Warranty, Breach of Contract, or Violation of Washington's Consumer Protection Act.

Mrs. Taylor clarifies that she is not claiming that the da Vinci surgical system was defectively designed or that some defect in the robot itself was introduced in the manufacturing process. She is also no longer pursuing a claim for breach of an express or implied warranty or for breach of contract. Mrs. Taylor is also no longer stating a claim under Washington's Consumer Protection Act.

C. WPLA Does Not Preempt Negligence Claims Unrelated to the Design, Manufacture, or Sale of the Product.

ISI claims that all common law negligence claims against it are preempted because it is a product manufacturer and distributor. This is incorrect. The Washington Product Liability Act ("WPLA") preempts common law ***product liability claims***, whether based in strict liability or negligence. It does not preempt all common law claims against a defendant that happens to be a

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product manufacturer for activity other than its manufacture and distribution of the product. It is the nature of the claim, not the nature of the defendant, that controls. As a result, Mrs. Taylor's claims against ISI for negligently training Dr. Bildsten and representing its training as sufficient are not preempted.

The Washington Supreme Court held that the WPLA preempted common law ***product liability claims*** in *Washington Water Power Co. v. Graybar Elec. Co.*, 112 Wn.2d 847, 853, 774 P.2d 1199, 1203 (1989). The Court's discussion of preemption and its holding emphasize repeatedly that only common law product liability claims are preempted; nothing in the decision indicates that preemption might apply to all common law claims against a defendant that happened to produce a product:

- "Two aspects of the WPLA are at issue in this case. First is the extent to which the WPLA preempts traditional common law remedies for product-related harms." 112 Wn.2d at 851, 774 P.2d at 1202 (emphasis added).
- [I]t is understandable why [the plaintiff] is anxious to preserve the option of bringing product liability claims for economic loss under common law tort theories." 112 Wn.2d at 853, 774 P.2d at 1203 (emphasis added).
- "[T]he WPLA means nothing if it does not preempt common law product liability claims." *Id.* (emphasis added).
- "To be sure, the Legislature might have stated is intent to preempt common law product liability claims more certainly than it has in the WPLA." *Id.* (emphasis added).

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- "Our holding that the WPLA preempts the variety of common law causes of action for harms caused by product defects applies also to equitable claims for such harms." 112 Wn.2d at 855 n.4, 774 P.2d at 1204 n.4 (emphasis added).

The *Graybar* Court based its decision largely on the definition of "product liability claim" in RCW 7.72.010(4). That definition further confirms that only common law product liability claims, not all common law claims, are preempted. A product liability claim is defined as

> any claim or action brought for harm caused by the manufacture, production, making, construction, fabrication, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, storage or labeling ***of the relevant product***. It includes, but is not limited to, any claim or action previously based on: Strict liability in tort; negligence; breach of express or implied warranty; breach of, or failure to, discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation, concealment, or nondisclosure, whether negligent or innocent; or other claim or action previously based on any other substantive legal theory except fraud, intentionally caused harm or a claim or action under the consumer protection act, chapter 19.86 RCW.

RCW 7.72.010(4) (emphasis added). Thus, a product liability claim is one arising from the defendants' specific actions regarding the "relevant product";[499] it does not include every claim against a defendant which happened to produce a product. The Supreme Court in *Graybar* described the definition of product liability claim as "the operative centerpiece of the statute, linking together the important concepts of 'claimant' and 'harm' to describe the liabilities of product manufacturers and sellers for product-related injuries." 112 Wn.2d at 854, 774 P.2d at 1204. As it is the textual basis for the Court's preemption decision, preemption cannot be any broader than the statutory definition of "product liability claim."

No court applying Washington law has held that every claim against a product manufacturer, regardless of the specific theory, must be brought under the WPLA, although a

[499] "The 'relevant product' under this chapter is that product or its component part or parts, which gave rise to the product liability claim." RCW 7.72.010(3).

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number of courts have determined that specific claims are product liability claims which must be brought under the act. *See Washington State Physicians Ins. Exch. & Ass'n v. Fisons Corp.*, 122 Wn.2d 299, 323, 858 P.2d 1054, 1066 (1993) (stating that because claim was predicated on alleged failure to warn of dangerous propensities of prescription drug, common law theories were preempted); *Laisure-Radke v. Par Pharmaceutical, Inc.*, 426 F.Supp.2d 1163, 1168-69 (W.D. Wash. 2006) (dismissing common law negligence claims relating to side effects of drug); *Macias v. Saberhagen Holdings, Inc.*, 175 Wn.2d 402, 409, 282 P.3d 1069, 1073-74 (2012) ("The WPLA is the exclusive remedy for product liability claims. ... ***Insofar as a negligence claim is product-based***, the negligence theory is subsumed under the WPLA product liability claim.") (emphasis added).

The training ISI provided Bildsten is no more a "product," than a driver's education course is a "product." The WPLA defines a "product" as "any object possessing intrinsic value, capable of delivery either as an assembled whole or as a component part or parts, and produced for introduction into trade or commerce. Human tissue and organs, including human blood and its components, are excluded from this term." Training is not a product. Because WPLA preemption applies only to product-based claims, Mrs. Taylor's claims against ISI for its negligent training of Dr. Bildsten are not preempted. These claims sound in negligence, not product liability.

If Boeing were to open a flight school at Boeing field to teach pilots how to fly 747s, the actions of its flight school would be subject to common law principles of negligence, not the WPLA. This is true even if it gave free 747 training to a certain number of its customers' employees. If General Motors had an auto manufacturing plant in Washington, and decided to

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also provide loans on its cars to customers, its loan activities would be subject to state lending statutes and common law principles, not the WPLA.

Simply stated, ISI could have decided to just sell its robots and leave it to medical schools and hospitals to develop programs for training doctors to operate the equipment and to develop additional procedures in which the equipment could be safely used. If it had done so, ISI would be responsible only for defects in its robotic system or associated warnings and instructions.

But ISI did not want to wait to see what training programs, if any, would develop, and what uses, if any, were found for its robotic system. It decided to implement its own training program to prepare *as many doctors* as possible to use its system. It represented that program as being a "pathway to ensure early success for Robotic Prostatectomy."[500] Essentially, ISI opened up a second business in support of its manufacturing business. It recognized that to sell its robots and the associated service and parts, it needed to have more and more surgeons trained to use the system. Hospitals would not buy a da Vinci robot if very few surgeons could use it. And if few hospitals had the system, the number of additional surgeons mastering the system each year would be small. The demand for additional ISI robots, therefore, would also be small. ISI had to "drive the curve."

ISI did so by starting its own training program, in order to prepare more doctors to use its system, and be able to assure hospitals purchasing the system that demand for the robot would increase quickly. While this training program certainly supports ISI's overall business plan, it is fundamentally different than attaching a warning label or enclosing set of instructions. Therefore, the claim for negligence in completing this undertaking—for providing an inadequate pathway for

[500] PT-42 at 42.

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Dr. Bildsten to take before working on live human beings—is not a product claim, but a common law negligence claim.

D. There Are Material Issues of Fact Regarding Whether ISI Undertook to Provide Additional Training to Doctors Interested in Using its Robotic System and Whether It Breached that Duty.

By arguing that all claims against it must be product liability claims, ISI essentially argues that its training program is just an extension of its product warnings or instructions. This is the most fundamental fact question in this case. Mrs. Taylor is prepared to show at trial that ISI undertook to do more than just provide instructions on how to operate its machine; it purported to prepare physicians, including doctors like Dr. Bildsten with no prior laparoscopic experience, to perform specific procedures and become "a skilled robotic surgeon."[501] Unfortunately, ISI did so negligently, telling doctors that they were ready to perform surgeries immediately upon their return from ISI's training center, and to do so without supervision after only two proctored surgeries, when ISI knew that it has not provided all the training it had represented as appropriate to the FDA, and it knew that the true pathway to safe, effective robotic surgery was much longer.

1. Washington Law Imposes Liability for Negligent Performance of a Voluntary Undertaking

Initially, there can be no doubt that under Washington law, a defendant may be liable for negligently performing a task it voluntarily undertakes to perform. One example is the rescue doctrine:

> One who undertakes, albeit gratuitously, to render aid to or warn a person in danger is required by our law to exercise reasonable care in his efforts, however commendable. If a rescuer fails to exercise such care and consequently increases the risk of harm to those he is trying to assist, he is liable for any physical damages he causes.

[501] *See* PT-42, Exhibit A, at 1.

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Brown v. MacPherson's, Inc., 86 Wn.2d 293, 299, 545 P.2d 13, 18 (1975). Although this is often referred to in Washington as "the voluntary rescue doctrine," the principle is broader: "In certain circumstances, a person may be liable in negligence if he or she gratuitously assumes a duty to act on behalf of another and fails to act with due care in performing that duty." *Meneely v. S.R. Smith, Inc.*, 101 Wn.App. 845, 856, 5 P.3d 49, 55 (2000).

In *Meneely*, the court determined that a trade association, which undertook to establish safety standards for swimming pools and diving boards, could be held liable for doing so negligently.[502]

> By promulgating industry wide safety standards that pool and board manufacturers relied upon, NSPI voluntarily assumed the duty to warn Mr. Meneely and other divers of the risk posed by this type of board on a Type II pool. It failed to exercise reasonable care in performing that duty, when it did not change the standard after it knew that studies showed the pool and board combination was dangerous for certain divers.

101 Wn. App. at 859-60, 5 P.3d at 57.

Similarly, in *Sheridan v. Aetna Cas. & Sur. Co.*, 3 Wn.2d 423, 439, 100 P.2d 1024 (1940), the Washington Supreme Court held that an insurance company, which had agreed under the terms of its policy with a building owner to inspect the building's elevator and file required reports, was liable to a third person injured when the elevator malfunctioned, for inspecting negligently.[503]

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[502] Notably, the *Meneely* court did not feel it necessary to wrestle with any question about whether such a claim would be preempted by the WPLA.

[503] A similar rule is stated in Restatement (Second) of Torts, § 324A, which provides,

> One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if
>
> (a) his failure to exercise reasonable care increases the risk of such harm, or

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Thus, although a manufacturer would *not* have any duty to train buyers how to use its product (beyond providing adequate instructions and warnings) simply because it built the product, if it undertakes to provide such training, it is liable if it does so negligently. This is true in the same way that a non-manufacturer, who undertook to provide training in the use of someone else's product, would be liable for doing so negligently.

If a party raises a question of fact regarding whether a defendant has assumed and breached a duty of care, the issue must go to the jury. *See Alston v. Blythe*, 88 Wn.App. 26, 37, 943 P.2d 692, 698 (1997) (holding that plaintiff had raised a fact question as to whether a truck driver had assumed a duty to help her safely cross the road by testifying that the driver, who was stopped in the line closest to her, had waved her to cross); *Panitz v. Orenge*, 10 Wn.App. 317, 319-21, 518 P.2d 726, 728-29 (1973) (finding jury question under facts very similar to *Alston*).

2. There is Substantial Evidence that ISI Undertook to Train Doctors, Including Dr. Bildsten, to Use its Robot in Surgeries.

The evidence discussed above establishes that ISI undertook to train doctors not just in how its machine worked, but in how to use that machine to perform operations. ISI created "clinical pathways" for its trainees, dictating a path from no robotic experience to performing surgeries without supervision on patients in a few short steps. "The Clinical Pathway and Training Protocol" was a "Prostatectomy" pathway and training protocol.[504] It stated it had been "put in place to ensure success in becoming a proficient robotic surgeon." ISI represents that the

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(b) he has undertaken to perform a duty owed by the other to the third person, or

(c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

Washington has not yet adopted Section 324A. See *Meneely*, 101 Wn.App. at 862 n.4 (noting that because Washington law supported trial court's finding that a duty existed, it did not have to consider Section 324A.

[504] PT-42, Exhibit A, at 1.

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pathway was developed from "the best practices around the country."[505] ISI specifically promised Harrison Hospital:

> Intuitive Surgical training programs are designed to provide surgeons with the knowledge and skills necessary to utilize the da Vinci® S™ Surgical System for its intended use in a variety of endoscopic surgical procedures.[506]

The Clinical Pathway itself focused on ISI's scaled-back training phases, including the off-site training at ISI's Porcine Lab. That training, however, had to be immediately followed by 2 proctored surgeries:

> 6. Off Site Training – Porcine Lab, 1-2 days.
>
> - Live Skills Lab at ISI training center – 2 Cases must be booked before departure for lab to ensure early success. Training will be cancelled if cases are not booked. Training fee $3,000.[507]

Given that surgeries need to be scheduled even before the training was received, and needed to be performed soon after the doctor returned from the training, ISI must have realized that the training it provided would be viewed as fully preparing surgeons to perform those procedures. In fact, ISI told its CSRs: "***All necessary training for surgeons and nurses is built into the Clinical Plan.***"[508]

ISI further represented to Harrison that it had expertise in starting a robotic practice and that its clinical pathway was the key to success. In April 2008, ISI made a presentation to Harrison. On a page titled, "Highlights of Best Practices," ISI stated,

> Consultant analyzed 20 robust robotic surgery programs to determine "Best Practices". Essential activities include:
>
> * * *
>
> - Partnership with Intuitive Surgical – experience from 600 other launches

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[505] PT-42, Exhibit A, at 1.
[506] PT-108, at ISI30611.
[507] PT-42, Exhibit A, at 1.
[508] PT-30, at ISI10878 (emphasis added).

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- Follow Intuitive's ***prescribed training pathway*** – surgeons and staff[509]

In fact, ISI has openly marketed its central role in surgical training. In one of its brochures, ISI summarizes its role in a hospital's da Vinci surgery program.

> Intuitive Surgical would like to be an integral part of your *da Vinci* Surgery program. We can:
>
> - **Take the lead in coordinating** *da Vinci* System installation, on-site training, staff in-servicing and **surgeon training**
>
> * * *
>
> - **Work with surgeons to develop and execute their clinical paths**
> - Coordinate site visits, case observations and proctors
> - **Actively support cases in the OR**; support surgeon as well as staff; provide verbal technical assistance in the safe and effective use of the *da Vinci* Surgical System
> - **Actively work with surgeons to help advance *da Vinci* surgical skills** – e.g. scheduling inanimate labs to develop technical skills[510]

ISI must have also known that Harrison, like other hospitals, was following its lead with respect to the amount of training required before surgeons like Dr. Bildsten could perform robotic surgery without supervision. Harrison's da Vinci Steering Committee relied on information from ISI's representatives, including "samples of credentialing criteria." [511] Shortly after receiving these samples and ISI's Clinical Pathway, the Committee started considering and eventually adopted draft Credentialing Criteria which mirrored ISI's Clinical Pathway. Under the adopted criteria, Dr. Bildsten could not perform robotic surgery at Harrison until he "documented successful completion of the hands-on training … required by the manufacturer."[512] Three ISI representatives – Dave Carson, Sean O'Connor, and Damon Daniels – attended the Committee

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[509] PT-1, at IS1026 (emphasis added)
[510] PT-72, at 8.
[511] PT-82.
[512] Exhibit Q to Mullenix Declaration (Bildsten deposition) at 53:25-54:8.

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meetings, so ISI must be charged with knowledge that Harrison was relying on the training it provided.

In this regard, ISI argues that it cannot be held liable for Harrison's credentialing decisions, such as its decision to allow Dr. Bildsten (and other doctors) to perform unsupervised robotic surgeries after they had only received ISI's limited training and had two proctored surgeries. But Mrs. Taylor does not seek to hold ISI responsible for Harrison's actions, only its own. ISI's discussion of this point somehow manages to overlook the fact that the Harrison committee that investigated possible credentialing standards received all of its information from ISI, which had promised to partner with Harrison in developing standards.[513] As they were taught to do in their ISI training, ISI's salespeople sat with the committee and provided "expertise" on what other hospitals were doing, with an eye toward preventing hospitals from adopting "credentialing guidelines … that might be challenging in starting their program" (that is, difficult for doctors to satisfy quickly).[514] Because ISI undertook to provide expertise to Harrison regarding credentialing, it can be liable if it did so unreasonably, regardless of whether Harrison can be blamed for following its advice.

Even more importantly, there is no dispute that ISI knew Harrison decided to adopt the standards ISI recommended, allowing a doctor to be credentialed after completing the manufacturer's training and two proctored surgeries. As a result, ISI was aware that Harrison and Dr. Bildsten were relying upon ISI's training – and nothing else – to equip Dr. Bildsten to safely perform operations without supervision after only two proctored surgeries. ISI also knew that it

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[513] Exhibit A to Mullenix Declaration (Daniels Deposition) at 225:13-16 ("Q. … [A]re you aware of anything that Harrison had as they're making their credentialing decision that wasn't provided by ISI? A. No. I'm not aware of it.").

[514] PT-137.

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would take at least 50 robotic procedures before a new robotic surgeon would be sufficiently competent to perform robotic surgery safely on a patient like Fred Taylor.[515] Yet ISI never told Dr. Bildsten or Harrison that the training it provided was not adequate. By withholding this information in this context, ISI further confirmed that it was undertaking to train Dr. Bildsten.

ISI also commissioned step-by-step procedure guides describing specific surgical procedures to be done with the da Vinci robot. It handed out those procedure guides to surgeons seeking training for those procedures. It told hospitals, including Harrison, that doctors needed to "learn" its guides as "part of training" for robotic surgery.[516]

ISI also provided its training separately from the sale of its machines, further demonstrating that the training was not just a part of the sale of the robot. As the sales contract between ISI and Harrison demonstrates, hospitals or doctors could pay for training separate from the purchase price.[517] At the time, the price was $3,000 per doctor.[518] And although Dr. Bildsten received his training through one of the training slots provided for no additional cost with the purchase, his training was no different from the training provided others.

ISI may claim that it cannot be liable for negligent training because in addition to the statements and conduct set forth above, it also often made fine print disclaimers of its ability to train "on procedures." For example, the same document that tells surgeons to "[l]earn the procedure guide"[519] as "part of training"[520] also states, in fine print, and on the last page: "Intuitive Surgical does not provide clinical training ... or train in surgical procedures or

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[515] Helton Declaration at ¶15.
[516] PT-73 at 6.
[517] PT-110 at 30627.
[518] *Id.*
[519] PT-73 at 6.
[520] PT-73 at 6.

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techniques."[521] Likewise, ISI's website at the time of the sale to Harrison described "Procedure Training" as one of "three components" of ISI's "comprehensive training pathway."[522] On the same page, ISI contradicted itself, stating: "Intuitive Surgical is in no way responsible ... for training in surgical procedure or technique[.]"

Pasting disclaimers at the end of documents to negate responsibility for things you have done in those documents might provide some defense if the plaintiff in this case were Dr. Bildsten or Harrison. But ISI's behavior also negligently endangered an entire class of foreseeable victims: the patients of surgeons who did not know they had received inadequate training.

Disclaimer or no, ISI convinced every relevant decision maker that its Clinical Pathway, including the training in Sunnyvale, was sufficient to get surgeons ready to perform unsupervised procedures on live humans. To CSRs, ISI made clear that its training was for use of the robot "in clinical applications,"[523] or "procedural applications,"[524] and was "[a]ll necessary training."[525] ISI told hospitals that it had a "***Comprehensive*** Clinical Training Continuum"[526] and that it would measure surgeons' progress "against state-of-the-art technique."[527] It specifically told Harrison that its programs were "designed to provide surgeons with the knowledge and skills necessary to utilize the da Vinci S Surgical System for ***its intended use in***

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[521] PT-72 at 8.
[522] May 13, 2008, version portion of ISI website devoted to explaining training program to hospitals; Mullenix Declaration at ¶ 6.
[523] PT 212 (emphasis added); Exhibit A to Mullenix Declaration (Daniels Deposition) at 258:10-22; 211:17-18 ("I told [surgeons] ... here's our clinical pathway document, you know, you should abide by this").
[524] Exhibit A to Mullenix Declaration (Daniels Deposition) at 266:1-8.
[525] PT-30 at 10878; Exhibit B to Mullenix Declaration (Nagel Deposition) at 59:10-11.
[526] PT-104 at 259 (emphasis added).
[527] PT-72 at 6.

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a variety of endoscopic surgical procedures."[528] And as noted, ISI told doctors to "[l]earn the procedure guide"[529] as "part of training."

ISI wants to be let off the hook for its inadequate training program because it, sometimes, spoke out of both sides of its mouth: stating that its training was in procedures and would ensure safety, followed by a disclaimer that it could not train in procedures nor ensure safety. A jury should decide whether those disclaimers allow ISI to avoid responsibility for its training program, *i.e.*, whether ISI *undertook* to train in procedures in spite of its disclaimers. It should be noted that many of ISI's documents did *not* contain these disclaimers. Most importantly, the Clinical Pathway document was disclaimer free.[530] In fact, Damon Daniels admitted that he would tell the surgeons, and wanted those surgeons to believe, that the clinical pathway would ensure the surgeon's success in becoming a proficient robotic surgeon.[531]

For all of these reasons, there is clearly a factual question regarding whether ISI undertook to provide training to Dr. Bildsten on how to use the robot in surgery. Therefore, the jury must answer this question. If the jury determines that ISI's assumed duties beyond the mere instruction and labeling of a product, product liability law does not apply, and the jury will have to determine whether ISI breached the duty it undertook.

3. There is Substantial Evidence that ISI Negligently Trained Dr. Bildsten

Because ISI undertook to provide training to Dr. Bildsten, it had a duty to provide reasonable training. Mrs. Taylor is prepared to show that ISI's training was not sufficient to make

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[528] PT-108 at 30611 (emphasis added).
[529] PT-73 at 6.
[530] PT-42.
[531] Exhibit A to Mullenix Declaration (Daniels Deposition) at 268:22-269:5.

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doctors competent to perform robotic surgery and that ISI withheld this information from doctors and hospitals while encouraging them to practice on patients.

As explained fully in Section II(G) above, the training actually provided to Dr. Bildsten was deficient in many ways. At the outset, ISI's trainers were not "expert" in any way: neither the Sunnyvale trainer nor Damon Daniels had any prior medical or educational expertise.[532] Moreover, as Dr. Helton has opined, the training program implemented as a whole "lacks depth and breadth, is incomplete, and is potentially unsafe."[533] Specifically, the program was not "comprehensive," was not marked by "consistent" assessments, was not conducted by "experts," and was not conducted using developed "metrics."[534] Rather, the assessments that were conducted were either not tests at all (such as the ten question online quiz for Phase One on which it was impossible to provide a wrong answer), or they were part of a protocol (Phase Two training in Sunnyvale) that, outside extraordinary exceptions, has never been failed. There was at no point the promised training on insufflator settings,[535] and surgeons were never required to perform the specific surgical skills for a given surgery.[536] Dr. Bildsten certainly never removed a prostate in Sunnyvale: pigs do not have prostates.[537] Surgeons did not even self-assess on specific skills, let alone their ability to perform specific procedures.[538] Phase

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[532] Helton Declaration at ¶5.
[533] Helton Declaration at ¶7.
[534] Exhibit H to Mullenix Declaration (Lederer Deposition) at 77:24-78:2.
[535] PT-10 at 27609; Exhibit B to Mullenix Declaration (Nagel Deposition) at 47:14-15.
[536] Exhibit H to Mullenix Declaration (Lederer Deposition) at 45:5-10 ("As it relates to urology is nonspecific."); Exhibit G to Mullenix Declaration (Curet Deposition) at 63:16-19 ("Q. As I am understanding what you're saying, you're saying ISI does not train on how to do procedures, including robotic prostatectomy. A. That's correct."); at 76:14-15 ("We aren't in the position to teach somebody how to do a procedure.").
[537] PT-243 (Liberman Article Excerpt) at 18 ("pigs have no fat or prostate gland").
[538] Exhibit B to Mullenix Declaration (Nagel Deposition) at 79:21-23, 81:8-18.

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Three did not require practice of procedures on cadavers;[539] it consisted solely of a dry run without an anesthesiologist.[540] At most, the surgeon might come in on his or her off-time to practice, though Damon Daniels cannot remember if Dr. Bildsten was actually required to even do that.[541] Dr. Bildsten was offered nothing with respect to Phase Four before actually performing (proctored) procedures on live humans.[542] ISI did not train Dr. Bildsten in the dangers of excessive blood loss, the dangers of extremely long surgeries, proper insufflation techniques, or the need for a watertight anastomosis after violating the peritoneum with robotic arms.[543] Patient positioning was discussed only insofar as surgeons (many of whom, like Bildsten, had no laparoscopic experience) were told "that it should be similar to what they would be doing laparoscopically."[544] ISI does not surgeons train on patient selection.[545] And perhaps most importantly, it does not provide them with realistic expectations about the truly steep learning curve for robotic surgery.[546] Rather, ISI discusses the learning curve as though the only issue were surgeon comfort, not patient safety and oncological outcome.[547] At trial, the testimony of Dr. Bildsten, Dr. Ramin, Dr. Lohrasbi, and Dr. Helton will show the danger that

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[539] *See* Exhibit I to Mullenix Declaration (O'Connor Deposition) at 53:23-54:9, 54:11-12.

[540] Exhibit I to Mullenix Declaration (O'Connor Deposition) at 54:11-12 (training between offsite training and first cases consists of 45 minute dry run the night before the first case); Exhibit B to Mullenix Declaration (Nagel Deposition) at 74:4-5.

[541] Exhibit A to Mullenix Declaration (Daniels Deposition) at 180:20-181:7.

[542] Exhibit A to Mullenix Declaration (Daniels Deposition) at 250:3-25.

[543] Exhibit H to Mullenix Declaration (Lederer Deposition) at 54:8-13 (blood loss); Exhibit B to Mullenix Declaration (Nagel Deposition) at 47:5-10 (long surgeries); Bildsten Declaration, at ¶ 9 (insufflation and anastomosis).

[544] Exhibit H to Mullenix Declaration (Lederer Deposition) at 103:21-23.

[545] Exhibit B to Mullenix Declaration (Nagel Deposition) at 42:14-25.

[546] Helton Declaration at ¶15.

[547] Helton Declaration at ¶¶16-17.

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training of this nature can pose, particularly with a difficult surgical candidate like Fred Taylor. In Dr. Helton's words, ISI was "irresponsible and reckless."[548]

4. Conclusion

There are genuine factual disputes as to whether ISI undertook to provide training to doctor Bildsten on how to use the robot in surgery, and as to whether it did so negligently. Accordingly, ISI's motion for summary judgment on Mrs. Taylor's negligence claim should be denied.

E. There is a Genuine Factual Dispute as to Whether, Under the WPLA, the Warnings Given by ISI Were Inadequate and Negligent.

The WPLA provides that a manufacturer is liable for providing inadequate warnings or instructions:

> (1) A product manufacturer is subject to liability to a claimant if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed or not reasonably safe because adequate warnings or instructions were not provided.
>
> . . .
>
> (b) A product is not reasonably safe because adequate warnings or instructions were not provided with the product, if, at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, rendered the warnings or instructions of the manufacturer inadequate and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate.
>
> (c) A product is not reasonably safe because adequate warnings or instructions were not provided after the product was manufactured where a manufacturer learned or where a reasonably prudent manufacturer should have learned about a danger connected with the product after it was manufactured. In such a case, the manufacturer is under a duty to act with regard to issuing warnings or instructions concerning the danger in the manner that a reasonably prudent manufacturer would act in the same or similar circumstances. This duty is satisfied if the manufacturer exercises reasonable care to inform product users.

[548] Helton Declaration at ¶¶20.

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RCW 7.72.030(1). In this case, because ISI's robotic surgical system is a medical device that can be legally used on patients only by licensed physicians, ISI's duty is to provide adequate warnings and instructions to Dr. Bildsten. *See Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 13, 577 P.2d 975, 977 (1978) (adopting the "learned intermediary" doctrine, under which "the duty of the manufacturer to warn of dangers involved in use of a product is satisfied if he gives adequate warning to the physician who prescribes it").

ISI also claims that because this case involves a medical product, all product claims are also subject to Restatement (Second) of Torts § 402A, comment k.[549] This is incorrect. Comment k addresses the fact that certain products, such as prescription drugs and medical products, cannot be made entirely safe for their intended use. It addresses defective design, not failure to warn. Pursuant to comment k, "[s]uch a product, properly prepared, ***and accompanied by proper directions and warnings***, is not defective, nor is it unreasonably dangerous." *Id.* (emphasis added). "The seller of such products, ***again with the qualification that*** they are properly prepared and marketed, and ***proper warning is given***, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use ...." *Id.* (emphasis added). As the Washington Supreme Court recognized in *Terhune*, "The comment does not purport to state what is 'proper warning' where such a product is involved." 90 Wn.2d at 13, 577 P.2d at 977. As comment k does not address when a warning or instruction is adequate and Mrs. Taylor's only remaining product claim is for improper warnings and instructions, comment k simply plays no role in resolving the issues in this case.[550]

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[549] The Washington Supreme Court adopted comment k in *Terhune*, 90 Wn.2d at 12-13, 577 P.2d at 977.

[550] In *Young v. Key Pharmaceuticals, Inc.* ("*Young II*"), 130 Wn.2d 160, 922 P.2d 59 (1996), the Washington Supreme Court, in a case arising before the adoption of the WPLA, divided

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Since the adoption of the WPLA in 1981, the standard for establishing a failure to warn claim is set forth in the Act, at RCW 7.72.030(1) (b & c). As quoted above, a manufacturer is liable if the product it supplies is "not reasonably safe because adequate warnings or instructions are not provided" or if the manufacturer should have learned of dangers of the product later, but fails to provide additional warnings reasonably necessary.

In order to determine if the warnings and instructions provided with the product are adequate, the jury must determine, "if, at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, rendered the warnings or instructions of the manufacturer inadequate and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate." RCW 7.72.030(1)(b); *see also* WPI 110.03 (failure to warn instruction containing similar language).

There is substantial evidence the risks associated with the use of ISI's robotic system by those without sufficient experience or training were great, and rendered the instructions and warnings provided by ISI inadequate.

1. There is a Question of Fact About Whether ISI's Instructions or Warnings Were Inadequate

Whether or not instructions and warnings are adequate is an inherently factual question. *See Estate of LaMontagne v. Bristol-Myers Squibb*, 127 Wn. App. 335, 343, 111 P.3d 857, 861 (2005) ("Generally, the adequacy of a warning will be a question of fact."), citing *Little v. PPG*

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equally over the question of whether a common law failure to warn claim arising from a defective drug should be subject to a negligence standard or a failure to warn standard. *Compare* 130 Wn.2d at 168-69 (stating the negligence standard should apply) with 130 Wn.2d at 179-88 (stating that comment k does not apply to failure to warn claims, and strict liability should continue to apply). As discussed in the main body of this opposition, this decision is no longer relevant because RCW 7.72.030, not the common law, now governs failure to warn claims.

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Indus., Inc., 92 Wash.2d 118, 123, 594 P.2d 911 (1979), and *Haysom v. Coleman Lantern Co.*, 89 Wn.2d 474, 573 P.2d 785 (1978). Such questions can be resolved on summary judgment only if "reasonable minds can reach only one conclusion from the admissible evidence." *Estate of LaMontagne*, 127 Wn. App. at 343, 111 P.3d at 861, citing *Smith v. Safeco Ins. Co.*, 150 Wn.2d 478, 485, 78 P.3d 1274 (2003). This is not such a case.

As Dr. Bildsten makes clear in his declaration, he was not warned that the training program was not FDA approved (and was given the contrary impression).[551] He was not warned the ISI training program ***did not*** prepare him to operate on live patients.[552] He was not warned that with no prior laproscopic experience, it was very unlikely he could achieve results comparable to his traditional approach for his patients until he had completed 100 or more robotic surgeries.[553] As Dr. Helton's declaration makes clear, these deficiencies in the warning Dr. Bildsten received were "irresponsible and reckless."[554]

Moreover, Dr. Bildsten was not warned of the need to ensure a watertight urethral anastomosis or of the dangers of insufflating patients during long surgeries at levels over 15 millimeters of mercury.[555] He was not warned that da Vinci Prostatectomy should be performed only in steepest Trendelenburg.[556]

As Dr. Bildsten further explains in his declaration, contrary to ISI's argument, Dr. Bildsten did not consider the information that was withheld from him obvious, and if he had been conveyed full information, it would altered his conduct, causing him to either not perform da

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[551] Bildsten Declaration at ¶3.
[552] Bildsten Declaration at ¶4.
[553] Bildsten Declaration at ¶8.
[554] Helton Declaration at ¶20.
[555] Bildsten Declaration at ¶9.
[556] PT-266 (ISI's Answers to Plaintiff's Second Requests for Production) at RFP 51.

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Vinci surgery on Mr. Taylor, or perform it in a different manner to reduce the risk of harm to Mr. Taylor.[557]

The jury may not agree with Drs. Bildsten and Helton, but there is no basis to find against their testimony as a matter of law.

2. ISI Could Have Provided Adequate Instructions and Warnings

The second requirement for establishing a failure to provide an adequate instruction or warning claim under RCW 7.72.030(1)(b) is showing "the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate." This is easily satisfied. ISI could very easily have provided proper warnings and instructions. For example, ISI's early training program, at least as proposed to the FDA, would likely have provided adequate instructions.

Moreover, in light of ISI's knowledge about the learning curve for da Vinci surgeries, ISI could easily have warned doctors, in these or similar words,

> **It takes experience with 20 patients or more to achieve basic competency in the use of the da Vinci surgical system. Physicians should operate only under the supervision of a more experienced da Vinci surgeon until that point. It is strongly recommended that doctors not attempt to use the da Vinci system to operate on high risk patients, such as those who are obese, have major or multiple prior abdominal surgeries, or have diabetes or heart conditions, until more than 50 da Vinci surgeries have been performed.**

It made no such effort.

F. ISI's Negligent Training and Inadequate Instructions and Warnings are a Proximate Cause of Mr. Taylor's Injuries and Her Damages

In its motion, ISI argues in two different sections that Mrs. Taylor cannot establish that its conduct was a proximate cause of Mr. Taylor's injuries. To make these arguments, ISI is forced to misrepresent Mr. Taylor's injuries and the nature of her claims. Properly understood, there is

[557] Bildsten Declaration at ¶¶6-9.

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ample evidence that ISI's breaches of its duty of care and its inadequate instructions and warnings caused Mr. Taylor's injuries and the resulting losses to his family.

"[I]ssues of negligence and proximate cause are generally not susceptible to summary judgment." *Owen v. Burlington Northern & Santa Fe R.R. Co.*, 153 Wn.2d 780, 788, 108 P.3d 1220, 1223 (2005), quoting *Ruff v. King County*, 125 Wn.2d 697, 703, 887 P.2d 886 (1995) (additional citations omitted); *see also Hertog, ex. rel. S.A.H. v. City of Seattle*, 138 Wn.2d 265, 275, 979 P.2d 400, 406 (1999) ("Breach and proximate cause are generally fact questions for the trier of fact.").

> [I]n cases involving alleged medical negligence,[558] if a reasonable person could infer, from the facts, circumstances, and medical testimony, that a causal connection exists, the evidence is sufficient to survive summary judgment. The plaintiff need not establish causation by direct and positive evidence, but only by a chain of circumstances from which the ultimate fact required is reasonably and naturally inferable.

Attwood v. Albertson's Food Centers, Inc., 92 Wn. App. 326, 330-31, 966 P.2d 351, 353 (1998), citing *Douglas v. Freeman*, 117 Wn.2d 242, 252, 814 P.2d 1160 (1991); *McLaughlin v. Cooke*, 112 Wash.2d 829, 837, 774 P.2d 1171 (1989); and *Teig v. St. John's Hosp.*, 63 Wn.2d 369, 381, 387 P.2d 527 (1963).

ISI argues that any failure to warn cannot have caused any harm because Dr. Bildsten admitted being told that he should choose patients with a relatively low BMI and relatively simple cases. But Dr. Bildsten had never had a complication in over 100 prostatectomies.[559] From this the jury can infer he was a competent, careful, conscientious surgeon. ISI undertook to train him in a new technique. After doing all the training they asked him to do, Dr. Bildsten then made a series of mistakes. Some of the mistakes had nothing to do with Mr. Taylor's weight—like failure

[558] The cause of action against ISI is not for medical negligence, but obviously, this case does involve injuries suffered in a medical procedure.

[559] Bildsten Declaration at ¶7.

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to attempt a water-tight anastomosis and creating too great insufflation pressure. Admittedly, ISI never trained or warned on these issues and, as outlined above, there is evidence from which a jury could conclude these mistakes caused injury to Mr. Taylor.

ISI gave Dr. Bildsten a Clinical Pathway he could not possibly follow. He was set up to either fail in his "commitment" to do "one case per week" or in his commitment to only do simple patients for his early cases.[560] A jury could find that the Clinical Pathway document itself was negligently constructed and invited failure.

Additionally, the jury could agree with Drs. Bildsten and Helton that simply telling Dr. Bildsten to refrain from operating on patients with high BMI was not an adequate warning. In fact, Damon Daniels would tell surgeons that the longer they waited between procedures, the more their skills would degrade.[561] They could agree with Dr. Bildsten that if he had been given adequate warnings, things would have been very different: "there may have been no complications, and injury to Fred E. Taylor, if any, ***would have been significantly less.***"[562] There is no basis to say otherwise as a matter of law.

ISI also states, "Dr. Bildsten testified at the time of the September 9, 2008 prostatectomy he felt well trained to use the da Vinci system." This does not, as ISI implies, establish that he ***was*** well trained, just that he thought so at the time. As shown above, Dr. Bildsten now believes that he was not adequately prepared and that if told additional information by ISI, he would have acted differently. Mr. Taylor was injured in this case ***because*** ISI convinced Dr. Bildsten that he would be ready to perform robotic surgeries after a brief training and two proctored surgeries and Dr. Bildsten proceeded with understandable, but misguided confidence.

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[560] PT-42 at 42.

[561] Exhibit A to Mullenix Declaration (Daniels Deposition) at 292:7-10.

[562] Bildsten Declaration, at ¶ 7 (emphasis added)

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In Section V.H. of its motion, ISI argues that Mrs. Taylor cannot establish any causal connection between its acts and the injuries involved in this case. This entire argument is based on two false premises: 1) that the only injury Mr. Taylor suffered was a rectal tear; and 2) that it is undisputed that the rectal tear occurred after Dr. Bildsten converted the Taylor surgery from robotic to open surgery.

As discussed above, Mr. Taylor suffered a number of harms in this surgery, including extreme loss of blood, hypovolemic shock, an extended period of time under anesthesia, acute renal failure (kidney failure), encephalopathy (impaired brain function), acute rhabdomyolosis (break down in muscle tissue), critical illness myopathy (muscle disease), urethral anastomotic leak (non-watertight urethra), femoral nerve injury, stroke, acute respiratory failure, metabolic acidosis (abnormally acidic body fluids), severe urethral contracture (shortened urethra), pleural effusions (fluid on the lungs), and permanent incontinence, all in addition to the rectal tear.[563] None of these injuries were solely caused by the rectal tear,[564] and many were directly related to the length of the surgery and Dr. Bildsten's difficulty in visualization within Mr. Taylor.[565]

Even if the rectal tear were the only injury, it is a disputed question of fact as to when it occurred. While Dr. Bildsten did assert in his deposition that he believed the tear did not occur until after he converted to an open procedure, and was caused by his finger, this is contradicted by the testimony of the surgeon who repaired the tear, Dr. Fleischhauer, and robotic urology expert Dr. Adam Ramin. Dr. Fleischhauer testified that the tear "looked clean," not "ragged" and that it

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[563] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 9-13, 16-18, 20-21, 24-26.

[564] PT-248 (ISI's Response to Plaintiffs' First Requests for Admission) at RFA 9-13, 16-18, 20-21, 24-26.

[565] Swerdlow Declaration at ¶¶

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looked like "it was a surgical instrument … that made the laceration."[566] Dr. Ramin testified at his deposition that, in his opinion, the tear occurred during the da Vinci procedure, as Dr. Bildsten's reported difficulty visualizing in an area extremely close to the rectum, where there is "a high risk of cutting into the rectum and not realizing it."[567]

Proximate cause is an issue for the jury here, just as it is in most cases.

G. It Is Irrelevant that ISI and Its Clinical Sales Representatives Are Not Health Care Providers

ISI argues extensively that neither it nor its clinical sales representatives are medical providers within the meaning of RCW 7.70.020. Mrs. Taylor never claimed otherwise. The services ISI performed or purported to perform were not health care. Chapter 7.70, Actions for Injuries Resulting From Health Care, is not at issue in this dispute between Mrs. Taylor and ISI. It does not follow, however, that ISI gets a free pass for its negligence and the negligence of its employees.

Nor is ISI's negligence analogous to that of the pharmacist in *McKee v. American Home Products*, 113 Wn.2d 701, 782 P.2d 1045 (1989), on which ISI relies. ISI is not being sued for not second-guessing Dr. Bildsten; it is being sued for not training him properly and not providing him with information he needed to know to exercise his proper medical judgment. Mrs. Taylor does assert that, because ISI assumed the duty to train Dr. Bildsten and undertook to "partner" with him in the implementation of a robotic surgery practice, its responsibility to properly inform Dr. Bildsten continued into the operating room. But this is neither the heart of the cause of the action nor an intrusion into the doctor patient relationship. If ISI had trained Dr. Bildsten properly, he would have known everything he needed to know to treat Mr. Taylor safely before

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[566] Exhibit T to Mullenix Declaration (Fleischhauer Deposition) at 59:4-19.
[567] Exhibit D to Mullenix Declaration (Ramin Deposition) at 79:10-80:3.

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the operation started. ISI's presence in the operating room, in the person of Damon Daniels, simply gave ISI one last chance to correct its prior errors. If ISI had done so, it would not have intruded on Dr. Bildsten's decision-making, it would simply have made his training more complete.[568]

ISI's discussion of decisions from other jurisdictions holding that medical product representatives are not liable for medical malpractice is similarly beside the point. ISI is not being sued for not exercising proper medical judgment in the operating room. It is being sued because it undertook to train Dr. Bildsten (or warn and instruct him) and it did so negligently.

H. Mrs. Taylor Is Not Making A Separate Claim Against ISI Regarding the Operating Table, Although its Advice Regarding the Table Is Evidence of the Extent of its Partnership with Harrison

ISI argues that it has no liability for any claims relating to the operating room table used during Mr. Taylor's operation. Mrs. Taylor is not bringing a separate claim regarding the operating table. But ISI's assertion that it does not make recommendations to hospitals regarding tables is incorrect. In fact, after ISI represented that it would "partner" with Harrison in its development of a robotic surgery practice, Harrison's da Vinci Task Force wanted to "assure table selected can better accommodate obese patients."[569] Harrison followed up by asking ISI's Dave Carson regarding table choice,[570] and he responded that "any table will work."[571] Damon Daniels,

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[568] There are also important differences between a pharmacist and ISI. As ISI points out in its brief, part of the Supreme Court's concern in *Mckee* was that imposing a duty on pharmacists would cause them to second guess numerous prescriptions to avoid liability, placing an undue burden on pharmacists and creating an antagonistic relationship between pharmacists and physicians. 113 Wn.2d at 716, 782 P.2d at 1053. Here, however, ISI's representative Daniels and Dr. Bildsten were in the same room for many hours, and Daniels was there precisely to assist and advise the doctor. As he was there to communicate with the doctor, there is no reason to believe that such communications would be burdensome, disruptive, or antagonistic.

[569] PT-82, at 2.

[570] PT-186.

[571] PT-187.

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a recipient of the email, conceded at his deposition that he interpreted this as "a recommendation that any table will work with the da Vinci."[572] While this does not constitute a separate claim, it is evidence of Harrison's reliance on ISI, ISI's knowledge of that reliance, and ISI's partnership with Harrison. As ISI told Harrison: "The success of your implementation is a direct reflection of our effectiveness and our support."[573] The inability of the ISI-trained operating staff to place Mr. Taylor in the proper surgical position, even with the help of Daniels, is evidence of the poor training and inadequate warnings that caused Mr. Taylor's disastrous outcome.

V. CONCLUSION

To be sure, there are many arguments ISI can make in an attempt to avoid liability in this case. Just as surely, all of those arguments require resolution of factual disputes in its favor. Ultimately, that may be the ultimate result in this case. But at this stage the Court must view all the facts and inferences in the light most favorable to plaintiffs. Such an analysis requires that ISI's motions for summary judgment be denied.

DATED this 25 day of January, 2013.

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[572] Exhibit A to Mullenix Declaration (Daniels Deposition) at 220:22-221:2.
[573] PT-72 at 8.

CERTIFICATE OF SERVICE

I hereby certify that on 1/25, 2013, that a copy of the foregoing document was hand delivered for filing with the Superior Court, Kitsap County with a copy e-mailed and mailed, via First Class Mail, to the following:

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Dated this 25th day of January, 2013.

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