No. 45052-6-II

IN THE COURT OF APPEALS FOR
THE STATE OF WASHINGTON
DIVISION II

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,

Appellants,

v.

INTUITIVE SURGICAL, INC., a foreign corporation doing business in Washington,

Respondent.

BRIEF OF APPELLANT

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INTRODUCTION

In the last four years of his life, Fred Taylor suffered from serious complications caused by a 13-hour prostate surgery. His surgeon, who had performed only two prior robotic procedures, had to convert to an open procedure after eight hours. Harrison Medical Center had credentialed this surgeon based on warnings and instructions from the manufacturer and seller of the da Vinci robot, Intuitive Surgical, Inc. Three ISI employees sat on Harrison's committee recommending these credentialing requirements.

Yet ISI had obtained FDA "clearance" (not approval) by telling the FDA that much greater training was necessary and that ISI would provide it. Studies known to ISI show that surgeons need between eight and 250 surgeries before achieving proficiency with the robot. Yet ISI failed to warn and instruct Harrison on these requirements.

The trial court refused to instruct the jury that ISI had a duty to warn and instruct Harrison – purchaser of an inherently dangerous product – misapplying the learned intermediary doctrine. It failed to instruct the jury that strict liability applies here. And it allowed no contradiction to ISI's false suggestion that no other similar incidents occurred at Harrison. The jury returned a defense verdict. This Court should reverse and remand for trial under proper instructions.

ASSIGNMENTS OR ERROR

1. The trial court erroneously failed to instruct the jury that ISI had a duty to warn and instruct Harrison Hospital, the purchaser of the Da Vinci robot. CP 5393 (No. 6); 5394 (No. 7); 5397 (No. 10); 5398 (No. 11) and 5404 (No. 17).

2. The trial court erroneously failed to give Taylor's proposed instructions including Harrison. CP 4134, 4145, 4164.

3. The trial court erroneously failed to instruct the jury that ISI is strictly liable for its failures to warn and instruct Harrison. CP 4294-4300, 4303-04.

4. The trial court erroneously instructed the jury to determine whether Dr. Bildsten's negligence was a superseding cause. CP 5406 (No 19).

5. The court improperly instructed the jury on mitigation of damages. CP 5407 (Ins. No. 20).

6. The court erroneously used a verdict form repeating the jury-instruction errors. CP 5628.

7. The court erroneously refused to permit testimony to rebut an ISI employee's testimony that aside from Taylor's procedure, the robotics program at Harrison was successful. RP 1427, 1429.

ISSUES RELATED TO ASSIGNMENTS OF ERROR

1. Did ISI have a duty to warn and instruct Harrison Hospital, the purchaser of the relevant, unavoidably unsafe product, where Harrison credentialed doctors to use its robot?

2. Did the trial court erroneously instruct the jury on negligence, rather than strict liability, for ISI's failures to warn and instruct?

3. Did the trial court erroneously instruct the jury to determine whether Dr. Bildsten's negligence was a superseding cause, where his negligence was a reasonably foreseeable consequence of ISI's failure to properly warn and instruct as a matter of law, and where the resulting harm was not different or independent?

4. Were the court's failure-to-mitigate instructions improper, where they instructed the jury: (a) not to include damages that could have been avoided, but also (b) to reduce damages by a percentage reflecting the failure to mitigate?

5. After an ISI employee testified that, aside from Taylor's surgery, the robotics program at Harrison was successful and that Harrison was purchasing a second robot, did the trial court erroneously refuse to allow Taylor to cross-examine witnesses on whether the robotics program was replete with problems?

STATEMENT OF THE CASE

A. Summary.

After discovering that he had prostate cancer in September 2008, Fred Taylor opted to have his prostate removed in a robotic laparoscopic procedure. RP 1067-68, 1145-48. Fred's surgeon, Dr. Scott Bildsten, had only recently completed robotics training, and was newly credentialed at Harrison Medical Center when he performed the surgery. RP 1060, 1662, 1664; CP 2309-2310. Harrison's robotics program was in its infancy. RP 1160.

Fred's procedure went horribly wrong, and it is undisputed that he suffered life-altering injuries as a result. *Infra*, Statement of the Case §§ O & P. As one friend succinctly put it, the operation "destroyed [Fred's] quality of life." RP 2093. The parties dispute whether the surgery hastened his death four years later. CP 1451.

The plaintiff's case theory was that Intuitive Surgical, Inc. ("ISI") the manufacturer of the "da Vinci" robot, used to perform Fred's surgery, misinformed and failed to adequately warn and instruct Harrison, which purchased the robot and credentialed Bildsten based on that inaccurate and incomplete information. The following explains how this tragedy came to pass.

B. The da Vinci robot is an unavoidably unsafe medical device.

The da Vinci robot is a "medical device," like an artificial joint or pacemaker, and is considered to be one of the most, if not the most, complex medical device on the market. RP 463, 1912. ISI agrees that the robot is an "unavoidably unsafe product." CP 110.

Robotic surgery is a subset of traditional laparoscopic surgery. RP 869, 1906. In both, tubes called trocars are inserted into small incisions to allow cameras and surgical instruments to pass into the body. RP 868-70. Both are "minimally invasive" in that they do not require any large incisions. RP 870.

In a robotic surgery, a "tableside assistant" attaches surgical instruments to the robotic arms. RP 869-70, 1906-07. The surgeon sitting at a "viewing console" about 10 feet from the patient manipulates the robotic arms using a control panel with a series of pedals, buttons, and "masters," which are essentially very sophisticated joysticks. RP 870, 896-97, 1907. The robotic arms in turn manipulate the surgical instruments inside the patient's body. RP 870.

C. The FDA originally "cleared" the robot to hold endoscopic instruments.

The Food and Drug Administration is essentially a consumer-safety group mandated by Congress to protect the public. RP 462. The FDA functions as a "gatekeeper" for all new drugs and medical devices coming into the market. *Id.* All non-exempt products, such as the robot, must be either "approved" or "cleared" by the FDA before they can be marketed to the public. RP 464.

A "Class 2 approval" allows a manufacture to request clearance of a medical device that is already familiar to the FDA under what is referred to as "510(k) process." RP 490-91, 2705-06. The 510(k) process applies when the product is as safe and effective as a product the FDA has cleared or approved in the past. RP 2706. The term "Class 2 approval" is a misnomer in that the product is not actually approved, but cleared. 2739-40. It is "misleading and constitutes misbranding" to refer to a cleared product as FDA-approved. RP 2739-41; 21 CFR 807.97.

Obtaining clearance is far simpler, faster, and cheaper than obtaining approval. RP 491. Clinical trials do not need to be as robust and there is "a lot less oversight for a 510(k)." *Id.*

No da Vinci robot has ever been approved by the FDA. RP 2709, 2712, 2723, 2741. In 1997, the FDA did clear the first da Vinci robot to hold endoscopic instruments (long flexible tubes that hold cameras). RP 467-68. The first robot was "substantially equivalent to other types of products that held instruments." RP 467.

D. ISI subsequently obtained numerous FDA clearances for robotic surgery, including prostatectomy.

When a manufacturer wants to use an FDA-cleared product for a new purpose or "indication," it must submit a new application to the FDA. RP 465-66. Following clearance as an "instrument holder," ISI obtained clearance to market the da Vinci robot to perform abdominal and thoracic surgeries, and eventually others. RP 468-69, 473, 487. For each new indication, ISI told the FDA that it was referring back to its prior 510(k) applications. RP 470, 487. By the time ISI sought clearance to market the robot for prostatectomy, there were approximately 14 related 510(k) clearances. RP 469.

E. To obtain clearance for prostatectomy, ISI told the FDA that it would train surgeons in four phases, and recommended basic and advanced laparoscopic requirements.

The FDA does not have experts on surgical robots – "[t]hey rely on the expert – the manufacturer . . . to be the expert and provide information . . . ." RP 463.

1. **Phase 1 – ISI told the FDA that surgeons would have to pass a 70-question test before moving to Phase 2.**

As part of its 510(k) application for prostatectomy, ISI submitted a comprehensive training program to the FDA, summarized as follows:

> The Intuitive Surgical Customer Training Program consists of four related, successive phases conducted at Intuitive and the installed clinical site. These four phases include: Distance Learning (Phase 1), Off-Site Workshop (Phase 2), Onsite/Installation (Phase 3), and Surgical Directed Training (Phase 4). The intent of the phases is to familiarize users with the system, its components and functions, as well as to provide instruction for performance of general surgical tasks using the device.

Ex 24, p.30; RP 1913. ISI stated that upon completing these four phases, "surgeons will have received training and demonstrated proficiency" in 23 areas including everything from basic system overview to "Surgical Skills." Ex 24, p. 30; *see also* RP 2605-06.

Phase 1 consisted primarily of an online PowerPoint presentation and 70 question multiple-choice test, designed to provide a basic understanding of the robot and "computer-assisted surgery." RP 2625; CP 4605-07; Ex 10, p. 30; Ex 24 p. 31. Phase 1 also involved putting together a surgical team consisting of a console surgeon, a bedside assistant, and others. CP 4603, 4611, 5050-51. ISI expected surgeons to schedule two patients for robotic

surgery before moving onto Phase 2, even though they had no training on the robot. RP 828-30; CP 4611. ISI would not "always" cancel Phase 2 if they failed to do so. RP 828-30; Ex 511.

2. Phase 2 – ISI told the FDA that surgeons would participate in a 3-day hands-on training program at ISI's lab, which would include standardized and expert evaluations.

Phase 2 had two components – "onsite" training conducted at the hospital purchasing the robot, and "offsite" training conducted at ISI's lab and corporate facility in Sunnyvale California. CP 4610, 4618-19. The onsite was essentially a hands-on systems overview, during which an ISI Clinical Sales Representative worked with the surgical team. RP 1417-18. ISI told the FDA that the off-site training would be a "three-day hands-on program" at ISI's lab, including class work and lab work on cadavers and animals. Ex 10 p. 31; Ex 24 p. 31; RP 2625; CP 4634-44. Surgeons would be expected to demonstrate familiarity with the robot, and would have the opportunity to "re-learn" basic surgical tasks on the robot, including cutting, grasping, and suturing. *Id.*

ISI promised that in Phase 2, "each customer's general proficiency with the da Vinci Surgical System will be evaluated using a standardized Training Assessment tool." Ex 24 p. 31. ISI also

promised that "[p]erformance evaluations will be ongoing within the hands-on training throughout the course" and that among other things, "[e]xpert evaluation . . . will determine mastery." Ex 10 p. 31.

3. Phase 3 – ISI told the FDA that an expert using ISI-developed metrics would evaluate mastery in an on-site dry-run.

ISI told the FDA that Phase 3 training – the "dry run" – would require demonstrated familiarity with the robot in a hospital setting. RP 4614, 4619; Ex 24 p. 31. A sales rep would score the team's performance using a "Likert-type scale from one to five." Ex 24 p. 32. ISI promised to develop "[m]etrics . . . to certify mastery, including time and accuracy"; "mastery" would also be determined by, among other things, "[e]xpert evaluation." Ex 10, p. 31.

4. Phase 4 – ISI told the FDA that it would develop a standardized series of exercises focusing on surgical tasks, in an otherwise self-directed phase.

ISI told the FDA that Phase 4 would be a "self-directed learning curriculum," during which surgeons would practice what they learned in earlier phases. Ex 10 p. 31. Surgeons also were to complete their credentialing requirements during this phase. *Id.* But while this Phase was mostly left to surgeons and hospitals, ISI told the FDA that it would "devise a standardized series of exercises" focusing on "the execution of surgical tasks." Ex 24, P. 32.

5. Testing – ISI told the FDA that ISI would assess surgeons throughout their training to ensure cognitive and motor-skills competency.

ISI told the FDA that each of its training centers would "follow a standard curriculum and utilize standard performance assessment" before moving a surgeon from Phase to Phase, and that "[d]eficiencies [would] be identified and remediated." Ex 10 p. 30; RP 1923-25, 1928-29. ISI stated that it would "quantitatively asses[]" the surgical team's ability to use the robot using a Likert-type scale of one to five. RP 1924; Ex 13, p. 15. ISI also stated that its "Surgical System Trainer will assess the surgical team's skill and ability using a standard training checklist of specific tasks with immediate feedback to the surgical team." RP 1924-25; Ex 13, p.15. In short, ISI repeatedly told FDA that surgeons could not move through the ISI training program without being assessed to ensure "cognitive and motor skills competency." Ex 10, p. 30.

This assessment was an important aspect of the training program ISI pitched to the FDA. RP 1928-29. As one of the expert robotic surgeons stated, there "has to be some sort of assessment that you're given that you have the skill set to go to the next level." RP 1929.

6. Laparoscopic skills – ISI told the FDA that surgeons should meet laparoscopic requirements.

ISI told the FDA that surgeons should "meet basic and advanced laparoscopic requirements as outlined by private and/or academic organizations." RP 1915; Ex 20, p. 55. At the time, there were only about 10 or 15 surgeons in the entire United States doing laparoscopic prostatectomies. RP 876-77.

This recommendation was important, where robotic surgery is an extension of traditional laparoscopic surgery. RP 1915-16. A surgeon needs to have laparoscopic training in order to do robotic procedures. *Id.* A surgeon who is very, very experienced and confident in open procedures is not qualified to sit down and start doing a robotic procedure. RP 1911.

F. After obtaining FDA clearance, ISI dramatically reduced the training it promised to provide.

Sometime after obtaining FDA clearance, but before selling the robot to Harrison, ISI made the following changes to the training program it promised to the FDA.

1. Phase 1 – the 70-question test became a 10-question test.

By the time ISI was trying to sell Harrison a robot in 2008, it had abandoned the 70-question test for a 10-question test. CP 4631. The entire Phase 1 distance-learning module took only one hour to

complete. RP 2939-40. Although ISI told the FDA that "[c]ontinuation to Phase 2 is dependent upon successful completion of Phase 1 . . .," ISI is not aware of anyone having ever failed the Phase 1 test. *Id.*; Ex 24 p. 31. It is impossible to fail. CP 4608-10.

2. Phase 2 – the three-day lab training program became a one-day program with no standardized evaluation.

By 2008 ISI had shortened off-site training from three days to only one day, if, as here, only one member of the surgical team was training on the console. RP 2625-26; CP 4613, 4634-35. Off-site training is two days only if both surgeons on the team will train on the console and at tableside. RP 2625-26; CP 4634-35. At times, one ISI trainer would train two different surgical teams at the same time, going back and forth between two different surgical bays. RP 2644.

By 2008, ISI had no "objective standard" to evaluate the duration of surgical procedures, despite its promise to use a "standardized Training Assessment tool." *Compare* Ex 24, p. 30, *with* RP 2627-28. ISI's "Vice [P]resident of training and development," Gene Nagel, admitted that ISI did not determine "mastery," contrary to its promises to the FDA, but only evaluated whether surgical tasks were "completed." *Compare* CP 4572, 4649-

50 *with* Ex. 10, p. 31. The ISI trainer who conducted Bildsten's off-site had never had an urologist fail. CP 5542.

3. Phase 3 – the dry run no longer included any evaluation or assessment.

Nagel was not sure whether ISI had ever developed the promised "metrics [to] certify mastery." *Compare* CP 4639 *with* Ex 24 p. 32 & Ex 10 p. 31. In fact, ISI had dropped even a 1-to-5 scale, acknowledging that it used no "standard performance assessment" in Phase 3 (or in any other Phase). CP 4652-54. In short, it is unclear what, if anything, ISI did to evaluate the surgical team in the Phase 3 dry-run. *Id.*[1]

4. Phase 4 – ISI no longer had any real involvement.

Although Phase 4 was left in large part to surgeons and hospitals, ISI promised to "devise a standardized series of exercises" focusing on "the execution of surgical tasks." Ex 24, p. 32. By 2008, ISI had nothing to do with Phase 4 other than possibly referring a surgeon to an advanced training program. CP 4619-20.

[1] ISI also stopped using surgeon-feedback forms in Phase 3. CP 4654-55.

5. Testing – ISI removed all standardized testing and evaluation.

By the time ISI sold a robot to Harrison, there was no standard performance assessment at any phase. CP 4621-22. Removing these assessments "made it dangerous" for patients. RP 1934-35. "[T]he foreseeable consequence of changing the program in this way" is that "[y]ou have surgeons who have not been adequately assessed if they could do the job." RP 1935. Regardless of any argument about surgical abilities, this is not sufficient training. *Id.*

6. ISI never told Bildsten or Harrison that it recommended laparoscopic requirements to the FDA.

ISI's Director of Customer Training, Sean O'Connor, did not recall being aware that ISI told the FDA that surgeons should have laparoscopic requirements. CP 658, 681. When asked whether he had ever told any surgeon or hospital about this recommendation, O'Connor admitted that ISI would "usually defer to whatever the surgeons' experience were." *Id.*

Ryan Rhodes, ISI's Vice President of Clinical Marketing, was also unaware of this recommendation, and could not recall it being in any marketing materials. RP 523, 526-27, 544-45, 552. He was unaware of ISI sharing this recommendation with hospitals. RP 543.

Only Damon Daniels, the ISI Clinical Sales Representative who did the Phase 3 dry-run training at Harrison, even wavered on this point. RP 1647-48, 1659. Although Daniels claimed that ISI might have trained him to tell surgeons that ISI recommends laparoscopic requirements, he admitted that he could not recall ever passing on the recommendation. RP 1647-48, 1651-52.

But most telling is a "target" list identifying surgeons ISI believed would have a "high interest" in the robot. RP 537; Ex 31, p. 7. The first category of target surgeons includes urologists with "basic or limited laparoscopic skills who currently perform open radical prostatectomies." *Id.* ISI directed sales reps to spend about 80% of their time on this target group. RP 541; Ex 294, p. 3.

ISI also directed its sales reps to target surgeons with only "basic laparoscopic skills." Exs 31, 294. The obvious implication of this list was that surgeons who had mastered laparoscopy might have limited interest in the robot. RP 541-42.

G. When ISI began marketing to hospitals, including Harrison, ISI sold itself as a partner in developing a successful robotics program.

ISI employees who worked directly with Harrison (and other customers) agreed that part of their job was to present themselves as partners in building a successful robotics program. RP 550, 657,

679-80, 1669, 1694; CP 4587-88; Ex 281, p. 5. Marketing materials extolled the virtues of partnering with ISI. CP 4584, 4587; Ex 48. Indeed, Daniels encouraged hospitals and surgeons to see him as a "leader" and an "expert." RP 1688.

H. Although the robot was only FDA cleared, ISI marketed the robot as FDA approved.

ISI agrees that "a surgical device should be marketed in accordance with FDA regulations," under which it is "misleading" and "misbranding" to market a FDA-cleared medical device as FDA-approved. 21 C.F.R. § 807.97; RP 492, 551.

ISI's Rhodes contributed to a chapter titled "Robotic Urology" that identified the da Vinci robot as FDA-approved. RP 612-13; Ex 69, p. 13. ISI expected surgeons and hospital directors to read this chapter for information on the robot. RP 613-14.

Dr. Soroush Ramin performs 75 to 100 robotic prostatectomies each year, and has performed, taught, or assisted others in over 1000 robotic prostatectomies using the da Vinci robot. RP 875. He is a self-described "[v]ery, very big believer" in robotic prostatectomy. *Id.* Ramin distinctly remembered ISI telling him that the robot was FDA-approved. RP 974-75, 986.

Bildsten thought the ISI training program was FDA-approved. RP 1028-29. Bildsten could not be sure how he would have reacted if, before Fred's surgery, he had learned that ISI's training program was not FDA-approved: but he thinks he would have asked questions and proceeded more cautiously. RP 1029.

I. Despite being aware of drawbacks associated with robotic prostatectomy, ISI did not share them with Bildsten or Harrison.

Part of ISI's job is to tell hospitals and surgeons about any "hidden problems they may not otherwise see," and to be candid about "the good[,] the bad and ugly, the pros and cons" associated with the robot. RP 799.

The term "margin rate" refers to the amount of cancer left behind after prostatectomy. RP 1720. In open surgeries, 1.8% is a typical positive margin rate.[2] RP 2054-55. The goal is to have the lowest margin rate possible. RP 1720, 2054-55.

A study conducted by Dr. Thomas Ahlering, an ISI consultant, showed that the margin rate in robotic prostatectomy is between 30% and 35%. RP 557, 1965-66, 2054. No one would consider this to be a good positive margin rate. RP 2055.

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[2] In a "radical" prostatectomy, the entire prostate is removed. RP 805.

A very experienced robotic surgeon might be able to achieve a margin rate around 1.8%, but it would likely take thousands of robotic prostatectomies. RP 2055. Thus, a rational patient would (1) chose an open procedure; or (2) seek out a very experienced robotic surgeon. RP 1950-51. There is no indication that ISI told Bildsten or Harrison that margin rates are considerably higher in robotic prostatectomy. RP 1720, Ex 177.

Immediately before Harrison decided to purchase a robot from ISI, the New York Times published an article titled "Mixed Outcomes in Laparoscopy for Prostates." RP 799-800; Ex 91. The article reported on a study conducted by Dr. Hu, demonstrating hidden risks for patients who opt for traditional laparoscopic or robotic-assisted laparoscopic surgery. RP 800-01. These risks include a 40% increase in scarring that interferes with organ function, and a 15% increase in the need for additional hormone drug therapy within six months of surgery. RP 801.

The article quotes expert witness and ISI consultant Dr. Mark Gonzalgo discussing additional disadvantages with laparoscopy. RP 801-02; CP 5337. John's Hopkins University, were Gonzalgo was an assistant Professor of Urology, continues to use open procedures

for most radical prostatectomies. RP 802. ISI did not give this article or the underlying study to Bildsten or Harrison. RP 802, 1040, 1723.

J. Despite knowing that experts in the field, including ISI-paid consultants, opined that the learning curve for robotic prostatectomy is between 8 and 250 surgeries depending on how it is defined, ISI did not share this information with Harrison or Bildsten.

ISI agrees that it is responsible to distribute accurate information, including medical literature, to surgeons and hospitals, and that it should "tell the whole truth." RP 520, 549, 551.

The term "learning curve" essentially means the number of surgeries required to achieve "basic competency" on the robot. CP 5364-65. Put another way, "learning curve" refers to the time it takes a surgeon to gain the experience necessary to perform an "adequate robotic prostatectomy." RP 960. An internal ISI document instructed sales reps to tell potential customers that "[t]here is a fairly short learning curve . . . ." RP 546; Ex 14, p. 2.

Medical literature varies greatly on the number of robotic prostatectomies ascribed to the learning curve, due in large part to variances in the definition of "basic competency." CP 5365. Variables include operative time, recovery time, margin rates, and functional outcomes. *Id.* There are guidelines, but the learning curve

differs from surgeon to surgeon. RP 1982-83. No surgeon should be operating until he has achieved basic competency. CP 5365.

1. Medical literature suggests that when margin rates – the rate of cancer removal – are accounted for, the learning curve is about 150 robotic prostatectomies.

In 2005, Drs. Herrell and Smith published an article titled "Robotic-Assisted Laparoscopic Prostatectomy: What Is The Learn Curve?" RP 803. Herrell was fellowship-trained in laparoscopic surgery, and Smith was well-recognized and highly-skilled in open prostatectomy. RP 1948-50. Herrell and Smith concluded that their robotic-surgery results were not comparable to routine open-surgery results until their team had completed 150 robotic prostatectomies. RP 804, 1949-50. "Surgeon comfort and confidence" was not comparable "until 250 robotic procedures." *Id.*

The article continues that hospitals considering a robotics program must consider that most surgeons "may never overcome the learning curve," where the median number of prostatectomies an urologist performs annually in the United States is only seven. RP 805-06, 1949. This is the only article that uses margin rates – cancer removal – as a basis for measuring the learning curve. RP 1949-50. This is, perhaps, the most important measure of a successful

prostatectomy – "making sure you get all the cancer out. That's the number one thing the patient wants." RP 1949.

The Herrell and Smith article is consistent with a 2010 article published in the New England Journal of Medicine, considered to be the most prestigious medical journal. RP 984-85. The article concludes that it took between 150 and 250 robotic procedures to become "adept." RP 985. Although this article post-dates Fred's procedure, there were many similar articles in 2008 talking about the steep learning curve in robotic procedures. *Id.*

Finally, Dr. James Eastham, the Chairman of Urology at Memorial Sloan-Kettering Cancer Center in New York City, published an article in European Urology titled "Robotic-Assisted Prostatectomy: Is There Truth in Advertising?" RP 1951-52. Eastham concludes that there is "a paucity of clinical data" or "randomized trials" supporting ISI's website claims that robotic prostatectomy improves cancer control, provides early return of sexual function, and provides improved and early return of continence. RP 1952. Eastham opines that for an open surgeon, the learning curve is at least 100 procedures. RP 1954-55. Thus, many will obtain inferior results as compared to their open

procedures, and many will not have the volume to get through the learning curve. RP 1955.

2. When the learning curve does not account for margin rates, medical literature suggests that the learning curve can be as low as 8 to 12, and more like 20 to 25 robotic prostatectomies.

In 2006, former ISI consultant Dr. Vip Patel reported that the learning curve for his surgical team was 20 to 25 cases. RP 567-69, 628, 1947. Patel is a highly respected leader in minimally invasive robotic surgery. RP 1947. He is a fellowship-trained laparoscopic surgeon, and his team included a skilled open surgeon, a surgical assistant, and four nurses. RP 569, 649.

Patel's learning curve means good surgical times, low blood loss and transfusions, and few complications. RP 1947. Despite extensive laparoscopic training, Patel's had a complication rate of 1%, with two rectal injuries in his first 15 cases. RP 2004, 2060.

Patel's learning curve is consistent with ISI's "surgeon locator," a feature on its website that allows users to search for robotic surgeons. RP 576-78. This group includes only surgeons who have completed at least 20 robotic procedures. RP 578. This is indicative of ISI's decision "that it was not going to endorse any surgeons who didn't have at least 20 surgeries under their belt." *Id.*

Defining "learning curve" solely as the number of surgeries necessary to complete a robotic prostatectomy in four hours, ISI consultant Dr. Ahlering reported that his team's learning curve was 8 to 12 cases. RP 557, 565, 630-36. Ahlering is one of the most prolific experts in robotic prostatectomy. CP 5366. Although he was an accomplished open surgeon during his study, he was assisted by a "very accomplished" laparoscopic surgeon. RP 1942-43. Ahlering's article touted the "single team approach." RP 648.

It took Ahlering's team 12 cases to perform a robotic prostatectomy in 4 hours. RP 1943. But speed is not everything. RP 1944. Ahlering's team had one surgical complication in the first three procedures and two complications in the next nine procedures, a 22% complication rate. RP 2052-53. And as above, the team's margin rate was 30% to 35%. RP 1966, 2054.

3. ISI gave none of these articles to Bildsten or Harrison.

When asked whether ISI had "ever distributed any articles to customers or potential customers . . . about the learning curve," Rhodes initially stated that ISI distributed an article written by Patel. RP 567. But he corrected himself: the article was distributed "in the context of outcomes," not of the learning curve. *Id.* Although Rhodes

was familiar with Ahlering's article, he was not aware of any ISI marketing materials mentioning Ahlering's findings. RP 565.

O'Connor was familiar with the Herrell and Smith article, but never mentioned it to Bildsten or Harrison. RP 810, 1037. ISI never even mentioned the article to sales rep Daniels, who was on the Harrison account. RP 657, 1654-55, 1681.

K. No medical literature supports ISI's recommendation to Harrison (and others) that surgeons should be credentialed after two proctored procedures.

Credentialing is how surgeons obtain privileges to perform specific procedures in a hospital, in this case robotic prostatectomy. RP 956-57. Though ISI maintained that credentialing is just up to hospitals, three of its employees, including Daniels and O'Connor, sat on Harrison's steering committee – the group that recommended the credentialing requirements that Harrison adopted. RP 720.

ISI acknowledged that new hospitals like Harrison look to ISI for its credentialing expertise, and its sales reps are required to raise the issue. RP 714-15. Harrison asked for credentialing examples, and ISI provided some from local hospitals, claiming that the area

average is only two proctored cases.[3] RP 714-16. Of course, ISI sold its robots to these hospitals as well. *See* RP 775-76, 4677-78.

O'Connor also gave Harrison ISI's "Clinical Pathway and Training Protocol For da Vinci Prostatectomy," purporting to lay out the steps to "ensure success in becoming a proficient robotic surgeon." Ex 511; RP 716, 840, 1036.[4] He agreed that Harrison would have understood this Clinical Pathway to recommend only two proctored procedures. Ex 511; RP 716, 840, 1036, 1827. But O'Connor was unaware of any medical literature supporting that claim. RP 711-12. And even taking into account "any definition of learning curve," ISI's Rhodes also acknowledged that he has never seen any medical literature "suggest[ing] that two proctored surgeries is enough before operating independently." RP 573. Expert Kavoussi plainly stated that none exists. RP 1956.

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[3] ISI led Bildsten to believe that two proctored cases and ISI training would adequately prepare him to use the robot without supervision. RP 1036-37.

[4] This particular clinical pathway is for Bildsten's partner, Dr. Hedges. Bildsten's clinical pathway could not be found, but was the same. RP 1036.

L. ISI sells the da Vinci for $1.8 million and makes more money each time it is used.

ISI sells the da Vinci for about $1.8 million. CP 867. When ISI was in the process of making a sales pitch to Harrison, it was also selling a second robot to St. Joseph Hospital in Tacoma. CP 868.

About two-thirds of an ISI sales representative's compensation directly correlates to the number of robotic procedures performed in his territory. RP 1674-75. The commission is not based on complication rates, or training hours, and has nothing to do with patient variables. RP 717, 857. It is based solely on the number of surgeries performed. RP 1674-75.

ISI also profits from the laparoscopic instruments, which are reused about 10 times. RP 662-63. The instruments cost about $1,200 per procedure. RP 663. In short, the more the robots are used, the more money ISI and its employees make. RP 1674-75.

M. Per ISI's recommendation, Harrison credentialed Dr. Bildsten after ISI training and two proctored procedures – Fred Taylor was his first unproctored robotic operation.

Bildsten completed ISI's reduced Phase 2 on July 17, 2008, and its reduced Phase 3 twelve days later. RP 1662. His two proctored procedures on July 28th and 29th lasted 10 hours and 7.5

hours. RP 1662-63; Ex 216. Although ISI thought these operative times were "long," it gave Bildsten only positive feedback. RP 1059.

Fred's procedure was five to six weeks later. RP 1060. This was Bildsten's first unproctored procedure. It took Bildsten and Daniels almost 1.5 hours to dock the robot, 2-to-3 times longer than it should take. RP 1074-75, 2357-58. After almost 8 hours, Bildsten could no longer proceed robotically, converting to an open procedure. RP 1287. Fred was in surgery for another 5 hours, totaling 13 hours in surgery. *Id.*

N. All agreed that before his da Vinci prostatectomy, Fred Taylor was a loving, charismatic, fun person who people loved to be around.

Fred and his wife Josette were married for 31 years when he died, four years after his da Vinci prostatectomy. CP 169; RP 1449, 2112-13. Fred was a good partner and they had a great relationship. RP 1554, 1585, 1203, 2113. "They adored each other." RP 1213.

Fred "was a pretty special guy" – the type of person others just wanted to be around. RP 1187, 1193. He was "very jovial, very easy-going, very fun to talk to." RP 1345. Friends and family described him as optimistic, funny, cheerful, upbeat, gregarious, outgoing, and perhaps most importantly, happy. RP 1203, 1212,

1554, 1623, 1887, 2144. He had a "wonderful smile," and a "twinkle" in his eye. RP 1212, 1623.

Although Fred was a big man, he was very strong and active. RP 1203, 1345, 2093, 2137, 2139-40. He was always busy. RP 1203, 1884-85, 2139-40. One friend said, "Freddy . . . just goes a hundred miles an hour. It's hard to keep up with him." RP 1188.

The Taylors travelled often, and Fred was an avid golfer and fisher. RP 1193-94, 1585, 1887. They were social, entertaining friends often. RP 1194, 1585. Fred built two homes, doing everything from laying foundation, to framing and wiring. RP 2079, 2093. He worked on cars, trucks, and motorhomes, inside and out. RP 1187-88, 2093. There wasn't much Fred couldn't do. RP 2079.

In short, Fred was hard working, reliable, and dependable – he could be counted on. RP 1189, 2079, 2093. He was a perfectionist who did things the right way, not the short way. RP 1548-49. Never a complainer, Fred was "very goal-oriented. He was always on a mission. He was an inspiration." RP 1193.

O. The surgery left Fred with life-altering complications.

Fred's prostatectomy was 13 hours, over three times the four-hour proficiency rate Dr. Ahlering's team achieved. *Compare* RP 1287 *with* RP 1943. Complications included Rhabdomyolysis, and

muscle necrosis (death), which occurs when a patient is sedated too long and no blood flows to the muscles. RP 1288-89. When this happens, the blood carries myoglobin to the kidneys, a toxin to the kidneys that caused acute renal failure. RP 1289.

Fred's rectum was perforated and repaired during the procedure. RP 1083-84. The repair broke down, allowing fecal matter to enter area. RP 927. Fred eventually needed a colostomy bag, requiring an additional operation. RP 927, 1301.

Fred developed Sepsis, a serious infection in the blood, likely caused by this fecal matter. RP 927, 1298-99. Sepsis bacteria release inflammatory substances that white blood cells try to fight off. RP 1298. The blood vessels then become "leaky" and dilated, causing blood pressure to drop significantly. RP 1298, 1301. This requires IV fluids and antibiotics. RP 1299.

Fred lost 7 pints of blood, "well beyond what you would expect," requiring transfusions. RP 1295-96. He had renal failure, acidosis, and brain edema or swelling. RP 927-28, 1291-92.

Fred suffered respiratory failure and was intubated for 17 of his 20 days in the ICU. RP 1287-88, 1296-97. Fred also had "critical illness," a nerve and muscle disorder occurring in the ICU that disabled Fred from weaning off the ventilator. RP 1301-02, 1306-07.

When Fred could not wean, his neurologist ordered a CT scan, revealing a stroke that likely occurred in the ICU as well. RP 1306.

As a result of Fred's surgery and many resulting complications, Fred suffered from general neurologic weakness affecting his shoulders, back, and hip; focal neurological weakness affecting his left forearm and hand; and focal joint injuries in his left arm and right thigh. RP 1312, 1320, 1326. He was incontinent, even after an additional surgery to put an artificial sphincter in place. RP 1311-12. He had cognitive deficits including poor memory, depression, and anxiety. RP 1311, 1321-22, 1326.

Fred also had a very numb and weak right thigh. RP 1316. His right thigh was visibly atrophied – almost two inches smaller than his left. *Id.* Fred injured his right shoulder from falling time and again after his surgery, likely caused by the "gross abnormality" in his thigh. RP 1316, 1320-21. He became "severely handicapped." RP 1318.

P. The da Vinci prostatectomy destroyed Fred's quality of life for four years until his death in August 2012.

A patient recovering from a robotic prostatectomy typically goes home in one or two days. RP 926-27. Fred was in the ICU for three weeks, main floor for another week, and sub-acute

rehabilitation for four months. RP 1322, 2142. Fred was never again able to walk unassisted into his home. RP 1318.

Fred lost all of his optimism after the surgery. RP 2144. He woke up after three weeks in the ICU and "it was just like night and day." *Id.* "[H]e was just a totally different guy." RP 2093. The operation "destroyed [Fred's] quality of life." *Id.*

Fred had chronic pain, ranging from a five to a six, but what really bothered him was his loss of function. RP 1325. Fred lost 50 pounds of muscle weight. RP 2142. He had very weak trunk muscles and poor balance, so it was hard for him to even sit. RP 1318-19, 1395. He had trouble getting in and out of chairs. RP 1319. He could not walk without a cane and fell often. RP 1198, 1204, 1319, 1328, 1395-96. The man who could do anything was trapped in his body, unable to walk, stand, or even sit up. RP 2142, 2144. He never really felt safe again. RP 1318.

Fred had to use his right hand to hold his cane, but had little function in his left hand, essentially preventing him from doing two-handed activities. RP 1328-29. He could no longer golf – he could not even bend over and get the tee in the ground. RP 1198, 1327. One time he hit a few balls with his son, but was "destroyed" for days.

RP 1591-92. Fred lacked the physical and mental ability to do projects around his home or fix things as he used to. RP 1327, 1588.

In Josette's words, Fred "lost half of his mental faculties." RP 2143. Friends noticed too. RP 1215. Things that used to be easy for him, like talking someone through a car repair, became difficult and frustrating. RP 2143. He finally stopped trying. RP 2143-44.

Fred had no control over his bowels or urinary tract. RP 1562-63. He lost sleep, having to get up to use the bathroom three times a night. RP 2146-47. Often, he fell out of bed. RP 2147.

Understandably, the incontinence was horribly embarrassing. RP 1205, 1563. Fred lost a lot of pride and dignity. RP 1205-06; 1562-63. This was a guy who used to have "a glimmer in his eye, kind of joking, and that was gone. [H]e was more subdued and depressed." RP 1562-63, 1588.

Josette became Fred's 24/7 nurse. RP 2146. Josette had to help Fred use the bathroom and get in and out of chairs. RP 1206, 1216. She could not leave him alone because he would fall. RP 1563-64. This was a huge physical toll on Josette. RP 1565, 1216-17. She was stressed, exhausted, anxious, and jittery, and things just grew worse. RP 1563-64, 1216-17, 1888, 2148.

It was difficult, frustrating, and embarrassing for Fred to be so dependent on Josette. RP 1206, 1216, 1563, 1588. He was angry, but laughing and trying to joke about his condition, which they knew would not improve, was the only way to survive. RP 2148-49, 1588.

Fred died in August 2012, four years after the prostatectomy. CP 169; RP 1449. The cause of death was cardiovascular disease, which pre-existed the surgery. RP 1450. But the parties disputed whether the surgery hastened Fred's death. RP 1451.

Q. Procedural history.

1. The Taylors filed suit, and Josette continued as the representative of Fred's estate after his death.

In December 2009, Fred and Josette filed suit against Bildsten, his partner, John Hedges, their medical practice, and Harrison, later adding ISI. CP 3-9, 29-37. Their claims included negligence, strict liability, breach of express and implied warranties, Consumer Protection Act violations, and breach of contract, and they sought punitive damages under California law. CP 35-36. After Fred's death in August 2012, Josette proceeded as the personal representative of his estate. CP 749, 2956. Josette settled with Bildsten, Hedges and their practice before trial. CP 770, 774.

ISI moved for summary judgment on all claims, and for partial summary judgment on punitive damages. CP 66-85, 86-133.

Josette opposed. CP 796-913. The court dismissed all claims, except these under the WPLA, and denied ISI's motion as to punitive damages, bifurcating that phase. CP 2952-53, 2955-59.

2. After ISI's O'Connor testified that Harrison's robotics program was very successful except for Taylor's procedure, the court prohibited Josette from putting on contradictory evidence.

The parties each filed 12 motions *in limine*. CP 4370-72. The only motion *in limine* relevant to the appeal is Josette's motion *in limine* Number 5 to exclude evidence of the absence of injuries, accidents, or bad outcomes from surgeries after Fred's procedure. CP 2626. ISI countered that Josette's motion was premature. CP 2716. The court reserved ruling. 3/12/13 RP 31-32.[5] This issue did not arise again until ISI's re-cross examination of O'Connor, during which he talked generally about doctor satisfaction with Harrison's robotics program, and Harrison's decision to purchase a second robot, volunteering that "outside of this incident we're talking about, its [*sic*] been a very successful program." RP 855.[6]

Josette objected, asked to revisit the issue after obtaining a transcript, and two-days later argued that O'Connor's testimony

[5] Pre-trial-ruling VRPs are separately paginated, so dates are cited.

[6] This testimony is discussed in greater detail in Argument § D.

plainly – and falsely – implied that Fred's procedure was the only "incident" at Harrison. RP 856, 879, 1229-30. Josette argued that O'Connor's testimony opened the door. RP 1221, 1229-30. The court again deferred ruling. RP 1232-33.

The next court day, Josette offered proposed exhibit 304, a record of the first 233 robotic procedures at Harrison, documenting other similar incidents. RP 1412-15; CP 4482. The court identified specific concerns with exhibit 304 related to foundation, authenticity and hearsay. RP 1428-29. Although Josette made an offer of proof, the court refused to allow any response to O'Conner's testimony. RP 1427-30; CP 4482.

The court then granted Josette's motion *in limine*, precluding evidence of other similar incidents at Harrison. RP 1429. The court prohibited ISI from arguing that there were not "other incidents," stating "[t]hat would not be consistent with the evidence." RP 1430. But there was no "evidence" of other incidents – the court had already rejected it. RP 1427-29.

The court subsequently refused to allow Josette to ask Daniels whether there were "incidents" at Harrison after Fred's surgery, clarifying that its ruling was intended "to preclude evidence of outcomes of robotic surgeries from other Harrison Medical Center

doctors or operations." RP 1626-27. Josette then moved to strike O'Connor's testimony. RP 1627. After counsel agreed to the language, the court read a curative instruction to the jury (RP 2164):

> Each side has its own views as to whether there were other incidences at Harrison after Mr. Taylor's incident. I have ruled that neither side should present that evidence, and, accordingly, I am instructing you to disregard Mr. O'Connor's testimony regarding whether or not there were other incidences in the Harrison da Vinci program and not to use that testimony in any way in your deliberations.

3. The court refused to instruct the jury that ISI had a duty to warn Harrison.

As detailed below, Josette proposed instructions consistent with the WPLA that ISI had a duty to warn not only Dr. Bildsten, but Harrison Hospital, which purchased the product. CP 4134, 4145, 4164. ISI objected that the learned intermediary doctrine obviated its duty to warn Harrison, and proposed instructions omitting Harrison. CP 4210-4289, 4697, 4699-4702. Josette objected, arguing that ISI misinterpreted the learned intermediary doctrine. CP 4936-38. Josette also argued that Harrison was a learned intermediary, entitled to warnings, because it purchased the robot and was responsible for establishing credentialing requirements. *Id.* The court's instructions omitted Harrison. CP 5384-5431. The parties submitted exceptions in writing, Josette excepting to the

court's instructions on the ground that they erroneously failed to include Harrison. CP 5217-5314, 5319-25.

4. The trial court instructed the jury that Josette's failure-to-warn claim is governed by a negligence standard, not strict liability.

The trial court instructed the jury to apply a negligence standard to determine whether ISI was liable for failing to adequately warn. CP 5398. As Josette noted, this instruction is consistent with the appellate court's decision in ***Estate of LaMontagne v. Bristol Meyers Squibb***, 127 Wn. App. 335, 111 P.3d 857 (2005). Although Josette agreed that the trial court was bound by ***LaMontagne***, she argued that ***LaMontagne*** is incorrect, and proposed strict liability instructions to preserve this argument for appellate review. 4/1/13 RP 92-94; CP 4294-96, 4301-06.

5. The jury returned a defense verdict.

Ten of the 12 jurors concluded that ISI was not negligent in warning and training Bildsten. CP 5628. The court entered judgment for ISI, ruling that as an out-of-state defendant served under the long-arm statute, ISI could move for attorney fees. CP 5632. Josette timely appealed. CP 5640.

ARGUMENT

A. Standards of Review.

Josette's challenges jury instruction challenges (Arguments B and C) concern statutory interpretation, a legal question reviewed *de novo*. ***State v. Wentz***, 149 Wn.2d 342, 346, 68 P.3d 282 (2003) (citing ***City of Pasco v. Pub. Emp't Relations Comm'n***, 119 Wn.2d 504, 507, 833 P.2d 381 (1992)). The remaining instructional and evidentiary issues are reviewed for an abuse of discretion. ***Kappelman v. Lutz***, 167 Wn.2d 1, 6, 217 P.3d 286 (2009); ***State v. Gallagher***, 112 Wn. App. 601, 609, 51 P.3d 100 (2002).

B. The trial court erred in failing to instruct the jury that ISI had a duty to warn the purchaser of the product, Harrison Hospital.

As noted, Josette offered jury instructions – consistent with the WPLA – that ISI had a duty to warn not only Bildsten, but also the purchaser, Harrison Hospital. Josette's proposed instructions 5 and 12 stated that ISI negligently gave inadequate and misleading warnings to Bildsten and Harrison. CP 4134, 4145.[7] Josette's proposed 28 states that Bildsten and Harrison were both consumers of the da Vinci robot. CP 4164.

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[7] Copies of the proposed instructions relevant here, and of the court's instructions, are attached as App. A and B.

1. The WPLA requires sellers of inherently dangerous products to warn purchasers.

Under the WPLA, ISI is a product seller and manufacturer of the da Vinci robot. A "product seller" is "any . . . entity that is engaged in the business of selling products." RCW 7.72.010(1). A "product" is "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." RCW 7.72.010(3). A "relevant product" "is that product . . . which gave rise to the product liability claim," – here, the da Vinci robot. *Id.* A "manufacturer" "includes a product seller who designs, produces, makes, fabricates, [or] constructs . . . the relevant product." RCW 7.72.010(2). Thus, ISI is undisputedly the product seller and manufacturer of the relevant product, the da Vinci robot.

Jossette is a claimant: "a person . . . asserting a product liability claim, including a wrongful death action, and, if the claim is asserted through or on behalf of an estate, the term includes claimant's decedent." RCW 7.72.010(5). A "product liability claim" "includes any claim or action brought for harm[8] caused by the . . .

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[8] "Harm" includes "any damages recognized by the courts of this state." RCW 7.72.010(6).

warnings, instructions, marketing, . . . or labeling of the relevant product." RCW 7.72.010(4). "It includes . . . any claim or action previously based on: . . . breach of, or failure to, discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation, concealment, or nondisclosure, whether negligent or innocent; . . . ." *Id.* Thus, Jossette is the claimant asserting a products liability claim against ISI for the harm caused to Fred by ISI's failure to warn Harrison, the purchaser of the relevant product, the da Vinci robot.

ISI may be liable for its failure to warn:

> 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.

RCW 7.72.030(1). Crucially here, ISI admits that its robot is not reasonably safe (CP 110) so "adequate warnings or instructions" had to be "provided with the product":

> 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.

RCW 7.72.030(1)(b) (emphasis added).

The only way to provide adequate warnings or instructions "with the product" is to provide them to the purchaser ***with the product***. Yet the trial court refused to instruct the jury that ISI had to provide adequate warnings and instructions with the product it sold to Harrison. Under the plain language of the statute, this was clear error. This Court should reverse and remand for trial of Josette's failure-to-warn-or-instruct claim.

2. ISI perverted the learned intermediary doctrine to escape its responsibility to warn Harrison.

Despite Josette's straightforward WPLA warnings-and-instructions claim, ISI objected to Josette's proposed instructions, arguing that under the learned intermediary doctrine, ISI had a duty to warn Bildsten only, not Harrison. CP 4697, 4699-4702. ISI proposed instructions omitting Harrison. CP 4224-46. Josette objected, arguing that ISI had perverted the learned intermediary doctrine. CP 4936-39. Josette also argued that, assuming the learned intermediary doctrine even applies, Harrison was a learned intermediary entitled to warnings because it purchased the robot and was responsible for establishing credentialing requirements. *Id.*

The court's instructions to the jury omitted Harrison. CP 5384-5431. The parties submitted exceptions in writing, and Josette

excepted to the court's instructions 6, 7, 10, 11 & 17, on the ground that they erroneously failed to include Harrison. CP 5217-5238, 5319-25. Josette argued that ISI affirmatively told Harrison that two proctored procedures was sufficient, despite knowing otherwise, and that Harrison credentialed Bildsten based on ISI's misinformation. CP 5320. Again, Josette also argued that ISI was misapplying the learned-intermediary doctrine and that Harrison was a learned intermediary in any event, so was entitled to warnings. *Id.*

The learned intermediary doctrine states that when a patient can obtain a product or service only from a physician, "the physician acts as a 'learned intermediary' ***between the manufacturer or seller and the patient***." ***Terhune v. A. H. Robins Co.***, 90 Wn.2d 9, 12-14, 577 P.2d 975 (1978) (emphasis added) (discussing RESTATEMENT (SECOND) OF TORTS § 402A, hereinafter "§ 402A"). Therefore, the manufacturer or seller does not have a duty to warn the patient, but rather the doctor. *Id.* The doctor then has the duty – and is the only entity that has the duty – to warn the patient. *Id.*

This doctrine says nothing about the statutory duty to provide necessary warnings and instructions "with the product" to the purchaser. RCW 7.72.030(1)(b). This case shows why these warnings are so important: Harrison is responsible for credentialing

doctors, which is crucial to keeping patients safe. Harrison sets the floor – the minimum requirements to permit surgeons to use the dangerous medical device. If the hospital is not adequately warned and instructed, it cannot safely set those requirements.

While ISI told the FDA that a great deal of training is required, and while the literature known to ISI at the time of the sale warned that anywhere from eight to 250 procedures were necessary before a physician could obtain proficiency, ISI never provided the promised intensive training, and instead told Harrison that only two proctored surgeries should be required for credentialing. Based on ISI's grossly inadequate – indeed false and misleading – warnings and instructions – Harrison credentialed a surgeon who was totally unqualified. Fred suffered the consequences. ISI should be held responsible for failing to warn and instruct Harrison.

This conclusion is consistent with the fundamental policy stated in ***Terhune***:

> [I]f the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient. It has also been suggested that the rule is made necessary by the fact that it is ordinarily difficult for the manufacturer to communicate directly with the consumer.

Terhune, 90 Wn.2d at 14. It follows that,

> if the product is [***not***] properly labeled and carries [***insufficient or negligent warnings or instructions, or fails to carry the***] necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may [***not***] reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, [***none of which is***] in the best interest of the patient. [***And while it***] has also been suggested that the rule is made necessary by the fact that it is ordinarily difficult for the manufacturer to communicate directly with the consumer[, ***here, ISI put three of its employees on Harrison's Steering Committee and worked directly with Harrison***.]

The learned intermediary doctrine thus should not be permitted to absolve sellers or manufacturers of their duties to warn the purchasers of their products, particularly where, as here, the purchaser is responsible for credentialing the use of the product.

The upshot of ISI's (successful) argument is that the seller and manufacturer have no obligation to warn a purchaser who plays an integral role in patient safety. Yet the learned intermediary doctrine literally has nothing to do with the seller/manufacturer's duty to provide adequate warnings and instructions with the product. This Court should reverse and remand for trial.

3. Assuming *arguendo* that the learned intermediary doctrine applies, then Harrison is a learned intermediary, where it purchased the robot and credentialed the doctors.

Josette also argued in the alternative that even if the learned intermediary doctrine applies here, Harrison was a learned intermediary entitled to adequate warnings because it purchased the medical device for use in its facility and was responsible for credentialing doctors to use it. As ***Terhune*** makes clear, the point of the learned intermediary doctrine is to get adequate warnings and instructions to those responsible for patient safety. 90 Wn.2d at 14. There can be no question here that Harrison is one of those responsible parties. Indeed, without Harrison's permission – its credential – no doctor may use the robot.

A hospital can be a learned intermediary in appropriate circumstances. *See, e.g.*, ***Ellis v. C. R. Bard, Inc.***, 311 F.3d 1272, 1283 (11 Cir. 2002) (morphine pump manufacturers sufficiently warned hospital physicians and nurses); ***Wright v. Abbott Labs., Inc.***, 259 F.3d 1226, 1233-34 (10th Cir. 2001) (manufacturer sufficiently warned hospital); ***Brown v. Drake-Willock Int'l., Ltd.***, 209 Mich. App. 136, 149 530 N.W.2d 510, 516 (1995) (hospital or physician was proper recipient of warning under learned

intermediary doctrine). In ***Brown***, for instance, the Court held that the doctrine applied to the manufacturer of a dialysis machine (209 Mich. App. at 149):

> We now hold that the reasoning and policy behind the learned intermediary rule applies not only to prescription drugs, but also to prescription devices such as dialysis machines. **Under the learned intermediary rule, the hospital or physician was the proper recipient of necessary information or warnings, not plaintiff.**

Indeed, ***Terhune*** itself cited to ***McEwen v. Ortho Pharm. Corp.***, 270 Or. 375, 528 P.2d 522 (1974), in which the Court held that the doctrine extends not only to the prescribing physician, but to "all members of the medical profession who come into contact with the patient in a decision-making capacity." 90 Wn.2d at 13 (*see* ***McEwen***, 270 Or. at 388). That is, the manufacturer has "a duty to warn the medical profession of untoward effects which the manufacturer knows, or has reason to know, are inherent in the use of its drug." ***McEwen***, 270 Or. at 389.[9] While ***McEwen*** is a drug case, its reasoning applies equally well to medical devices.

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[9] Citing, *inter alia*, ***Sterling Drug, Inc. v. Cornish***, 370 F.2d 82 (8th Cir. 1966); ***Parke-Davis & Co. v. Stromsodt***, 411 F.2d 1390 (8th Cir. 1969); ***Basko v. Sterling Drug, Inc.***, 416 F.2d 417 (2d Cir. 1969); ***Love v. Wolf***, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); ***Krug v. Sterling Drug, Inc.***, 416 S.W.2d 143 (Mo.1967).

Just as doctors must exercise independent judgment based on a particular patient and medical device, so must hospitals establishing credentialing requirements exercise independent judgment based on doctors' abilities and the product they will be credentialed to use. The only way a hospital can know the minimal requirements for safely using such a complex medical device is if the manufacturer and seller properly warns and instructs on its use. Eliminating that duty – as the trial court did here – places patients at grave risk. The Court should reverse and remand for trial under proper instructions.

C. Strict liability, not negligence, governs the inadequate-warning claims.

Under the WPLA, Washington common law and § 402A, manufacturers and sellers are strictly liable for product defects. Comment *k* to § 402A provides a narrow exemption from strict liability, applying a negligence standard where an "unavoidably unsafe product" is "properly prepared, and accompanied by proper directions and warning." § 402A cmt. *k*.[10] Thus, the questions presented here are: (1) whether comment *k* applies at all to

[10] An "unavoidably unsafe product" is one that cannot be made safe for its intended and ordinary use. § 402A, cmt. *k*. The most common example is prescription drugs.

inadequate-warning claims, despite its language requiring that proper directions and warnings are provided; and if not, then (2) whether courts should apply a product-by-product inquiry to determine whether a particular prescription drug or medical device should be exempt from strict liability.

1. Our Supreme Court has left open the question whether comment *k* applies to inadequate-warning claims, and whether its application depends on the product's social utility greatly outweighing its inherent risks.

In ***Falk v. Keene***, our Supreme Court held that under RCW 7.72.030(1)(a), strict liability, not ordinary negligence, is the standard for design-defect claims. 113 Wn.2d 645, 654, 782 P.2d 974 (1989). Following ***Falk*** in ***Ayers v. Johnson & Johnson Baby Prods. Co.***, the Court held that strict liability is also the standard in subsection (b) governing inadequate-warning claims. 117 Wn.2d 747, 762-63, 818 P.2d 1337 (1992). And in ***Anderson v. Weslo, Inc.***, this Court held that "[t]he standard for allegations of defective design and of inadequate warnings is one of strict liability." 79 Wn. App. 829, 836, 906 P.2d 336 (1995)). This is consistent with § 402A, which imposes strict liability on manufacturers and sellers of defective products.

Comment *k* to § 402A creates an exemption from strict liability only for "unavoidably unsafe products" that are "properly prepared, and accompanied by proper directions and warning":

> *k. Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. . . . **Such a product, properly prepared, and accompanied by proper directions and warning, is not defective**, nor is it *unreasonably* dangerous. . . . 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, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

§ 402A, cmt. *k* (bold emphases added). Since the Legislature did not expressly provide for comment *k* in the WPLA, the courts "must be sparing in its application lest [they] defeat the letter or policy of the WPLA." ***Ruiz-Guzman v. Amvac Chem. Corp.***, 141 Wn.2d 493, 7 P.3d 795 (2000).

There are four major Washington Supreme Court cases addressing comment *k*, beginning with ***Terhune***, in which the Court held that the manufacturer of the Dalkon Shield, a contraceptive device, would not be liable for injuries caused by its product if it gave adequate warnings to the prescribing physician. 90 Wn.2d at 9, 13-

14. In other words, the ***Terhune*** Court adopted the learned intermediary doctrine. *Id.* at 14.

The second case addressing comment *k*, ***Rogers v. Miles Labs, Inc.***, involved a blood product supplied to hemophiliacs to promote clotting. 116 Wn.2d 195, 198, 802 P.2d 1346 (1991). There, the Court was confronted with a question certified from the federal district court, asking whether strict liability applied to a for-profit pharmaceutical company for injuries allegedly resulting from blood products derived from plasma obtained from compensated donors. 116 Wn.2d at 197. The Court held that blood and blood products fell under comment *k*'s strict-liability exemption (*id.* at 204):

> The alternative would be that a product, essential to sustain the life of some individuals, would not be available – thus resulting in a greater harm to the individual than that risked through use of the product.

The third major case, ***Young v. Key Pharmaceuticals, Inc.***, is a 4-4 plurality decision affirming (for lack of a constitutional majority) summary judgment dismissing plaintiff Young's strict liability claims, holding that Young's inadequate-warning claims were governed by a negligence standard under comment *k*. 130 Wn.2d 160, 168-71, 922 P.2d 59 (1996). The plurality adopted an

unpublished holding that comment *k* applies to all prescription drugs, rejecting a product-by-product determination. *Id.* at 170.

The dissent, authored by Chief Justice Madsen, disagreed with the plurality's application of a negligence standard to inadequate-warning claims, stating that strict liability applies and that the contrary suggestion in ***Rogers*** is *dicta* based on a California case that had since been clarified in a manner inconsistent with ***Rogers***:

> [W]hile application of the comment *k* exception . . . depends upon adequate warnings having been given, the adequacy of warnings is *not* measured by comment *k,* but is instead measured by the strict liability standard of § 402A. [***Rogers***] contains language supporting the majority. However, the analysis in ***Rogers*** was founded on a California Supreme Court decision which the California Court subsequently explained did not hold that comment *k* alters the § 402A rule of strict liability when the claim is failure to adequately warn. ***Rogers*** is, thus, inconsistent with the California law it purports to follow. It is also inconsistent with the court's holding that a failure to warn claim is a strict liability claim.

Id. at 179 (Madsen, J., dissenting). The dissent also distinguished ***Rogers*** on the ground that it involved a product-defect claim, not a failure-to-warn claim:

> [I]t is important to recognize that the plaintiff in ***Rogers*** did not claim that the warning in that case was inadequate. Thus, the adequacy of warnings under comment *k* was not before that court.

Id. at 182. And the portion of ***Rogers*** applying comment *k* to inadequate-warning claims is *dicta*:

> Although the plaintiff argued neither manufacturing flaw nor inadequate warnings, ***Rogers*** nevertheless went on to make additional gratuitous observations regarding any possible issues based on the defendants' duty to warn . . .
>
> Justice Callow, writing for the majority, was correct – it *could* have been argued that the failure to adequately warn would deprive the manufacturer of comment *k* protection and thus render it strictly liable under the common law. It is clear, however, that neither the question nor the argument were before the court in ***Rogers***. . . . ***Rogers*** is simply not binding authority on the issues in this case.

Id. at 183-84 (Madsen, J., dissenting).

After ***Young***, the Court again revisited comment *k* in ***Ruiz-Guzman***, involving two questions certified by the Ninth Circuit Court of Appeals, the second of which is relevant here: whether a pesticide can be "an 'unavoidably unsafe product' as described in comment *k*?" 141 Wn.2d at 495. The Court was also asked to revisit the ***Young*** plurality decision that all prescription drugs are governed by a negligence standard under comment *k*. *Id.* at 508.

In ***Ruiz-Guzman***, manufacturer Amvac agreed that the ***Young*** plurality would treat all drugs equally regardless of their vastly different social utility "and that this is a result arguably incongruent with the social utility reasoning in ***Terhune*** and ***Rogers***." *Id.* Yet the Court declined amicus WSTLA Foundation's "invitation to 'reject the view that all prescription drugs are exempted from strict liability analysis' and exchange it for a product-by-product approach,"

holding that the only question properly before the Court on certification was whether comment *k* applied to pesticides. *Id.* The Court held that whether a pesticide is governed by comment *k* "is to be determined on a product-by-product basis, as opposed to a blanket exemption like that for medical products," with the jury determining the products' "value to society relative to the harm it causes." *Id.* at 511.

2. This Court should hold that strict liability applies to inadequate-warning claims.

As above, § 402A, the WPLA, and Washington common law hold manufacturers and sellers strictly liable when their product warnings and instructions are inadequate, or as here, non-existent. By its express terms, comment *k*'s exemption from strict liability applies only when the seller has satisfied a very important predicate – the product is "properly prepared and marketed" and "accompanied by proper directions and warning." § 402A, cmt *k*. Thus, comment *k* cannot apply to inadequate-warning claims.

None of the Supreme Court cases discussed above compel a different result. ***Terhune*** does not address the standard applied to inadequate-warning clams, but adopts the learned-intermediary doctrine. ***Ruiz-Guzman*** also does not address the standard applied

to inadequate-warning claims, noting that "Plaintiffs [did] not dispute the adequacy of the warnings or instructions provided," arguing only design defects. 141 Wn.2d at 498 (citing RCW 7.72.030(1).[11] While on point, the ***Young*** plurality "has limited precedential value and is not binding." ***Lauer v. Pierce Cnty.***, 173 Wn.2d 242, 258, 267 P.3d 988 (2011) (quoting ***In re Pers. Restraint of Isadore***, 151 Wn.2d 294, 302, 88 P.3d 390 (2004)).

Rogers is inapposite, as it is properly limited to blood and blood products. *Id.* at 204-06. ***Rogers*** relied heavily on ***Howell v. Spokane & Inland Empire Blood Bank***, in which the Court "unanimously concluded that '[t]he purposes of strict liability are not furthered when applied to blood and blood products.'" *Id.* at 204 (quoting 114 Wn.2d 42, 53, 785 P.2d 815 (1990)).[12] ***Rogers*** addresses blood products only, not medical devices or drugs. 116 Wn.2d at 203-06.

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[11] While the parties disputed whether plaintiff had also raised warning claims in the federal district court, our Supreme Court reserved that issue for the Ninth Circuit, holding that resolution of that inquiry was irrelevant to the certified question. 141 Wn.2d at 499 n.3.

[12] Since the WPLA excludes blood and blood products from coverage, ***Howell*** examined strict liability under the common law. 114 Wn.2d at 51; RCW 7.72.010(3) – (5).

The part of ***Rogers*** purporting to address inadequate-warning claims is *dicta*. The issue in ***Rogers*** was design defect – the plaintiff did not claim that warnings were inadequate. 116 Wn.2d at 197. Indeed, the ***Rogers*** Court deferred "*any issues regarding defendants' duty to warn*" to the federal court. *Id.* at 207 (emphasis added). Since the discussion of the standard applicable to inadequate-warning claims was not necessary to the Court's holding, it is *dicta*, so is not binding. ***Protect the Peninsula's Future v. City of Port Angeles***, 175 Wn. App. 201, 215, 304 P.3d 914, *rev. denied*, 178 Wn.2d 1022 (2013).

And the *dicta* in ***Rogers*** is simply wrong. As discussed above, if ***Rogers*** is interpreted to apply comment *k* to inadequate-warning claims, then it ignores comment *k*'s plain language requiring proper instructions and warnings. This is at odds with the Supreme Court's more recent holding that comment *k* must be sparingly applied. ***Ruiz-Guzman***, 141 Wn.2d at 506.

The *dicta* in ***Rogers*** is also contrary to numerous Washington cases beginning with ***Little v. PPG Industries, Inc.***, establishing strict liability as the standard applicable to inadequate-warning claims. 92 Wn.2d 118, 594 P.2d 911 (1979). And as Justice Madsen pointed out in her ***Young*** dissent, ***Rogers*** relied heavily on foreign

precedent that no longer supports ***Rogers***. 130 Wn.2d at 184-87 (Madsen, J., dissenting).

In short, none of these cases requires this Court to apply comment *k* to Josette's inadequate-warning claims.[13] This Court should decline to do so, where such an application of comment *k* is inconsistent with its plain language and years of common law applying strict liability to inadequate-warning claims. Thus, Josette respectfully asks this Court to disagree with Division One's holding in ***LaMontagne*** that under comment *k*, a negligence standard governs inadequate-warning claims. 127 Wn. App. at 343. ***LaMontagne*** provides no analysis, and does not address ***Young*** or ***Rogers***. It's reliance on ***Ruiz-Guzman*** is misplaced, where ***Ruiz-Guzman*** does not address this issue or even involve a negligent-warning claim. This Court should reverse.

3. This Court should hold that comment *k* is not a blanket exemption, but applies only on a product-by-product basis.

Alternatively, this Court should hold that comment *k* does not apply unless and until the jury concludes that the da Vinci robot's

[13] The WASHINGTON PATTERN JURY INSTRUCTIONS commentators have also noted that strict liability may be an open question in warnings cases. *See, e.g.*, Comments to WPI 110.03 regarding "Comment *k*."

social utility greatly outweighs its inherent risk. In ***Ruiz-Guzman***, the Supreme Court adopted a "product-by-product approach" for pesticides, holding that "the defendant manufacturer of a challenged product would have to demonstrate that an inherently dangerous product is also 'necessary regardless of the risks involved to the user.'" 141 Wn.2d at 509-10 (quoting ***Rogers***, 116 Wn.2d at 204). This approach is "Consistent with the social utility reasoning of ***Rogers***," focusing "on the product and its *relative value to society* . . . ." *Id.* (emphasis in original).

> The Court found the following test "helpful":
>
> For the rule precluding liability for unavoidably unsafe products to apply to a given product, ***the product's utility must greatly outweigh the risk created by its use***, the risk must be a known one, ***the product's benefit must not be achievable in another manner***, and the risk must be unavoidable under the state of knowledge existing at the time of manufacture.

*Id. (*quoting ***Arkansas-Platte & Gulf P'ship v. Dow Chem. Co.***, 886 F.Supp. 762, 767 (D. Colo. 1995) (citing ***Camacho v. Honda Motor Co.***, 741 P.2d 1240, 1244 n.5 (Colo. 1987), *cert. dismissed,* 485 U.S. 901, 108 S. Ct. 1067, 99 L. Ed. 2d 229 (1988))) (emphasis added). The ***Ruiz-Guzman*** Court held that this analysis was consistent with both ***Terhune*** and ***Rogers***. 141 Wn.2d at 510.

The Court did not determine whether the product-by-product approach applied to pesticides should also apply to prescription drugs, where that question was not properly before the Court on certification. *Id.* at 508. But as discussed in ***Ruiz-Guzman***, treating all prescription drugs equally, regardless of their "*vastly differing* social utility," is "incongruent with the social utility reasoning in ***Terhune*** and ***Rogers***." *Id.* This is equally true for medical devices.

A jury could easily find that the da Vinci robot's "utility" does not "greatly outweigh the risk created by its use," particularly where its benefits are "achievable in another manner." *Id.* at 510 (quoting ***Arkansas-Platte*** and ***Camacho***, *supra*). There were numerous other treatments available to Fred, ranging from radiation to radical prostatectomy using an open and traditional laparoscopic approach. RP 1061. As compared to other procedures, the benefits of robotic prostatectomy are minimal. RP 1950-51. These minimal benefits are plainly outweighed by the risks associated with robotic prostatectomy, including dramatically higher margin rates. *Supra*, Statement of the Case § J. Any rational patient, properly warned, would chose an open procedure, or seek out a very experienced surgeon, rather than face a 35% chance that the cancer will survive the surgery. RP 1949-51, 1965.

In sum, this Court should hold that comment *k* applies only when a product is "accompanied by proper directions and warning," so it does not exempt adequate-warning claims from the strict-liability rule imposed by § 402A, the WPLA, and our common law. Alternatively, this Court should hold that comment *k* is not a sweeping exemption applied to all medical products, but a narrow one applied only if a jury determines that a product's social utility greatly outweighs its inherent risk. The Court should reverse.

D. The trial court erred in prohibiting Josette from rebutting testimony that the robotics program at Harrison was very successful other than Fred's procedure.

While re-cross-examining O'Connor, ISI raised, for the first time, the overall success of Harrison's robotics program, strongly suggesting that there were no other similar incidents. RP 855. That is false. RP 1430; CP 4482. Thus, ISI "opened the door" to Josette's proposed exhibit 304 and to testimony that would explain, clarify or contradict O'Connor's assertion.[14] ***State v. Gefeller***, 76 Wn.2d 449, 455, 458 P.2d 17 (1969). The trial court erroneously prohibited any such evidence. This Court should reverse.

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[14] Exhibit 304 is not in the record, but it is discussed in detail at RP 1412-30, 1625-30, and CP 4481-84.

The term "opening the door" is commonly used in two different but overlapping senses:

> (1) a party who introduces evidence of questionable admissibility may open the door to rebuttal with evidence that would otherwise be inadmissible, and (2) a party who is the first to raise a particular subject at trial may open the door to evidence offered to explain, clarify, or contradict the party's evidence.

5 Karl B. Tegland, WASH. PRAC.: EVIDENCE LAW & PRACTICE § 103.14 (5th ed. 2007). Our courts often repeat the "sound general rule" that one who opens a subject must expect that the opponent may inquire. ***Gefeller***, 76 Wn.2d at 455; ***Ang v. Martin***, 118 Wn. App. 553, 562, 76 P.3d 787 (2003), *aff'd*, 154 Wn.2d 477, 114 P.3d 637 (2005).

As this Court put it, "The rule is aimed at fairness and truth-seeking." ***Ang***, 118 Wn. App. at 562. Stated another way:

> It would be a curious rule of evidence which allowed one party to bring up a subject, drop it at a point where it might appear advantageous to him, and then bar the other party from all further inquiries about it. Rules of evidence are designed to aid in establishing the truth. To close the door after receiving only a part of the evidence not only leaves the matter suspended in air at a point markedly advantageous to the party who opened the door, but might well limit the proof to half-truths. Thus, it is a sound general rule that, when a party opens up a subject of inquiry on direct or cross-examination, he contemplates that the rules will permit cross-examination or redirect examination, as the case may be . . . .

Gefeller, 76 Wn.2d at 455.

1. The trial court erroneously refused to allow Josette to contradict ISI's false impression that there were no similar incidents at Harrison.

The line of questioning at issue began when Taylor asked O'Connor about an ISI email that circulated immediately before Harrison began its robotics program. RP 731-33, 811; Ex 116. The email, drafted by O'Connor's superior, Dave Carson (Capital Sales Manager on Harrison's account) acknowledged O'Connor's concerns about the "potential quality" of a robotics program at Harrison, but instructed O'Connor not to say anything:

> I have a concern and I just want to bring it up before Monday. As managers, it is important neither of us communicate any bias against Harrison. I know you expressed some doubt about the potential quality of their program after our surgeon administration meeting two weeks ago. That concern, however, shouldn't extend beyond you and me. . . .

RP 732-33, 811; Ex 116. Carson instructed O'Connor to "exhibit enthusiasm toward the Harrison rollout," twice stating that hospitals like Harrison are ISI's "future." Ex 116. When asked whether he had "ever expressed doubt to Harrison about the potential quality of their program," O'Connor answered, "No." RP 733, 811.

On cross-examination, O'Connor acknowledged his concern about poor communication at ISI regarding "proper accountability and transition of activities" as they were "getting ready to implement

and launch the program" at Harrison. RP 795. He was afraid someone was going to drop the ball. RP 795-96.

On re-cross, ISI asked O'Connor why he "did not express doubts about the quality." RP 855. Rather than address the context of the email – the time right before Harrison's robotics program began – O'Connor opined that "outside this incident . . . it's been a very successful program," divulged that Harrison was purchasing another robot, and concluded that Harrison too had no concerns (*id.*):

> Because outside this incident we're talking about, its [*sic*] been a very successful program. The surgeons that were involved from the beginning are still involved today. The hospital made the decision to buy SI [*sic*] technology this past December. They're currently talking to our clinical team to buy another one. These are all the same doctors that were involved in 2008 minus Dr. Bildsten. So if they were concerned about the quality the technology was providing to the patient care, they wouldn't be reinvesting in the program.

This plainly suggests that there were no other similar incidents.

The truth is that there were a number of other incidents at Harrison, ranging from problems with the robot and robotic instruments, to excessive console time, leaky anastomosis,[15] and

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[15] Anastomosis is a surgical connection between two organs, here the bladder and urethra. RP 915-16. It is not uncommon to have anastomotic leaks in an open procedure, in which a watertight seal is not crucial. RP 947, 1055. But a watertight seal is crucial in a robotic procedural, in which a leaky seal can increase the risk of infection. *Id.* ISI did not train on the importance of a watertight seal. RP 1055.

unintended lacerations and conversions to open procedures. RP 1416-18 (discussing proposed Ex 304); CP 4482. Bildsten had all of these. RP 911, 1107, 1111, 1287. The jury never heard the truth.

Instead, the jury heard that aside from Fred's procedure, Harrison's program was "very successful." RP 855. It was told that Harrison was purchasing another robot and that except Bildsten, all of Harrison's surgeons who started out in 2008 were still participating in its "very successful" program. *Id.* This testimony was incredibly damaging because it created the false impression that the problems in Fred's procedure were isolated. CP 4482; RP 1414, 1629.

O'Connor's inaccurate testimony furthered ISI's principal defense – that it did nothing wrong and that Bildsten was solely to blame. Prohibiting Josette from presenting contradictory evidence, deprived her of the opportunity to rebut ISI's false impression and prevented her from arguing her case theory that ISI's inadequate warnings were a cause of Fred's injuries. RP 1418. The court's error deprived the jury of the truth.

In this regard, this case is similar to ***Gallagher***, a prosecution for the manufacture of methamphetamine, where the trial court ruled *in limine* that drug paraphernalia found in the defendant's home were inadmissible. 112 Wn. App. at 609. During cross-examination,

defense counsel pressed a police detective to admit that the police found no paraphernalia in the defendant's home, taking advantage of the ruling prohibiting such evidence. 112 Wn. App. at 609. This opened the door to the otherwise inadmissible evidence. *Id.* at 610.

The appellate court affirmed, holding that if the trial court had not allowed contradictory evidence, the defense "would have succeeded in painting a false picture that no drug-related activities took place in the home." *Id.* But here, the trial court excluded Josette's contradictory evidence, so ISI succeeded in painting the false picture that there were no other similar incidents at Harrison.

2. The trial court mistakenly believed that O'Connor's testimony was responsive to Josette's initial inquiry.

The trial court mistakenly believed that "O'Connor's testimony was responsive to the broad question, did you ever express concerns." RP 1429. Indeed, ISI argued that Josette's inquiry was "open ended and not limited to any time period." CP 4477, 4488-89. That is false.

When Josette examined O'Connor, she was under the impression that either by motion *in limine* or by agreement, neither party would inquire about surgical outcomes at Harrison post-dating Fred's procedure. RP 878-79, 1221. Consistent with that

understanding, Josette asked about an email that circulated immediately before Harrison started its robotics program, addressing concerns about Harrison's "potential" program. RP 733, 811; Ex 116. This inquiry is not broad, but was "limited to [the] time period" right before Harrison purchased a robot, when its program was "potential." *Compare id. with* RP 1429; CP 4477, 4488-89.

It ISI who posed a "broad" question to O'Connor, asking why he had not "express[ed] doubts about the quality?" RP 855. This elicited a broad response about the program's eventual success, which cannot and does not explain O'Connor's failure to be candid with Harrison *before* it purchased a robot. RP 855.

3. ISI opened the door by first raising the issue – it is irrelevant that O'Connor's testimony did not violate an order *in limine*.

As noted, "a party who is the first to raise a particular subject at trial may open the door to evidence offered to explain, clarify, or contradict the party's evidence." WASH. PRAC. § 103.14. That O'Connor's testimony did not violate an *in limine* ruling the court had not yet made is irrelevant. RP 1429; CP 4483. ISI gratuitously characterized Harrison's robotic program as "very successful," falsely suggesting that there were no other similar incidents. CP 4483. ISI opened the door. ***Gefeller***, 76 Wn.2d at 455.

4. The curative instruction could not remove the prejudice O'Connor's testimony created.

Some evidence is simply too prejudicial to be overcome by an instruction to disregard it:

> [W]here evidence is admitted which is inherently prejudicial and of such a nature as to be most likely to impress itself upon the minds of the jurors, a subsequent withdrawal of that evidence, even when accompanied by an instruction to disregard, cannot logically be said to remove the prejudicial impression created.

State v. Suleski, 67 Wn.2d 45, 51, 406 P.2d 613 (1965). In other words, some bells cannot be unrung. ***Suleski***, 67 Wn.2d at 51. For example, when a defendant's credibility is at issue, admitting evidence of a prior conviction cannot be cured by an instruction to disregard. ***State v. Dixon***, 17 Wn. App. 804, 808-09, 565 P.2d 1207 (1977); ***State v. Mathes***, 22 Wn. App. 33, 587 P.2d 609 (1978).

The obvious implication of O'Connor's testimony was that Fred's procedure was an outlier; that Bildsten was the only robotics surgeon at Harrison to experience problems; and that Harrison's robotics program was otherwise problem-free. RP 855. This is not something that can be ignored. ISI misled the jury that there were no other similar incidents at Harrison. The court erred in refusing exhibit 304 or other contrary testimony.

E. This Court should address two addition errors to avoid repetition on review.

Two additional errors are not necessarily reversible error, but they should be addressed to avoid repetition on remand. First, no superseding cause instruction should have been given, as Dr. Bildsten's negligence was a foreseeable and direct consequence of ISI failures to warn. Second, the mitigation of damages instruction improperly invited the jury to reduce Fred's damages twice.

1. The trial court erred in giving a superseding cause instruction, where Dr. Bildsten's negligence was a foreseeable consequence of ISI's failures to warn and instruct him and Harrison, and it omitted Harrison.

ISI proposed a superseding cause instruction, No. 28 ("PI 28"). CP 4753. Josette objected to PI 28 because (1) a superseding cause instruction was inappropriate; (2) PI 28 failed to refer to negligence; (3) it failed to reference Harrison; and (4) it omitted crucial portions of WPI 15.05. CP 4943-44. Nonetheless, the trial court gave a superseding cause instruction, No. 19. CP 5406 ("JINS 19"). Josette formally objected. CP 5322.

Specifically, a superseding cause instruction is inappropriate where, as here, the alleged intervening act (Dr. Bildsten's negligence) did not bring about a different type of harm than would be anticipated from the alleged negligence (ISI's failures to warn Dr.

Bildsten and Harrison), the Dr. Bildsten's act was not extraordinary and did not act independently from the ISI's failures to warn. *Id.* *See* ***Campbell v. ITE Imperial Corp.***, 107 Wn.2d 807, 812-13, 733 P.2d 969 (1987) (error in giving superseding cause instruction). It is foreseeable as a matter of law that a doctor and hospital who are not properly warned or instructed might commit negligence. ***Campbell***, 107 Wn.2d at 813. The likelihood of the doctor and hospital committing error is one of the hazards that makes ISI negligent, so it cannot be a superseding cause. *Id.* at 814-15 (citing RESTATEMENT (SECOND) OF TORTS § 449).

In ***Campbell***, the Court specifically addressed and rejected the anomalous idea that a manufacturer's failure to warn would be a superseding cause, perhaps even shifting the burden to warn to purchasers like Harrison (107 Wn.2d at 814):

> The manufacturer bears responsibility for affixing an adequate warning to its product. Thus, it would be anomalous to hold that an employer's failure to warn constituted a superseding cause. **Such a rule might improperly shift the duty of warning to product purchasers.** Although such a purchaser might be held jointly liable for breach of its duty to warn, its negligence generally should not relieve the manufacturer of liability for failure to warn. [Cites omitted; emphasis added.]

This instruction was clear error. Although the jury did not reach the question, the error might be repeated on remand. The Court should hold that superseding cause is not applicable here.

2. The mitigation instruction improperly invited the jury to reduce the damages award twice.

The trial court gave a failure-to-mitigate instruction that ISI "is not liable for any damages" caused by Fred's failure to mitigate. CP 5407. This instruction told the jury not to include in its total damages award any amount Fred could have avoided by exercising ordinary care. CP 5323. But the verdict form required the jury to account for any failure to mitigate by assigning a percentage of fault to Fred "for his failure, if any, to mitigate his damages." CP 5629. Taking the instruction and verdict form together, the jury was asked to reduce damages twice – first by omitting damages off the top, and again by allocating fault to Fred. CP 5323, 5629. This is plain error.

Allocating fault to Fred is also an inappropriate way to account for any failure to mitigate. *Id.* As the court properly instructed, ISI had "the burden to prove [Fred's] failure to exercise ordinary care and the amount of damages, if any, that would have been minimized or avoided." CP 5407; ***Young v. Whidbey Island Bd. of Realtors,***

96 Wn.2d 729, 734, 638 P.2d 1235 (1982). Allowing the jury to apply a percentage reduction improperly reduced ISI's burden. CP 5323.

Josette objected to Instruction 20 and to the verdict form, raising all of the points addressed above. CP 5322-23, 5324. Although the jury did reach this issue, this Court should address it so that the error is not repeated in remand.

CONCLUSION

For the reasons stated, the Court should reverse and remand for trial of Josette's claims against Harrison, under proper instructions.

RESPECTFULLY SUBMITTED this 10th day of February, 2014.

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CERTIFICATE OF SERVICE BY MAIL

I certify that I caused to be mailed, a copy of the foregoing BRIEF OF APPELLANT, postage prepaid, via U.S. mail on the 10th day of February, 2014, to the following counsel of record at the following addresses:

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APPENDICES TO BRIEF OF APPELLANT
Taylor v. Intuitive Surgical, Inc
No. 45052-6-II

Appendix A	Excerpts from Plaintiff's Proposed Instructions
Appendix B	Court's Instructions to the Jury
Appendix C	Exhibit 116
Appendix D	Restatements, Statutes & WPIs

INSTRUCTION NO. 5

I will now describe for you the basic elements of the claims and defenses that the parties intend to prove in this case. I am doing so for only one purpose: to help you evaluate the evidence as it is being presented.

Please remember that the claims and defenses might change during the course of a trial. For this reason, this instruction is preliminary only. It may differ from the final instructions you receive at the end of the trial. Your deliberations will be guided entirely by those final instructions.

Mrs. Taylor claims that ISI was negligent because it engaged in improper and misleading marketing of the robotic surgical system, provided inadequate and misleading warnings, and inadequately trained Dr. Bildsten and the Harrison Medical Center staff.

Mrs. Taylor claims that ISI's conduct was a proximate cause of injuries and damage to her husband, her, and her husband's estate.

ISI denies these claims and asserts that Dr. Bildsten and Fred Taylor are the proximate cause of any injuries and damages suffered by plaintiffs.

ISI further denies the nature and extent of the claimed injuries and damage.

WPI 1.01.03.

INSTRUCTION NO. 12

Issues

Mrs. Taylor claims that ISI was negligent because it engaged in improper and misleading marketing of the robotic surgical system, provided inadequate and misleading warnings, and inadequately trained Dr. Bildsten and the Harrison Medical Center staff.

Mrs. Taylor claims that ISI's conduct was a proximate cause of injuries and damage to her husband, her, and her husband's estate.

ISI denies these claims and asserts that Dr. Bildsten and Fred Taylor are the proximate cause of any injuries and damages suffered by plaintiffs.

ISI further denies the nature and extent of the claimed injuries and damage.

The foregoing is merely a summary of the claims of the parties. You are not to consider the summary as proof of the matters claimed and you are to consider only those matters that are admitted or are established by the evidence. These claims have been outlined solely to aid you in understanding the issues.

WPI 20.01 (modified); WPI 20.05; CR 12(i); Court's Memorandum Opinion of 3/25/13. *See also Estate of LaMontagne v. Bristol-Myers Squibb*, 127 Wn. App. 335, 111 P.3d 857 (2005) ("Whether a prescription drug

manufacturer provides adequate warnings to physicians is governed by the negligence standard under the Restatement (Second) of Torts § 402A, cmt. k (1965).."). Plaintiff disagrees with this statement from the *Estate of LaMontagne* and wishes to preserve her position that a strict liability standard should apply in accordance with the statutory requirements of RCW 7.72.030. *See* Alternative strict liability instructions, filed in conjunction with these instructions. In the face of *Estate of LaMontagne*, however, a negligence standard must be applied to Plaintiff's WPLA claims.

INSTRUCTION NO. 28

For purposes of this case, the "consumers" of the da Vinci robotic surgical system are Dr. Bildsten and Harrison Medical Center.

Adams v. Synthes Spine Co., LP, 298 F.3d 1114 (9th Cir. 2002) ("Under Washington law, the "consumer" of a prescription-only medical device such as this is the physician, not the patient in whom it is installed.") (citing *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 14, 577 P.2d 975, 978 (1978)); *Washington State Physicians Ins. Exchange & Ass'n v. Fisons Corp.*, 122 Wn.2d 299, 313, 858 P.2d 1054, 1061 (1993) (relying on cases that "have concluded that it is the physician who stands in the shoes of the 'ordinary consumer' of the drug.") (citing *Phelps v. Sherwood Med. Indus.*, 836 F.2d 296, 302 (7th Cir.1987); *Carmichael v. Reitz*, 17 Cal.App.3d 958, 989, 95 Cal.Rptr. 381, 401 (1971)) .

ALTERNATIVE INSTRUCTION NO. 1

Issues

(1) Mrs. Taylor claims that the robotic surgical system manufactured and sold by ISI was not reasonably safe because ISI engaged in insufficeint and misleading marketing, or failed to provide adequate warnings, instructions or training to Dr. Bildsten and the Harrison Medical Center staff.

(2) Mrs. Taylor claims that ISI's conduct was a proximate cause of injuries and damage to her husband, her, and her husband's estate.

(4) ISI denies these claims.

(5) In addition, ISI claims as an affirmative defense that the proximate cause of Mr. Taylor's injuries and death was due to the fault of Dr. Bildsten.

(5) ISI further denies the nature and extent of the claimed injuries and damage.

The foregoing is merely a summary of the claims of the parties. You are not to consider the summary as proof of the matters claimed and you are to consider only those matters that are admitted or are established by

the evidence. These claims have been outlined solely to aid you in understanding the issues.

WPI 20.01 (modified); WPI 20.05; CR 12(i).

ALTERNATIVE INSTRUCTION NO. 2

Manufacturer's Duty to Provide Warnings or Instructions With Product

A manufacturer has a duty to supply products that are reasonably safe.

A product may not be reasonably safe because of improper marketing, or because inadequate or misleading warnings or instructions or inadequate training, were provided with the product.

There are two tests for determining whether a product is not reasonably safe because of improper marketing, or because inadequate or misleading warnings or instructions or inadequate training, were provided with the product.

The Plaintiffs may prove that the product was not reasonably safe because of improper marketing, or because inadequate or misleading warnings or instructions or inadequate training, were provided with the product, using either of these two tests.

The first test is whether, at the time of manufacture:

a. the likelihood that the product would cause injury or damage similar to that claimed by the Plaintiffs, and the seriousness of such injury or damage, rendered the marketing, warnings, instructions or training of the

manufacturer inadequate; and

b. the manufacturer could have provided adequate marketing, warnigns, instructions or training.

The second test is whether the product is unsafe to an extent beyond that which would be contemplated by an ordinary user. In determining what an ordinary user would reasonably expect, you should consider the following:

a. the relative cost of the product;

b. the seriousness of the potential harm from the claimed defect;

c. the cost and feasibility of eliminating or minimizing the risk; and

d. such [other] factors as the nature of the product and the claimed defect indicate are appropriate.

A product can be "not reasonably safe" even though the risk that it would cause the plaintiff's harm or similar harms was not foreseeable by the manufacturer at the time the product left the manufacturer's control.

If you find that the product was not reasonably safe because of adequate marketing, warnings, instructions or training were not provided with the product and this was a proximate cause of the Plaintiffs' injuries and damages, then the manufacturer is subject to liability and fault. WPI 110.03 (modified).

ALTERNATIVE INSTRUCTION NO. _____

Issues

(1) Mrs. Taylor claims that the robotic surgical system manufactured and sold by ISI was not reasonably safe because ISI engaged in insufficeint and misleading marketing, or failed to provide adequate warnings, instructions or training to Dr. Bildsten and the Harrison Medical Center staff.

(2) Mrs. Taylor claims that ISI's conduct was a proximate cause of injuries and damage to her husband, her, and her husband's estate.

(4) ISI denies these claims.

(5) In addition, ISI claims as an affirmative defense that the proximate cause of Mr. Taylor's injuries and death was due to the fault of Dr. Bildsten.

(5) ISI further denies the nature and extent of the claimed injuries and damage.

The foregoing is merely a summary of the claims of the parties. You are not to consider the summary as proof of the matters claimed and you are to consider only those matters that are admitted or are established by

the evidence. These claims have been outlined solely to aid you in understanding the issues.

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manufacturer inadequate; and

b. the manufacturer could have provided adequate marketing, warnigns, instructions or training.

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a. the relative cost of the product;

b. the seriousness of the potential harm from the claimed defect;

c. the cost and feasibility of eliminating or minimizing the risk; and

d. such [other] factors as the nature of the product and the claimed defect indicate are appropriate.

A product can be "not reasonably safe" even though the risk that it would cause the plaintiff's harm or similar harms was not foreseeable by the manufacturer at the time the product left the manufacturer's control.

If you find that the product was not reasonably safe because of adequate marketing, warnings, instructions or training were not provided with the product and this was a proximate cause of the Plaintiffs' injuries and damages, then the manufacturer is subject to liability and fault.

SUPERIOR COURT OF WASHINGTON FOR KITSAP COUNTY

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, Plaintiffs, v. INTUITIVE SURGICAL, INC., a foreign corporation doing business in Washington, Defendants.	NO. 09-2-03136-5 CTINJY

COURT'S INSTRUCTIONS TO THE JURY

DATED this 20th day of May, 2013.

HONORABLE JAY B. ROOF

654B

INSTRUCTION NO. 1

It is your duty to decide the facts in this case based upon the evidence presented to you during this trial. It also is your duty to accept the law as I explain it to you, regardless of what you personally believe the law is or what you personally think it should be. You must apply the law from my instructions to the facts that you decide have been proved, and in this way decide the case.

The evidence that you are to consider during your deliberations consists of the testimony that you have heard from witnesses, and the exhibits that I have admitted during the trial. If evidence was not admitted or was stricken from the record, then you are not to consider it in reaching your verdict.

Exhibits may have been marked by the court clerk and given a number, but they do not go with you to the jury room during your deliberations unless they have been admitted into evidence. The exhibits that have been admitted will be available to you in the jury room.

In order to decide whether any party's claim has been proved, you must consider all of the evidence that I have admitted that relates to that claim. Each party is entitled to the benefit of all of the evidence, whether or not that party introduced it.

You are the sole judges of the credibility of the witness. You are also the sole judges of the value or weight to be given to the testimony of each witness. In considering a witness's testimony, you may consider these things: the opportunity of the witness to observe or know the things they testify about; the ability of the witness to observe accurately; the quality of a witness's memory while testifying; the manner of the witness while testifying; any personal interest that the witness might have in the outcome or the issues; any bias or prejudice that the witness may have shown; the reasonableness of the witness's statements in the context of all of the other evidence; and any other factors that affect your evaluation or belief of a witness or your evaluation of his or her testimony.

One of my duties has been to rule on the admissibility of evidence. Do not be concerned during your deliberations about the reasons for my rulings on the evidence. If I have ruled that any evidence is inadmissible, or if I have asked you to disregard any evidence, then you must not discuss that evidence during your deliberations or consider it in reaching your verdict.

The law does not permit me to comment on the evidence in any way. I would be commenting on the evidence if I indicated my personal opinion about the value of testimony or other evidence. Although I have not

intentionally done so, if it appears to you that I have indicated my personal opinion, either during trial or in giving these instructions, you must disregard it entirely.

As to the comments of the lawyers during this trial, they are intended to help you understand the evidence and apply the law. However, it is important for you to remember that the lawyers' remarks, statements, and arguments are not evidence. You should disregard any remark, statement, or argument that is not supported by the evidence or the law as I have explained it to you.

You may have heard objections made by the lawyers during trial. Each party has the right to object to questions asked by another lawyer, and may have a duty to do so. These objections should not influence you. Do not make any assumptions or draw any conclusions based on a lawyer's objections.

As jurors, you have a duty to consult with one another and to deliberate with the intention of reaching a verdict. Each of you must decide the case for yourself, but only after an impartial consideration of all of the evidence with your fellow jurors. Listen to one another carefully. In the course of your deliberations, you should not hesitate to re-examine your own views and to change your opinion based upon the evidence. You

should not surrender your honest convictions about the value or significance of evidence solely because of the opinions of your fellow jurors. Nor should you change your mind just for the purpose of obtaining enough votes for a verdict.

As jurors, you are officers of this court. You must not let your emotions overcome your rational thought process. You must reach your decision based on the facts proved to you and on the law given to you, not on sympathy, bias, or personal preference. To assure that all parties receive a fair trial, you must act impartially with an earnest desire to reach a proper verdict.

Finally, the order of these instructions has no significance as to their relative importance. They are all equally important. In closing arguments, the lawyers may properly discuss specific instructions, but you must not attach any special significance to a particular instruction that they may discuss. During your deliberations, you must consider the instructions as a whole.

INSTRUCTION NO. 2

The evidence that has been presented to you may be either direct or circumstantial. The term "direct evidence" refers to evidence that is given by a witness who has directly perceived something at issue in this case. The term "circumstantial evidence" refers to evidence from which, based on your common sense and experience, you may reasonably infer something that is at issue in this case.

The law does not distinguish between direct and circumstantial evidence in terms of their weight or value in finding the facts in this case. One is not necessarily more or less valuable than the other.

INSTRUCTION NO. 3

A witness who has special training, education, or experience may be allowed to express an opinion in addition to giving testimony as to facts.

You are not, however, required to accept his or her opinion. To determine the credibility and weight to be given to this type of evidence, you may consider, among other things, the education, training, experience, knowledge, and ability of the witness. You may also consider the reasons given for the opinion and the sources of his or her information, as well as considering the factors already given to you for evaluating the testimony of any other witness.

INSTRUCTION NO. 4

There are multiple claims in this case. The instructions apply to all claims unless a specific instruction states that it applies only to a specific claim.

INSTRUCTION NO. 5

The law treats all parties equally whether they are corporations or individuals. This means that corporations and individuals are to be treated in the same fair and unprejudiced manner.

Defendant Intuitive is a corporation. A corporation can act only through its officers and employees. Any act or omission of an Intuitive employee is the act or omission of Intuitive.

INSTRUCTION NO. 6

Plaintiff Mrs. Taylor claims that Defendant Intuitive was negligent because it did not provide adequate warnings and instructions/training to Dr. Bildsten about the da Vinci surgical system.

Mrs. Taylor claims that Intuitive's conduct was a proximate cause of injuries and damage to her husband, her, and her husband's estate.

Intuitive denies Mrs. Taylor's claims, denies the nature and extent of the alleged injuries, and denies that it was a proximate cause of Plaintiffs' injuries and Fred Taylor's death.

Intuitive claims that Dr. Scott Bildsten was negligent and that his actions were a proximate cause of plaintiff's injuries and Fred Taylor's death.

Intuitive claims that Fred Taylor failed to mitigate his damages.

The foregoing is merely a summary of the claims of the parties. You are not to consider the summary as proof of the matters claimed and you are to consider only those matters that are admitted or are established by the evidence. These claims have been outlined solely to aid you in understanding the issues.

INSTRUCTION NO. 7

Plaintiff Mrs. Taylor has the burden of proving each of the following propositions by a preponderance of the evidence:

1. Intuitive was negligent in failing to provide adequate warnings or instructions/training to Dr. Bildsten;
2. That Plaintiffs were injured; and
3. The negligence of Intuitive was a proximate cause of the injury.

If you find from your consideration of all the evidence that each of these propositions has been proved, your verdict should be for Plaintiffs. On the other hand, if any of these propositions has not been proved, your verdict should be for Intuitive.

INSTRUCTION NO. 8

In this case, Defendant Intuitive is claiming that Dr. Bildsten is responsible for Fred Taylor's injuries. In order to establish this claim, Intuitive has the burden of proving each of the following propositions:

First, that Dr. Bildsten failed to follow the applicable standard of care and was therefore negligent;

Second, that Fred Taylor was injured;

Third, that the negligence of Dr. Bildsten, was a proximate cause of the injury to the Plaintiffs.

If you find from your consideration of all of the evidence that each of these propositions has been proved against Dr. Bildsten your verdict should state that you find Dr. Bildsten responsible for Fred Taylor's injuries. On the other hand, if any of these propositions has not been proved against Dr. Bildsten, your verdict should indicate that that individual bears no responsibility.

INSTRUCTION NO. 9

When it is said that a party has the burden of proof on any proposition by a preponderance of the evidence, or the expression "if you find" is used, it means that you must be persuaded, considering all the evidence in the case bearing on the question, that the proposition on which that party has the burden of proof is more probably true than not true.

INSTRUCTION NO. 10

A medical device manufacturer's duty to provide adequate warnings or instructions/training is to the patient's doctor. A medical device manufacturer does not have a duty to adequately warn or instruct/train the patient. Therefore, any duty to adequately warn or instruct/train on the part of Intuitive ran only to Dr. Bildsten, and you may not find Intuitive liable for any failure to adequately warn or instruct/train directed to Fred Taylor or Mrs. Taylor.

INSTRUCTION NO. 11

When a medical device manufacturer becomes aware or should have become aware of dangerous aspects of one of its products, it has a duty to warn of such dangerous aspects. In such a case, the manufacturer is under a duty to use reasonable care in regard to issuing warnings or instructions/training concerning any such danger. This duty is satisfied if the manufacturer exercises reasonable care to inform doctors who use the product.

The failure to use reasonable care is negligence. "Reasonable care" means the care that a reasonably prudent medical product manufacturer would exercise in the same or similar circumstances.

The question of whether a manufacturer exercised reasonable care is to be determined by what the manufacturer knew or reasonably should have known prior to the time of Plaintiff's injury.

You should consider these definitions only in relation to Intuitive's conduct. Definitions related to Dr. Bildsten's conduct are provided later in these instructions.

INSTRUCTION NO. 12

In considering whether warnings given by Intuitive were adequate, you may consider the manner in which Intuitive promoted, advertised, or sold the da Vinci surgical system.

INSTRUCTION NO. 13

A medical device manufacturer has no duty to warn a physician of risks and dangers of which the physician knows.

INSTRUCTION NO. 14

A regulation provides that

> Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

The violation, if any, of a regulation is not necessarily negligence, but may be considered by you as evidence in determining negligence.

INSTRUCTION NO. 15

Evidence of compliance with FDA regulations does not necessarily relieve a medical device manufacturer of liability for failure to furnish an adequate warning about its product. The FDA regulations merely set minimum requirements and do not relieve the manufacturer of the duty to warn.

INSTRUCTION NO. 16

You are instructed that any causal relationship between the use of the da Vinci surgical system and Fred Taylor's injuries or death must be established by expert medical testimony to a reasonable degree of medical probability.

The fact that Fred Taylor experienced medical complications and died is insufficient, in itself, to prove causation. To prove causation, Mrs. Taylor must prove that the injuries to Fred Taylor, or death of Fred Taylor, would not have occurred but for the use of the da Vinci surgical system.

INSTRUCTION NO. 17

If you find that Intuitive's warnings and instructions/training regarding the proper use of or the risks of the da Vinci surgical system to Dr. Bildsten were adequate, then you need not deliberate any further, and you should direct a verdict in favor of Intuitive.

However, if you find that the warnings or instructions/training were inadequate, then you will consider the element of proximate cause.

The term "proximate cause" means a cause which in a direct sequence produces the injury complained of and without which such injury would not have happened.

INSTRUCTION NO. 18

There may be more than one proximate cause of the same injury. If you find that a defendant was negligent and that such negligence was a proximate cause of injury or damage to the Plaintiffs, it is not a defense that some other cause or the act of some other person who is not a party to this lawsuit may also have been a proximate cause.

However, if you find that the sole proximate cause of injury or damage to the Plaintiffs was some other cause or the act of some other person who is not a party to this lawsuit, then your verdict should be for Intuitive.

INSTRUCTION NO. 19

A superseding cause is a new, independent cause that breaks the chain of proximate causation between a defendant's alleged failure to adequately warn, instruct, or train and an injury. If you find that Intuitive failed to adequately warn or instruct/train Dr. Bildsten, but that the sole proximate cause of Plaintiffs' injuries was a later, independent, intervening act of Dr. Bildsten, which Intuitive, in the exercise of ordinary care, could not reasonably have anticipated, then any failure to adequately warn or instruct/train on the part of Intuitive is superseded, and such failure was not a proximate cause of Plaintiffs' injuries.

If, however, you find that Intuitive was negligent, and that in the exercise of ordinary care, Intuitive should reasonably have anticipated the later independent intervening act of Dr. Bildsten, then that act does not supersede Intuitive's original negligence, and you may find that Intuitive's negligence was a proximate cause of the Plaintiffs' injuries.

It is not necessary that the sequence of events or the particular resultant injuries be foreseeable. It is only necessary that the resultant injuries fall within the general field of danger which Intuitive should reasonably have anticipated.

INSTRUCTION NO. 20

A person who is liable for an injury to another is not liable for any damages arising after the original injury that are proximately caused by failure of the injured person to exercise ordinary care to avoid or minimize such new or increased damage, also known as failure to mitigate.

"Ordinary care" means the care a reasonably careful person would exercise under the same or similar circumstances.

Intuitive has the burden to prove Fred Taylor's failure to exercise ordinary care and the amount of damages, if any, that would have been minimized or avoided.

INSTRUCTION NO. 21

Before a percentage of negligence may be attributed to Dr. Bildsten, Intuitive has the burden of proving each of the following propositions:

First, that Dr. Bildsten was negligent; and

Second, that that Dr. Bildsten's negligence was a proximate cause of the injuries to the Plaintiffs.

INSTRUCTION NO. 22

If you find that both Dr. Bildsten and Intuitive were negligent, you must determine what percentage of the total negligence is attributable to each person or entity that proximately caused the injuries to Plaintiff. The Court will provide you with a special verdict form for this purpose. Your answers to the questions in the special verdict form will further the basis by which the Court will apportion damages, if any.

Persons or entities whose negligence may have proximately caused Plaintiff's injuries may include Intuitive and Dr. Bildsten.

INSTRUCTION NO. 23

A physician is not liable for selecting one of two or more alternative courses of treatment if, in arriving at the judgment to follow a particular course of treatment, the physician exercises reasonable care and skill within the standard of care the physician was obliged to follow.

INSTRUCTION NO. 24

A physician owes to the patient a duty to comply with the standard of care for one of the profession or class to which he or she belongs.

A physician has a duty to exercise the degree of skill, care and learning expected of a reasonably prudent physician in the State of Washington acting in the same or similar circumstances at the time of the care or treatment in question.

Failure to exercise such skill, care and learning constitutes a breach of the standard of care and is negligence.

The degree of care actually practiced by members of the medical profession is evidence of what is reasonably prudent. However, this evidence alone is not conclusive on the issue and should be considered by you along with any other evidence bearing on the question.

INSTRUCTION NO. 25

If your verdict is for the Plaintiffs and if you find that:

(1) before this occurrence Fred Taylor had a bodily condition that was not causing pain or disability; and

(2) because of this occurrence the pre-existing condition was lighted up or made active,

then you should consider the lighting up and any other injuries that were proximately caused by the occurrence, even though these injuries, due to the pre-existing condition, may have been greater than those that would have been incurred under the same circumstances by a person without that condition.

There may be no recovery, however, for any injuries or disabilities that would have resulted from natural progression of the pre-existing condition even without this occurrence.

INSTRUCTION NO. 26

If your verdict is for the Plaintiffs and if you find that:

(1) before this occurrence Fred Taylor had a bodily condition that was not causing pain or disability; and

(2) the condition made Fred Taylor more susceptible to injury than a person in normal health,

then you should consider all the injuries and damages that were proximately caused by the occurrence, even though these injuries, due to the pre-existing condition, may have been greater than those that would have been incurred under the same circumstances by a person without that condition.

There may be no recovery, however, for any injuries or disabilities that would have resulted from natural progression of the pre-existing condition even without this occurrence.

INSTRUCTION NO. 27

Plaintiffs are seeking damages for both wrongful death and other injuries. If your verdict is in favor of Plaintiffs, you must take care to avoid awarding Plaintiffs double recovery for the same damage or injury.

INSTRUCTION NO. 28

It is the duty of the Court to instruct you as to the measure of damages on Mrs. Taylor's claim for losses suffered by Mrs. Taylor as a result of Fred Taylor's death. By instructing you on damages, the Court does not mean to suggest for which party your verdict should be rendered.

If your verdict is for Mrs. Taylor, and you have determined that Intuitive proximately caused Fred Taylor's death, then you must determine the amount of money that will reasonably and fairly compensate Mrs. Taylor for such damages as you find were proximately caused by the death of Fred Taylor.

If you find for Mrs. Taylor, you should consider the following items: What Fred Taylor reasonably would have been expected to contribute to Mrs. Taylor in the way of marital consortium. "Marital consortium" means the fellowship of husband and wife and the right of one spouse to the company, cooperation, and aid of the other in the matrimonial relationship. It includes emotional support, love, affection, care, services, companionship, including sexual companionship, as well as assistance from one spouse to the other.

In making your determinations, you should take into account Fred Taylor's age, health, life expectancy, occupation, and habits. In determining

the amount that Fred Taylor reasonably would have been expected to contribute in the future to Mrs. Taylor in the way of marital consortium, you should also take into account the amount you find Fred Taylor customarily contributed to Mrs. Taylor.

The burden of proving damages rests upon Mrs. Taylor. It is for you to determine, based upon the evidence, whether any particular element has been proved by a preponderance of the evidence.

Your award must be based upon evidence and not upon speculation, guess, or conjecture.

The law has not furnished us with any fixed standards by which to measure noneconomic damages. With reference to these matters you must be governed by your own judgment, by the evidence in the case, and by these instructions.

INSTRUCTION NO. 29

Mrs. Taylor has a claim for the loss of the consortium of Fred Taylor while he was still alive.

The term "consortium" means the fellowship of husband and wife and the right of one spouse to the company, cooperation, and aid of the other in the matrimonial relationship. It includes emotional support, love, affection, care, services, companionship, including sexual companionship, as well as assistance from one spouse to the other.

INSTRUCTION NO. 30

In addition to pursuing claims in her own name, Plaintiff Mrs. Taylor is Personal Representative of the Estate of Fred Taylor. As Personal Representative of the Estate of Fred Taylor, Mrs. Taylor brings two separate legal claims on behalf of the Estate:

1. In one claim, she represents the Estate for the personal losses suffered by Fred Taylor; and

2. In the other claim, she represents the Estate for the losses suffered by the beneficiaries of the Estate, Josette Taylor, Jason K. Taylor, Elizabeth A. Streutker-Lumsden, and Victoria L. Streutker.

INSTRUCTION NO. 31

It is the duty of the Court to instruct you as to measure of damages on Plaintiff Mrs. Taylor's claim for personal losses suffered by Fred Taylor during his life. By instructing you on damages, the Court does not mean to suggest for which party your verdict should be rendered.

If your verdict is for Mrs. Taylor, then you must determine the amount of money that will reasonably and fairly compensate Fred Taylor's estate for such damages as you find were proximately caused by the negligence of Defendant Intuitive.

If you find for Mrs. Taylor, you should consider the following items: The pain, suffering, anxiety, emotional distress, humiliation, and fear experienced by Fred Taylor prior to his death as a result of Intuitive's failure to adequately warn, instruct, or train Dr. Bildsten.

The burden of proving damages rests upon Mrs. Taylor. It is for you to determine, based upon the evidence, whether any particular element has been proved by a preponderance of the evidence.

Your award must be based on evidence, and not upon speculation, guess, or conjecture.

The law has not furnished us with any fixed standards by which to measure noneconomic damages. With reference to these matters, you

must be governed by your own judgment, by the evidence in the case, and by these instructions.

INSTRUCTION NO. 32

It is the duty of the Court to instruct you as to the measure of damages on Mrs. Taylor's claims for losses suffered by Jason K. Taylor, Elizabeth A. Streutker-Lumsden, and Victoria L. Streutker. By instructing you on damages, the Court does not mean to suggest for which party your verdict should be rendered.

If your verdict is for Mrs. Taylor, and you have determined that Intuitive proximately caused Fred Taylor's death, then you must determine the amount of money that will reasonably and fairly compensate Jason K. Taylor, Elizabeth A. Streutker-Lumsden, and Victoria L. Streutker for such damages as you find were proximately caused by the death of Fred Taylor.

If you find for Mrs. Taylor, you should consider the following items: What Fred Taylor reasonably would have been expected to contribute to Jason K. Taylor, Elizabeth A. Streutker-Lumsden, and Victoria L. Streutker in the way of love, care, companionship, and guidance.

In making your determinations, you should take into account Fred Taylor's age, health, life expectancy, occupation, and habits. In determining the amount that Fred Taylor reasonably would have been expected to contribute in the future to Jason K. Taylor, Elizabeth A. Streutker-Lumsden, and Victoria L. Streutker in the way of love, care, companionship, and

guidance, you should take into account the amount you find Fred Taylor customarily contributed to Jason K. Taylor, Elizabeth A. Streutker-Lumsden, and Victoria L. Streutker.

The burden of proving damages rests upon the plaintiff, Mrs. Taylor. It is for you to determine, based upon the evidence, whether any particular element has been proved by a preponderance of the evidence.

Your award must be based upon evidence and not upon speculation, guess, or conjecture.

The law has not furnished us with any fixed standards by which to measure noneconomic damages. With reference to these matters you must be governed by your own judgment, by the evidence in the case, and by these instructions.

INSTRUCTION NO. 33

If you decide that Defendant's conduct caused Plaintiffs harm, you must decide whether Plaintiffs have proven that Defendant engaged in that conduct with malice or oppression. To do this, Plaintiffs must prove one of the following by clear and convincing evidence:

1. That the conduct constituting malice or oppression was committed by one or more officers, directors, or managing agents of defendant who acted on behalf of Defendant; or

2. That the conduct constituting malice or oppression was authorized by one or more officers, directors, or managing agents of defendant; or

3. That one or more officers, directors, or managing agents of defendant knew of the conduct constituting malice or oppression and adopted or approved that conduct after it occurred.

"Malice" means that defendant acted with intent to cause injury or that defendant's conduct was despicable and was done with a willful and knowing disregard of the rights or safety of another. A person acts with knowing disregard when he or she is aware of the probable dangerous consequences of his or her conduct and deliberately fails to avoid those consequences.

"Oppression" means that defendant's conduct was despicable and subjected plaintiffs to cruel and unjust hardship in knowing disregard of plaintiffs' rights.

"Despicable conduct" is conduct that is so vile, base, or contemptible that it would be looked down on and despised by reasonable people.

"Clear and convincing evidence" is a higher burden of proof than "preponderance of the evidence." This means Plaintiffs must persuade you that it is highly probable that the facts required to establish malicious or oppressive conduct are true.

An employee is a "managing agent" if he or she exercises substantial independent authority and judgment in his or her corporate decision making such that his or her decisions ultimately determine corporate policy.

INSTRUCTION NO. 34

Damon Daniels was not an officer, director, or managing agent of Intuitive and did not act in a managerial capacity.

INSTRUCTION NO. 35

In determining whether Intuitive engaged in malicious or oppressive conduct, you may consider only Intuitive's conduct, if any, that occurred in the State of California. Accordingly, you may not find malicious or oppressive conduct by Intuitive based on conduct occurring in the State of Washington.

INSTRUCTION NO. 36

When you begin to deliberate, your first duty is to select a presiding juror. The presiding juror's responsibility is to see that you discuss the issues in this case in an orderly and reasonable manner, that you discuss each issue submitted for your decision fully and fairly, and that each one of you has a chance to be heard on every question before you.

You will be given the exhibits admitted in evidence and these instructions. You will also be given a special verdict form that consists of several questions for you to answer. You must answer the questions in the order in which they are written, and according to the directions on the form. It is important that you read all the questions before you begin answering, and that you follow the directions exactly. Your answer to some questions will determine whether you are to answer all, some, or none of the remaining questions.

During your deliberations, you may discuss any notes that you have taken during the trial, if you wish. You have been allowed to take notes to assist you in remembering clearly, not to substitute for your memory or the memories or notes of other jurors. Do not assume, however, that your notes are more or less accurate than your memory.

You will need to rely on your notes and memory as to the testimony presented in this case. Testimony will rarely, if ever, be repeated for you during your deliberations.

If, after carefully reviewing the evidence and instructions, you feel a need to ask the court a legal or procedural question that you have been unable to answer, write the question out simply and clearly. In your question, do not state how the jury has voted, or in any other way indicate how your deliberations are proceeding. The presiding juror should sign and date the question and give it to the bailiff. I will confer with the lawyers to determine what response, if any, can be given.

In order to answer any question on the special verdict form, ten jurors must agree upon the answer. It is not necessary that the jurors who agree on the answer be the same jurors who agreed on the answer to any other question, so long as ten jurors agree to each answer.

When you have finished answering the questions according to the directions on the special verdict form, the presiding juror will sign the verdict form. The presiding juror must sign the verdict whether or not the presiding juror agrees with the verdict. The presiding juror will then tell the bailiff that you have reached a verdict. The bailiff will bring you back into court where your verdict will be announced.

INSTRUCTION NO. 37

Now that you've heard the Court's instructions on the law and the closing arguments, you are ready to begin your deliberations. You are free to conduct your deliberations in any way that seems suitable to you and is consistent with the instructions I've given [and the information posted in the jury room]. However, I have a few suggestions that may help you proceed more smoothly. Unlike the instruction as to the law, these remarks are only suggestions and will not be given to you in writing.

As you deliberate, consider the following guidelines:

- Respect each other's opinions and the different viewpoints each of you brings to the process. Don't be afraid to speak up and express your views.
- Be patient and generous in allowing everyone an opportunity to speak. Differences of opinion are healthy—they bring the evidence into focus and bring out points you might not have considered.
- Listen carefully to each other. It's okay to change your mind, but don't allow yourself to be bullied into doing so, and don't bully anyone else.
- Don't rush into a verdict to save time. The parties in this case deserve your thoughtful deliberation. The jury system depends on it.

Each of you must decide the case for yourself, but you should do so only after you've reviewed the law, carefully considered all the evidence, discussed the issues fully and fairly with the other jurors, and listened to their views.

Discuss the law and the evidence to your satisfaction before you take a vote. You should organize your discussions in whatever way you believe will be productive and fair. Some juries begin by reviewing the Court's instructions on the law, because those instructions identify each claim and proposition you must consider. Others begin by proceeding around the table with each juror in turn identifying the issues or concerns he or she would like to have discussed, because that encourages free expression by all jurors before positions are taken. It is helpful to list the issues on which there are differences of opinion. Whatever approach you take, you should separately consider each claim, and examine the evidence—both the testimony and any exhibits—on each proposition that is part of a claim.

There is no set way to conduct a vote. You might vote by show of hands, by voice vote, or by written ballot. Use a method that will encourage each juror to freely express opinions and conclusions.

Finally, I remind you that these remarks are merely suggestions. I hope they are helpful to you. Nothing I've said or done should suggest to you what your verdict should be—that is entirely for you to decide.

You may now return to the jury room.

Debbie Wu

From: Dave Carson
Sent: Saturday, June 21, 2008 7:17 AM
To: Sean O'Connor
Subject: Harrison Clinical Support

Sean:

I am thinking ahead to the conference call Monday 7:30am about Harrison. Thanks for requesting that call; it was a good idea.

I have a concern and I just want to bring it up before Monday. As managers, it is important neither of us communicate any bias against Harrison. I know you expressed some doubt about the potential quality of their program after our surgeon/administration meeting two weeks ago. That concern, however, shouldn't extend beyond you and me.

A couple things worry me. First is Damon's reply to one of my emails yesterday (read below). The answer yes, I will help with training whenever I can. But I cannot on July 17. I sent a meeting request to Damon on June 6th asking him to train Bildsten in Sunnyvale July 17th. He has not accepted yet. That night I have a market development event in Everett with Drescher; I explained that in my meeting request. As a CSR, he should be thrilled at this opportunity; a training pipeline is the clinical team's bloodline.

On an even larger scale, my concern is Harrison won't be taken as seriously as our other installs. That would be a mistake. Hospitals like Harrison are our future. We need positive reference stories from Harrison to maintain our growth throughout Washington. Obviously you are understaffed, and that is the biggest issue. I will help out. But at the same time let's make sure we exhibit enthusiasm towards the Harrison rollout because hospitals like this are our future. Thanks

-----Original Message-----
From: Damon Daniels
Sent: Friday, June 20, 2008 10:00 AM
To: Dave Carson
Subject: RE: OR Table Needs for daVinci

I hope u plan on training some of these people...

Damon Daniels
Intuitive Surgical
425-785-0265

-----Original Message-----
From: Dave Carson <Dave.Carson@intusurg.com>
Sent: Friday, June 20, 2008 8:58 AM
To: kraney@harrisonmedical.org <kraney@harrisonmedical.org>; Dianna Kjenner <dkjenner@harrisonmedical.org>
Cc: Sean O'Connor <Sean.O'Connor@intusurg.com>; Damon Daniels <Damon.Daniels@intusurg.com>
Subject: OR Table Needs for daVinci

Kim, Dianna:

APP C

Kim asked me to look into any special OR table needs for use with daVinci. I have spoken to 5 different sources; the consensus is that any table will work. However some are easier to work with than others.

At Swedish, they prefer to use the McKay table because its legs spread and there is no need to use stirrups.

At Good Samaritan in Portland, they use a new Stryker table. It also has leg spreaders, doesn't require stirrups, and can go very low to keep that patient abdomen at a comfortable working height.

Dr. Bildsten has notes in his office of a brand of table that worked very well; you might want to check with him. He observed that table being used and was very impressed.

Let me know if you have further questions - thanks

Dave Carson | Area Sales Manager | Intuitive Surgical, Inc.
M: 206-310-9193 | dave.carson@intusurg.com | F: 425-413-7377
www.intuitivesurgical.com | www.davincisurgery.com

RCW 7.72.010
Definitions.

For the purposes of this chapter, unless the context clearly indicates to the contrary:

(1) Product seller. "Product seller" means any person or entity that is engaged in the business of selling products, whether the sale is for resale, or for use or consumption. The term includes a manufacturer, wholesaler, distributor, or retailer of the relevant product. The term also includes a party who is in the business of leasing or bailing such products. The term "product seller" does not include:

(a) A seller of real property, unless that person is engaged in the mass production and sale of standardized dwellings or is otherwise a product seller;

(b) A provider of professional services who utilizes or sells products within the legally authorized scope of the professional practice of the provider;

(c) A commercial seller of used products who resells a product after use by a consumer or other product user: PROVIDED, That when it is resold, the used product is in essentially the same condition as when it was acquired for resale;

(d) A finance lessor who is not otherwise a product seller. A "finance lessor" is one who acts in a financial capacity, who is not a manufacturer, wholesaler, distributor, or retailer, and who leases a product without having a reasonable opportunity to inspect and discover defects in the product, under a lease arrangement in which the selection, possession, maintenance, and operation of the product are controlled by a person other than the lessor; and

(e) A licensed pharmacist who dispenses a prescription product manufactured by a commercial manufacturer pursuant to a prescription issued by a licensed prescribing practitioner if the claim against the pharmacist is based upon strict liability in tort or the implied warranty provisions under the uniform commercial code, Title 62A RCW, and if the pharmacist complies with recordkeeping requirements pursuant to chapters 18.64, 69.41, and 69.50 RCW, and related administrative rules as provided in RCW 7.72.040. Nothing in this subsection (1)(e) affects a pharmacist's liability under RCW 7.72.040(1).

(2) Manufacturer. "Manufacturer" includes a product seller who designs, produces, makes, fabricates, constructs, or remanufactures the relevant product or component part of a product before its sale to a user or consumer. The term also includes a product seller or entity not otherwise a manufacturer that holds itself out as a manufacturer.

A product seller acting primarily as a wholesaler, distributor, or retailer of a product may be a "manufacturer" but only to the extent that it designs, produces, makes, fabricates, constructs, or remanufactures the product for its sale. A product seller who performs minor assembly of a product in accordance with the instructions of the

manufacturer shall not be deemed a manufacturer. A product seller that did not participate in the design of a product and that constructed the product in accordance with the design specifications of the claimant or another product seller shall not be deemed a manufacturer for the purposes of RCW 7.72.030(1)(a).

(3) Product. "Product" means 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.

The "relevant product" under this chapter is that product or its component part or parts, which gave rise to the product liability claim.

(4) Product liability claim. "Product liability claim" includes 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.

(5) Claimant. "Claimant" means a person or entity asserting a product liability claim, including a wrongful death action, and, if the claim is asserted through or on behalf of an estate, the term includes claimant's decedent. "Claimant" includes any person or entity that suffers harm. A claim may be asserted under this chapter even though the claimant did not buy the product from, or enter into any contractual relationship with, the product seller.

(6) Harm. "Harm" includes any damages recognized by the courts of this state: PROVIDED, That the term "harm" does not include direct or consequential economic loss under Title 62A RCW.

[1991 c 189 § 3; 1981 c 27 § 2.]

RCW 7.72.030
Liability of manufacturer.

(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.

(a) A product is not reasonably safe as designed, 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, outweighed the burden on the manufacturer to design a product that would have prevented those harms and the adverse effect that an alternative design that was practical and feasible would have on the usefulness of the product: PROVIDED, That a firearm or ammunition shall not be deemed defective in design on the basis that the benefits of the product do not outweigh the risk of injury posed by its potential to cause serious injury, damage, or death when discharged.

(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.

(2) A product manufacturer is subject to strict liability to a claimant if the claimant's harm was proximately caused by the fact that the product was not reasonably safe in construction or not reasonably safe because it did not conform to the manufacturer's express warranty or to the implied warranties under Title 62A RCW.

(a) A product is not reasonably safe in construction if, when the product left the control of the manufacturer, the product deviated in some material way from the design specifications or performance standards of the manufacturer, or deviated in some material way from otherwise identical units of the same product line.

(b) A product does not conform to the express warranty of the manufacturer if it is made part of the basis of the bargain and relates to a material fact or facts concerning

the product and the express warranty proved to be untrue.

(c) Whether or not a product conforms to an implied warranty created under Title 62A RCW shall be determined under that title.

(3) In determining whether a product was not reasonably safe under this section, the trier of fact shall consider whether the product was unsafe to an extent beyond that which would be contemplated by the ordinary consumer.

[1988 c 94 § 1; 1981 c 27 § 4.]

Restatement of the Law, Second, Torts § 402A Special Liability of Seller of Product for Physical Harm to User or Consumer

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

CAVEAT: Caveat:

The Institute expresses no opinion as to whether the rules stated in this Section may not apply

(1) to harm to persons other than users or consumers;

(2) to the seller of a product expected to be processed or otherwise substantially changed before it reaches the user or consumer; or

(3) to the seller of a component part of a product to be assembled.

COMMENTS & ILLUSTRATIONS: Comment:

a. This Section states a special rule applicable to sellers of products. The rule is one of strict liability, making the seller subject to liability to the user or consumer even though he has exercised all possible care in the preparation and sale of the product. The Section is inserted in the Chapter dealing with the negligence liability of suppliers of chattels, for convenience of reference and comparison with other Sections dealing with negligence. The rule stated here is not exclusive, and does not preclude liability based upon the alternative ground of negligence of the seller, where such negligence can be proved.

b. History. Since the early days of the common law those engaged in the business of

selling food intended for human consumption have been held to a high degree of responsibility for their products. As long ago as 1266 there were enacted special criminal statutes imposing penalties upon victualers, vintners, brewers, butchers, cooks, and other persons who supplied "corrupt" food and drink. In the earlier part of this century this ancient attitude was reflected in a series of decisions in which the courts of a number of states sought to find some method of holding the seller of food liable to the ultimate consumer even though there was no showing of negligence on the part of the seller. These decisions represented a departure from, and an exception to, the general rule that a supplier of chattels was not liable to third persons in the absence of negligence or privity of contract. In the beginning, these decisions displayed considerable ingenuity in evolving more or less fictitious theories of liability to fit the case. The various devices included an agency of the intermediate dealer or another to purchase for the consumer, or to sell for the seller; a theoretical assignment of the seller's warranty to the intermediate dealer; a third party beneficiary contract; and an implied representation that the food was fit for consumption because it was placed on the market, as well as numerous others. In later years the courts have become more or less agreed upon the theory of a "warranty" from the seller to the consumer, either "running with the goods" by analogy to a covenant running with the land, or made directly to the consumer. Other decisions have indicated that the basis is merely one of strict liability in tort, which is not dependent upon either contract or negligence.

Recent decisions, since 1950, have extended this special rule of strict liability beyond the seller of food for human consumption. The first extension was into the closely analogous cases of other products intended for intimate bodily use, where, for example, as in the case of cosmetics, the application to the body of the consumer is external rather than internal. Beginning in 1958 with a Michigan case involving cinder building blocks, a number of recent decisions have discarded any limitation to intimate association with the body, and have extended the rule of strict liability to cover the sale of any product which, if it should prove to be defective, may be expected to cause physical harm to the consumer or his property.

c. On whatever theory, the justification for the strict liability has been said to be that the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it; that the public has the right to and does expect, in the case of products which it needs and for which it is forced to rely upon the seller, that reputable sellers will stand behind their goods; that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.

d. The rule stated in this Section is not limited to the sale of food for human consumption, or other products for intimate bodily use, although it will obviously include them. It extends to any product sold in the condition, or substantially the same

condition, in which it is expected to reach the ultimate user or consumer. Thus the rule stated applies to an automobile, a tire, an airplane, a grinding wheel, a water heater, a gas stove, a power tool, a riveting machine, a chair, and an insecticide. It applies also to products which, if they are defective, may be expected to and do cause only "physical harm" in the form of damage to the user's land or chattels, as in the case of animal food or a herbicide.

e. Normally the rule stated in this Section will be applied to articles which already have undergone some processing before sale, since there is today little in the way of consumer products which will reach the consumer without such processing. The rule is not, however, so limited, and the supplier of poisonous mushrooms which are neither cooked, canned, packaged, nor otherwise treated is subject to the liability here stated.

f. Business of selling. The rule stated in this Section applies to any person engaged in the business of selling products for use or consumption. It therefore applies to any manufacturer of such a product, to any wholesale or retail dealer or distributor, and to the operator of a restaurant. It is not necessary that the seller be engaged solely in the business of selling such products. Thus the rule applies to the owner of a motion picture theatre who sells popcorn or ice cream, either for consumption on the premises or in packages to be taken home.

The rule does not, however, apply to the occasional seller of food or other such products who is not engaged in that activity as a part of his business. Thus it does not apply to the housewife who, on one occasion, sells to her neighbor a jar of jam or a pound of sugar. Nor does it apply to the owner of an automobile who, on one occasion, sells it to his neighbor, or even sells it to a dealer in used cars, and this even though he is fully aware that the dealer plans to resell it. The basis for the rule is the ancient one of the special responsibility for the safety of the public undertaken by one who enters into the business of supplying human beings with products which may endanger the safety of their persons and property, and the forced reliance upon that undertaking on the part of those who purchase such goods. This basis is lacking in the case of the ordinary individual who makes the isolated sale, and he is not liable to a third person, or even to his buyer, in the absence of his negligence. An analogy may be found in the provision of the Uniform Sales Act, § 15, which limits the implied warranty of merchantable quality to sellers who deal in such goods; and in the similar limitation of the Uniform Commercial Code, § 2-314, to a seller who is a merchant. This Section is also not intended to apply to sales of the stock of merchants out of the usual course of business, such as execution sales, bankruptcy sales, bulk sales, and the like.

g. Defective condition. The rule stated in this Section applies only where the product is, at the time it leaves the seller's hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him. The seller is not liable when he delivers the product in a safe condition, and subsequent mishandling or other causes make it harmful by the time it is consumed. The burden of proof that the product was in a defective condition at the time that it left the hands of the particular seller is upon the injured plaintiff; and unless evidence can be produced which will support the conclusion

that it was then defective, the burden is not sustained.

Safe condition at the time of delivery by the seller will, however, include proper packaging, necessary sterilization, and other precautions required to permit the product to remain safe for a normal length of time when handled in a normal manner.

h. A product is not in a defective condition when it is safe for normal handling and consumption. If the injury results from abnormal handling, as where a bottled beverage is knocked against a radiator to remove the cap, or from abnormal preparation for use, as where too much salt is added to food, or from abnormal consumption, as where a child eats too much candy and is made ill, the seller is not liable. Where, however, he has reason to anticipate that danger may result from a particular use, as where a drug is sold which is safe only in limited doses, he may be required to give adequate warning of the danger (see Comment *j*), and a product sold without such warning is in a defective condition.

The defective condition may arise not only from harmful ingredients, not characteristic of the product itself either as to presence or quantity, but also from foreign objects contained in the product, from decay or deterioration before sale, or from the way in which the product is prepared or packed. No reason is apparent for distinguishing between the product itself and the container in which it is supplied; and the two are purchased by the user or consumer as an integrated whole. Where the container is itself dangerous, the product is sold in a defective condition. Thus a carbonated beverage in a bottle which is so weak, or cracked, or jagged at the edges, or bottled under such excessive pressure that it may explode or otherwise cause harm to the person who handles it, is in a defective and dangerous condition. The container cannot logically be separated from the contents when the two are sold as a unit, and the liability stated in this Section arises not only when the consumer drinks the beverage and is poisoned by it, but also when he is injured by the bottle while he is handling it preparatory to consumption.

i. Unreasonably dangerous. The rule stated in this Section applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer. Many products cannot possibly be made entirely safe for all consumption, and any food or drug necessarily involves some risk of harm, if only from over-consumption. Ordinary sugar is a deadly poison to diabetics, and castor oil found use under Mussolini as an instrument of torture. That is not what is meant by "unreasonably dangerous" in this Section. The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics. Good whiskey is not unreasonably dangerous merely because it will make some people drunk, and is especially dangerous to alcoholics; but bad whiskey, containing a dangerous amount of fusel oil, is unreasonably dangerous. Good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful; but tobacco containing something like marijuana may be unreasonably dangerous. Good butter is not unreasonably dangerous merely because, if such be the case, it deposits cholesterol in

the arteries and leads to heart attacks; but bad butter, contaminated with poisonous fish oil, is unreasonably dangerous.

j. Directions or warning. In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. The seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them. Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger. Likewise in the case of poisonous drugs, or those unduly dangerous for other reasons, warning as to use may be required.

But a seller is not required to warn with respect to products, or ingredients in them, which are only dangerous, or potentially so, when consumed in excessive quantity, or over a long period of time, when the danger, or potentiality of danger, is generally known and recognized. Again the dangers of alcoholic beverages are an example, as are also those of foods containing such substances as saturated fats, which may over a period of time have a deleterious effect upon the human heart.

Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.

k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. 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, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a

known but apparently reasonable risk.

l. User or consumer. In order for the rule stated in this Section to apply, it is not necessary that the ultimate user or consumer have acquired the product directly from the seller, although the rule applies equally if he does so. He may have acquired it through one or more intermediate dealers. It is not even necessary that the consumer have purchased the product at all. He may be a member of the family of the final purchaser, or his employee, or a guest at his table, or a mere donee from the purchaser. The liability stated is one in tort, and does not require any contractual relation, or privity of contract, between the plaintiff and the defendant.

"Consumers" include not only those who in fact consume the product, but also those who prepare it for consumption; and the housewife who contracts tularemia while cooking rabbits for her husband is included within the rule stated in this Section, as is also the husband who is opening a bottle of beer for his wife to drink. Consumption includes all ultimate uses for which the product is intended, and the customer in a beauty shop to whose hair a permanent wave solution is applied by the shop is a consumer. "User" includes those who are passively enjoying the benefit of the product, as in the case of passengers in automobiles or airplanes, as well as those who are utilizing it for the purpose of doing work upon it, as in the case of an employee of the ultimate buyer who is making repairs upon the automobile which he has purchased.

Illustration:

1. A manufactures and packs a can of beans, which he sells to B, a wholesaler. B sells the beans to C, a jobber, who resells it to D, a retail grocer. E buys the can of beans from D, and gives it to F. F serves the beans at lunch to G, his guest. While eating the beans, G breaks a tooth, on a pebble of the size, shape, and color of a bean, which no reasonable inspection could possibly have discovered. There is satisfactory evidence that the pebble was in the can of beans when it was opened. Although there is no negligence on the part of A, B, C, or D, each of them is subject to liability to G. On the other hand E and F, who have not sold the beans, are not liable to G in the absence of some negligence on their part.

m. "Warranty." The liability stated in this Section does not rest upon negligence. It is strict liability, similar in its nature to that covered by Chapters 20 and 21. The basis of liability is purely one of tort.

A number of courts, seeking a theoretical basis for the liability, have resorted to a "warranty," either running with the goods sold, by analogy to covenants running with the land, or made directly to the consumer without contract. In some instances this theory has proved to be an unfortunate one. Although warranty was in its origin a matter of tort liability, and it is generally agreed that a tort action will still lie for its breach, it has become so identified in practice with a contract of sale between the plaintiff and the defendant that the warranty theory has become something of an obstacle to the recognition of the strict liability where there is no such contract. There is nothing in this

Section which would prevent any court from treating the rule stated as a matter of "warranty" to the user or consumer. But if this is done, it should be recognized and understood that the "warranty" is a very different kind of warranty from those usually found in the sale of goods, and that it is not subject to the various contract rules which have grown up to surround such sales.

The rule stated in this Section does not require any reliance on the part of the consumer upon the reputation, skill, or judgment of the seller who is to be held liable, nor any representation or undertaking on the part of that seller. The seller is strictly liable although, as is frequently the case, the consumer does not even know who he is at the time of consumption. The rule stated in this Section is not governed by the provisions of the Uniform Sales Act, or those of the Uniform Commercial Code, as to warranties; and it is not affected by limitations on the scope and content of warranties, or by limitation to "buyer" and "seller" in those statutes. Nor is the consumer required to give notice to the seller of his injury within a reasonable time after it occurs, as is provided by the Uniform Act. The consumer's cause of action does not depend upon the validity of his contract with the person from whom he acquires the product, and it is not affected by any disclaimer or other agreement, whether it be between the seller and his immediate buyer, or attached to and accompanying the product into the consumer's hands. In short, "warranty" must be given a new and different meaning if it is used in connection with this Section. It is much simpler to regard the liability here stated as merely one of strict liability in tort.

n. Contributory negligence. Since the liability with which this Section deals is not based upon negligence of the seller, but is strict liability, the rule applied to strict liability cases (see § 524) applies. Contributory negligence of the plaintiff is not a defense when such negligence consists merely in a failure to discover the defect in the product, or to guard against the possibility of its existence. On the other hand the form of contributory negligence which consists in voluntarily and unreasonably proceeding to encounter a known danger, and commonly passes under the name of assumption of risk, is a defense under this Section as in other cases of strict liability. If the user or consumer discovers the defect and is aware of the danger, and nevertheless proceeds unreasonably to make use of the product and is injured by it, he is barred from recovery.

Comment on Caveat:

o. Injuries to non-users and non-consumers. Thus far the courts, in applying the rule stated in this Section, have not gone beyond allowing recovery to users and consumers, as those terms are defined in Comment *l.* Casual bystanders, and others who may come in contact with the product, as in the case of employees of the retailer, or a passer-by injured by an exploding bottle, or a pedestrian hit by an automobile, have been denied recovery. There may be no essential reason why such plaintiffs should not be brought within the scope of the protection afforded, other than that they do not have the same reasons for expecting such protection as the consumer who buys a marketed product; but the social pressure which has been largely responsible for the development of the rule stated has been a consumers' pressure, and there is not the same demand

for the protection of casual strangers. The Institute expresses neither approval nor disapproval of expansion of the rule to permit recovery by such persons.

p. Further processing or substantial change. Thus far the decisions applying the rule stated have not gone beyond products which are sold in the condition, or in substantially the same condition, in which they are expected to reach the hands of the ultimate user or consumer. In the absence of decisions providing a clue to the rules which are likely to develop, the Institute has refrained from taking any position as to the possible liability of the seller where the product is expected to, and does, undergo further processing or other substantial change after it leaves his hands and before it reaches those of the ultimate user or consumer.

It seems reasonably clear that the mere fact that the product is to undergo processing, or other substantial change, will not in all cases relieve the seller of liability under the rule stated in this Section. If, for example, raw coffee beans are sold to a buyer who roasts and packs them for sale to the ultimate consumer, it cannot be supposed that the seller will be relieved of all liability when the raw beans are contaminated with arsenic, or some other poison. Likewise the seller of an automobile with a defective steering gear which breaks and injures the driver, can scarcely expect to be relieved of the responsibility by reason of the fact that the car is sold to a dealer who is expected to "service" it, adjust the brakes, mount and inflate the tires, and the like, before it is ready for use. On the other hand, the manufacturer of pigiron, which is capable of a wide variety of uses, is not so likely to be held to strict liability when it turns out to be unsuitable for the child's tricycle into which it is finally made by a remote buyer. The question is essentially one of whether the responsibility for discovery and prevention of the dangerous defect is shifted to the intermediate party who is to make the changes. No doubt there will be some situations, and some defects, as to which the responsibility will be shifted, and others in which it will not. The existing decisions as yet throw no light upon the questions, and the Institute therefore expresses neither approval nor disapproval of the seller's strict liability in such a case.

q. Component parts. The same problem arises in cases of the sale of a component part of a product to be assembled by another, as for example a tire to be placed on a new automobile, a brake cylinder for the same purpose, or an instrument for the panel of an airplane. Again the question arises, whether the responsibility is not shifted to the assembler. It is no doubt to be expected that where there is no change in the component part itself, but it is merely incorporated into something larger, the strict liability will be found to carry through to the ultimate user or consumer. But in the absence of a sufficient number of decisions on the matter to justify a conclusion, the Institute expresses no opinion on the matter.

Restatement of the Law, Second, Torts, § 449 Tortious or Criminal Acts the Probability of Which Makes Actor's Conduct Negligent

If the likelihood that a third person may act in a particular manner is the hazard or one of the hazards which makes the actor negligent, such an act whether innocent, negligent, intentionally tortious, or criminal does not prevent the actor from being liable for harm caused thereby.

COMMENTS & ILLUSTRATIONS: Comment:

a. This Section should be read together with § 302 B, and the Comments to that Section, which deal with the foreseeable likelihood of the intentional or even criminal misconduct of a third person as a hazard which makes the actor's conduct negligent. As is there stated, the mere possibility or even likelihood that there may be such misconduct is not in all cases sufficient to characterize the actor's conduct as negligence. It is only where the actor is under a duty to the other, because of some relation between them, to protect him against such misconduct, or where the actor has undertaken the obligation of doing so, or his conduct has created or increased the risk of harm through the misconduct, that he becomes negligent.

b. The happening of the very event the likelihood of which makes the actor's conduct negligent and so subjects the actor to liability cannot relieve him from liability. The duty to refrain from the act committed or to do the act omitted is imposed to protect the other from this very danger. To deny recovery because the other's exposure to the very risk from which it was the purpose of the duty to protect him resulted in harm to him, would be to deprive the other of all protection and to make the duty a nullity.

Illustrations:

1. A is traveling on the train of the B Railway Company. Her ticket entitles her to ride only to Station X, but she intentionally stays on the train after it has passed that station. When she arrives at Station Y the conductor puts her off the train. This occurs late at night after the station has been closed and the attendants have departed. The station is situated in a lonely district, and the only way in which she can reach the neighboring town is by passing a place where to the knowledge of the conductor there is a construction camp. The construction crew is known to contain many persons of vicious character. While attempting to pass by this camp, A is attacked and ravished by some of the construction crew. The B Railway Company is subject to liability to A.

2. The A Railway Company permits a number of drunken rowdies to ride in its day coach. No effort is made by the conductor or train crew to eject them, although their conduct is insulting and threatening to the other passengers. One of the rowdies attempts to take liberties with B, a female passenger, and in the scuffle harms her. The intentional misconduct of the rowdy is not a superseding cause of B's harm.

3. The train crew of the coal trains of the A Railway Company are in the habit of throwing out coal to their families as the train passes through the streets of a village. The Company knows of this practice but takes no steps to prevent it. B, while walking on the street, is injured by coal so thrown from one of the Company's trains. The trainman's act in throwing out the coal without looking to see whether there was anyone likely to be hit by it is not a superseding cause of B's harm.

c. Section 294 states in substance that an act or omission which negligently puts a third person in peril subjects the actor to liability to others who are led by their perception of the third person's peril to bring themselves within reach of the dangerous effect of the actor's conduct. It is an obvious corollary of this rule that the act of the other in voluntarily going to the rescue of the third person cannot be a superseding cause which prevents the actor's conduct from being the legal cause of harm which the other sustains while attempting the rescue and therefore relieve the actor from liability. So also, there are many precautions, such as locking a door or substituting an alternative barrier where a gap is lawfully made in the wall of a building or room, which are designed to protect the chattels contained in the building or room from theft. The fact that the thief's act in taking advantage of the opportunity is criminal does not make it a superseding cause of the loss of the stolen chattels.

21 C.F.R. 807.94
Subpart E--Premarket Notification Procedures Sec. 807.97 Misbranding by reference to premarket notification.

Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

WPI 15.05 Proximate Cause—Supserseding Cause

A superseding cause is a new independent cause that breaks the chain of proximate causation between a defendant's negligence and an [injury] [event].

If you find that [the] [a] defendant was negligent but that the sole proximate cause of the [injury] [event] was a later independent intervening [cause] [force] [act of one of the other defendants in this case] [act of a person not a party to this action] that the defendant, in the exercise of ordinary care, could not reasonably have anticipated, then any negligence of the defendant is superseded and such negligence was not a proximate cause of the [injury] [event]. If, however, you find that the defendant was negligent and that in the exercise of ordinary care, the defendant should reasonably have anticipated the later independent intervening [cause] [force][act], then that [cause] [force] [act] does not supersede defendant's original negligence and you may find that the defendant's negligence was a proximate cause of the [injury] [event].

It is not necessary that the sequence of events or the particular resultant [injury] [event] be foreseeable. It is only necessary that the resultant [injury] [event] fall within the general field of danger which the defendant should reasonably have anticipated.

NOTE ON USE

Use this instruction only when there are issues of multiple causation set forth in the issues instruction, WPI 20.01. Use WPI 15.01 (Proximate Cause—Definition) or WPI 15.01.01 (Proximate Cause—Definition—Alternative) with this instruction.

Use bracketed material as applicable.

If the intervening act relied upon is the act of another defendant, this instruction should be modified to apply by name to the particular defendant. If other concurring causes are in issue, use WPI 15.04, Negligence of Defendant Concurring with Other Causes, with this instruction.

If juror comprehension would be aided, the instruction may be tailored to a particular case by using the names of the parties and specifying the acts in question, as long as this can be done without appearing to comment on the evidence.

COMMENT

If the original negligence of a defendant is followed by an unforeseeable independent intervening cause, force, or act of a third person (not a party to the case) which is the proximate cause of an injury or event, the chain of proximate causation is broken. Qualls v. Golden Arrow Farms, 47 Wn.2d 599, 288 P.2d 1090 (1955); Bracy v. Lund, 197 Wash. 188, 84 P.2d 670 (1938). If the independent intervening cause, force or act is not reasonably foreseeable, it is deemed to supersede the defendant's original

negligence. The defendant's original negligence ceases to be the proximate cause. Maltman v. Sauer, 84 Wn.2d 975, 530 P.2d 254 (1975); Cook v. Seidenverg, 36 Wn.2d 256, 217 P.2d 799 (1950); Estate of Keck By and Through Cabe v. Blair, 71 Wn.App. 105, 856 P.2d 740 (1993).

On the other hand, the chain of proximate causation is not broken when the defendant, in the exercise of ordinary care, should reasonably have anticipated that the independent intervening cause, force, or act was likely to happen. Adamson v. Traylor, 60 Wn.2d 332, 373 P.2d 961 (1962); Qualls v. Golden Arrow Farms, supra; McLeod v. Grant County School Dist. No. 128, 42 Wn.2d 316, 255 P.2d 360 (1953); Gies v. Consolidated Freightways, 40 Wn.2d 488, 244 P.2d 248 (1952); Bracy v. Lund, supra. If there are varying inferences to be derived from the evidence, the range of reasonable anticipation of foreseeability is a question for the jury. Kennett v. Yates, 41 Wn.2d 558, 250 P.2d 962 (1952). "If the acts are ... within the ambit of the hazards covered by the duty imposed upon the defendant, they are foreseeable and do not supersede the defendant's negligence." Cramer v. Department of Highways, 73 Wn.App. 516, 870 P.2d 999 (1994).

In Christen v. Lee, 113 Wn.2d 479, 780 P.2d 1307 (1989), the court held that a criminal assault may be a foreseeable result of furnishing intoxicating liquor to an obviously intoxicated person, but only if the drinking establishment that furnished the intoxicating liquor had some notice of the possibility of harm from prior actions of the person causing the injury, either on the occasion of the injury or on previous occasions. Accord, Cox v. Keg Restaurants U.S., Inc., 86 Wn.App. 239, 935 P.2d 1377 (1997). The court in Christen stated that foreseeability is normally an issue for the jury, but it will be decided as a matter of law when reasonable minds cannot differ.

A court order prohibiting a father's contact with his child may be an intervening cause breaking the chain from a negligent CPS investigation only if all the material information was presented to the court that issued the order. Tyner v. State Dept. of Social and Health Services, Child Protective Services, 141 Wn.2d 68, 82, 1 P.3d 1148 (2000); Petcu v. State, 121 Wn.App. 36, 86 P.3d 1234 (2004). A court's refusal to revoke a DUI probationer two days before he drove and killed plaintiff decedent was a superseding intervening cause to the county's negligent probation supervision preceding the court hearing. Bishop v. Miche, 137 Wn.2d 518, 973 P.2d 465 (1999). The decision to prosecute a parent was a superseding intervening cause breaking the causal connection to a negligent CPS investigation. Gausvik v. Abbey, 126 Wn.App. 868, 107 P.3d 98 (2005).

A criminal act by a third party is not a superseding cause if it was reasonably foreseeable. See Johnson v. State, 77 Wn.App. 934, 894 P.2d 1366 (1995). The court may determine that a criminal act is unforeseeable as a matter of law "only if the occurrence is so highly extraordinary or improbable as to be wholly beyond the range of expectability. Otherwise, the foreseeability of the criminal act is a question for the trier of fact." Johnson v. State, 77 Wn.App. at 942. See also Tegman v. Accident & Medical

Investigations, Inc., 150 Wn.2d 102, 75 P.3d 497 (2003) (jury required to segregate damages caused by intentional versus negligent tortfeasors).

It may be a foreseeable result of selling alcohol to a minor that the purchasing minor will share the alcohol with other minors whose intoxication will proximately cause injury to themselves or third persons. See Crowe v. Gaston, 134 Wn.2d 509, 951 P.2d 1118 (1998); Schooley v. Pinch's Deli Market, Inc., 134 Wn.2d 468, 951 P.2d 749 (1998); Rinks v. Bearss, 83 Wn.App. 334, 921 P.2d 558 (1996). Foreseeability of the result is normally a question of fact, as to which the trier of fact may consider the amount and nature of the alcohol purchased, the time of day, the presence of other minors on the premises or in a vehicle, and statements made by the purchaser to determine whether it was foreseeable the alcohol would be shared. Crowe v. Gaston, 134 Wn.2d at 517; Schooley v. Pinch's Deli Market, Inc., 134 Wn.2d at 754.

The second paragraph of this instruction, which relates to the foreseeability of a sequence of events or a particular harm or occurrence, is cited with approval in Koker v. Armstrong Cork, Inc., 60 Wn.App. 466, 804 P.2d 659 (1991). In Koker, the court stated that the test for foreseeability is whether the result of the act of the defendant is within the "ambit of the hazards" covered by the duty imposed on the defendant. In Walker v. State, 67 Wn.App. 611, 837 P.2d 1023 (1992), reversed on other grounds at 121 Wn.2d 214, 848 P.2d 721 (1993), the court held that it is proper to give this instruction without the second paragraph if the issue of general field of danger is not raised as a defense.

Changes to the instruction made in 2009. The instruction has been modified as part of the 2009 revisions. The changes are intended to help jurors understand the relationship between this instruction and the definition of proximate cause in WPI 15.01, and to clarify the language used in communicated these complicated concepts.

For further discussion of intervening or superseding causes, see. DeWolf and Allen, 16 Washington Practice: Tort Law and Practice § 4.23 (3d ed.).
[Current as of June 2009.]

WPI 110.03 Manufacturer's Duty to Provide Warnings or Instructions With Product

A manufacturer has a duty to supply products that are reasonably safe.

A product may be not reasonably safe because adequate warnings or instructions were not provided with the product.

There are two tests for determining whether a product is not reasonably safe because adequate warnings or instructions were not provided with the product. The plaintiff may prove that the product was not reasonably safe because adequate warnings or instructions were not provided with the product using either of these two tests.

The first test is whether, at the time of manufacture:

a the likelihood that the product would cause injury or damage similar to that claimed by the plaintiff, and the seriousness of such injury or damage, rendered the warnings or instructions of the manufacturer inadequate; and

b the manufacturer could have provided adequate warning or instructions.

The second test is whether the product is unsafe to an extent beyond that which would be contemplated by an ordinary user. In determining what an ordinary user would reasonably expect, you should consider the following:

a the relative cost of the product;

b the seriousness of the potential harm from the claimed defect;

c the cost and feasibility of eliminating or minimizing the risk; and

d such [other] factors as the nature of the product and the claimed defect indicate are appropriate

[A product can be "not reasonably safe" even though the risk that it would cause the plaintiff's harm or similar harms was not foreseeable by the manufacturer at the time the product left the manufacturer's control.]

If you find that the product was not reasonably safe because adequate warnings or instructions were not provided with the product and this was a proximate cause of the plaintiff's [injury] [and] [or] [damage], then the manufacturer is [subject to liability] [at fault].

NOTE ON USE

Use this instruction if there is a claim against a manufacturer that the product was not reasonably safe because adequate warnings or instruction were not provided with the product. If only one of the two tests is being used by the court, modify the instruction accordingly.

Use bracketed material as applicable. Use the bracketed paragraph concerning foreseeability when there are claims of negligence as well as strict liability or when foreseeability concepts have otherwise been injected into the trial. The bracketed "at fault" language is intended to be used in conjunction with WPI 110.31.01.02 (defining "fault") and with WPI 110.31.01.01 (the corresponding special verdict form) for cases involving mixed standards of care (e.g., negligence and strict liability); see the Notes on Use and Comments for WPI 110.31.01.01 and WPI 110.31.01.02.

Use WPI 110.04, Seller—Manufacturer—Defined, with this instruction.

Use either WPI 110.21.01 (Burden of Proof—Duty to Provide Warnings with Product—No Affirmative Defense) or WPI 110.23.01 (Burden of Proof—Duty to Provide Warnings With Product—Assumption of Risk or Contributory Negligence) with this instruction.

COMMENT

RCW 7.72.030(1).

The instruction was rewritten in 2012 to improve the use of plain language. These plain-language changes are intended for ease of juror understanding; no substantive change is intended. The committee also added to the instruction a bracketed paragraph on foreseeability, based on the holding in Ayers v. Johnson & Johnson Baby Products Co., 117 Wn.2d 747, 765, 818 P.2d 1337 (1991).

The statute. The statute states in part that 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 because adequate warnings or instructions were not provided." RCW 7.72.030(1).

The Washington Product Liability Act (WPLA) provides two different ways for plaintiffs to prove inadequate warnings. First, the plaintiff may use the balancing-test approach from RCW 7.72.030(1)(b), which provides that:

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.

Second, the plaintiff may show under RCW 7.72.030(3) that the product "was unsafe to an extent beyond that which would be contemplated by the ordinary consumer." The balancing-test approach of RCW 7.72.030(1)(b) and the consumer-expectations approach of RCW 7.72.030(3) are alternative, independent means of proving inadequate warnings. A plaintiff needs to prove only one, not both, of these alternatives. Ayers v. Johnson & Johnson Baby Prods. Co., 117 Wn.2d at 765.

Balancing test—Factors. The court in Ayers characterized the factors in the balancing test as follows:

[O]n one side of the balance in subsection (b) are the likelihood that the product would cause the claimant's harm or similar harms and the seriousness of those harms. On the other side of subsection (b)'s balance are the adequacy of the warnings that were provided and the ability of the manufacturer to have provided an alternative warning that would have prevented the injury.

117 Wn.2d at 763.

Balancing test—Strict liability. The balancing-test approach of RCW 7.72.030(1)(b) is based on the strict liability principles expressed in Seattle-First National Bank v. Tabert, 86 Wn.2d 145, 542 P.2d 774 (1975). Ayers v. Johnson & Johnson Baby Prods. Co., 117 Wn.2d at 761–65. As such, foreseeability is not an element of the balancing test for a failure-to-warn claim. 117 Wn.2d at 764–65.

Balancing test—Proof of alternative warnings. The language of RCW 7.72.030(1)(b), which requires the trier of fact in a failure to warn case to consider whether "the manufacturer could have provided warnings or instructions which the claimant alleges would have been adequate," does not require the claimant to establish the exact wording of the alternative warning. The statute's requirement is satisfied if the claimant specifies the substance of the warning. Ayers v. Johnson & Johnson Baby Prods. Co., 117 Wn.2d at 755–56.

Consumer-expectations test. See Comment to WPI 110.02, Manufacturer's Duty—Design.

Comment k—Unavoidably unsafe products. See related discussion in the Comment to WPI 110.02, Manufacturer's Duty—Design (discussing comment k of Restatement (Second) of Torts § 402A). In Ruiz-Guzman v. Amvac Chemical Corp., 141 Wn.2d 493, 7 P.3d 795 (2000), the Washington Supreme Court incorporated comment k into the WPLA. Comment k has most often been applied to prescription drug and medical products cases. While the law seems settled that the standard of liability in a comment k case for design is negligence and not strict liability, it is less clear in warnings cases. Young v. Key Pharms., Inc., 130 Wn.2d 160, 922 P.2d 59 (1996). In Young, the court

was split 4-4 on the issue of whether the standard of liability in a warnings case for a comment k product, there a prescription drug, was one of negligence or strict liability. The plurality approved the trial court's instruction which set forth a common law negligence standard. The four dissenting justices recognized that common law negligence was the proper standard for the duty to design in comment k products, but argued that strict liability was the proper standard for the duty to warn. Young v. Key Pharms., Inc., 130 Wn.2d at 181. On the other hand, Division I has held that negligence and not strict liability is the standard. Estate of LaMontagne v. Bristol-Myers-Squib, 127 Wn.App. 335, 111 P. 3d 857 (2005) ("Whether a prescription drug manufacturer provides adequate warnings to physicians is governed by the negligence standard under the Restatement (Second) of Torts Sec.402A, comment k (1965)"). If the trial court decides that common law negligence is the correct standard, the committee believes the following instruction, patterned after the instruction specifically approved in Young (130 Wn.2d at 175–78), is an accurate statement of the common law negligence standard in a failure to warn case:

A [pharmaceutical] [medical product] manufacturer is under a duty to use reasonable care to test, analyze, and inspect the [drugs] [medical products] it sells, and is presumed to know what such tests would have revealed.

A [pharmaceutical] [medical product] manufacturer has a duty to use reasonable care to keep abreast of scientific knowledge, discoveries, advances, and research in the field, and is presumed to know what is imparted thereby.

When a [pharmaceutical] [medical product] manufacturer becomes aware or should have become aware of dangerous aspects of one of its products, it has a continuing duty to warn of such dangerous aspects. In such a case, the manufacturer is under a duty to use reasonable care in regard to issuing warnings or instructions concerning any such danger. This duty is satisfied if the manufacturer exercises reasonable care to inform healthcare providers who prescribe or utilize the product.

The failure to use reasonable care is negligence. "Reasonable care" means the care that a reasonably prudent [pharmaceutical] [medical product] manufacturer would exercise in the same or similar circumstances.

The question of whether a manufacturer exercised reasonable care is to be determined by what the manufacturer knew or reasonably should have known prior to the time of plaintiff's injury.

See Koker v. Armstrong Cork, Inc, 60 Wn.App 466, 477–79, 804 P. 2d 659 (1991) (asbestos case holding that under common law negligence, manufacturers have a duty to use reasonable care to test, inspect, and analyze their products and to stay abreast of scientific knowledge). The duty to warn in prescription drug and medical products cases usually runs to the prescribing health care provider, often the prescribing doctor,

and not directly to the patient under the learned intermediary doctrine. Terhune v. A. H. Robins Co., 90 Wn.2d 9, 577 P. 2d 975 (1978) (Dalkon Shield IUD). See discussion of the learned intermediary doctrine below.

Learned intermediary doctrine. In prescription drug and medical products cases, if adequate warning has been given to the prescribing health care provider, often a physician, the seller or manufacturer usually has no duty to warn the ultimate user. Terhune v. A.H. Robins Co., supra (prescription medical product); Washington State Physicians Ins. Exch. v. Fisons Corp., 122 Wn.2d 299, 858 P. 2d 1054 (1993) (prescription drug). In such cases, the committee recommends that "ordinary [physician] [healthcare provider] user" be substituted for "ordinary user" when the court decides that the strict liability standard set forth in WPI 110.03 is proper instead of the common law negligence instruction set forth above. If the manufacturer provides information directly to the consumer, as in a user manual or promotional materials, the manufacturer may assume the duty to provide adequate warnings directly to the user. Restatement (Second) Torts § 324A.

The learned intermediary doctrine has occasionally been applied to cases not involving prescription drugs or medical products. In Lunt v. Mount Spokane Skiing Corp., 62 Wn.App. 353, 814 P.2d 1189 (1991), the court held that the manufacturer of ski bindings met its duty to warn under RCW 7.72.030(1) by providing detailed warnings to the operator of the ski area. The Lunt court noted that the manufacturer had a reasonable basis to believe that the ski area operator would pass along those warnings. The court also noted that a ski binding manufacturer who makes bindings for rental use has limited opportunities to communicate directly with the consumer.

Duty to warn under common law. The following discussion relates to the law on warnings prior to RCW 7.72.030(1)(b). RCW 7.72.020 provides that "the previous existing applicable law of this state" on product liability is modified only to the extent set forth in RCW Chapter 7.72. The cases below should be carefully studied with the new statute in mind.

The duty to warn exists, even if the danger is unknown to the supplier and the product has been faultlessly manufactured and designed, if it is not reasonably safe when used in the absence of warnings. Teagle v. Fischer & Porter Co., 89 Wn.2d 149, 570 P.2d 438 (1977). When the danger is obvious or known, there is no duty to warn. Haysom v. Coleman Lantern Co., 89 Wn.2d 474, 573 P.2d 785 (1978).

In Little v. PPG Industries, Inc., 92 Wn.2d 118, 594 P.2d 911 (1979),the court approved instructions that set out several aspects of the duty to warn, including advising of the nature of the danger, the seriousness of the consequences of improper use, and measures to take to avoid the danger. The court does not need to furnish guidelines to aid the jury in determining whether the warning is adequate in a case when the danger is not clearly latent. Berry v. Coleman Sys. Co., 23 Wn.App. 622, 596 P.2d 1365 (1979). The adequacy of warnings to minors who use dangerous products is discussed in

Baughn v. Honda Motor Co., 107 Wn.2d 127, 727 P.2d 655 (1986), and Novak v. Piggly Wiggly Puget Sound Co., 22 Wn.App. 407, 591 P.2d 791 (1979).

The fact that the user knew of the dangerous condition, thus eliminating the need for a warning, does not, of itself, absolve the manufacturer of liability for defective design. Lamon v. McDonnell Douglas Corp., 19 Wn.App. 515, 576 P.2d 426 (1978), affirmed 91 Wn.2d 345, 588 P.2d 1346 (1979).
[Current as of January 2012.]

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February 10, 2014 - 2:58 PM

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