2011 AUGUST. A. RENDIGS, JR. NATIONAL PRODUCTS LIABILITIY MOOT COURT COMPETITION No. XX-XXXX SUPREME COURT OF THE UNITED STATES

Firefly Systems, Inc., Defendant - Petitioner,		
vs.		
In re Estate of Zoe Washburne, Plaintiff - Respondent.		
On Writ of Certiorari from the	ne United States Court of Appeals	s for the Thirteenth Circuit.
	RESPONDENT'S BRIEF	
		Team #4 Counsel for Respondent

QUESTIONS PRESENTED

- I. Was the US Court of Appeals for the Thirteenth Circuit correct when it held that, under a Conflict of Law Analysis, the state of Grace has the most significant relationship to the litigation when Respondent died in Grace, Respondent was domiciled and worked in Grace, and the relationship between the parties was formed in Grace?
- II. Regardless of the answer to the above question, has Respondent stated a claim for strict products liability sufficient to dismiss a 12(b)(6) motion when she dies as a result of biphasic anaphylaxis from a penicillin shot administered because Petitioner's product omitted her penicillin allergy in its digitization of Respondent's medical records?

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	b. The Court of Appeals for the Thirteenth Circuit was correct in determining that Miss Washburne stated a sufficient claim for strict products liability on which relief can be granted based on a claim for design and warning defects under Grace substantive law because Petitioner failed to implement a valid warning system informing both the seller and consumer of errors in its product.
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STATEMENT OF THE CASE

Zoe Washburne was born in 1982 and died in 2008. At age five, Miss Washburne was found to have an allergy to penicillin, a common antibiotic. Since this diagnosis, Miss Washburne and her parents had taken active steps to protect her from exposure to penicillin, including notifying new doctors. (R. at 2)

At some time in late 2008, Miss Washburne received a letter from her physician, Dr. Frye, stating that Dr. Frye's practice would be switching their record keeping systems into digital format, and that Miss Washburne could receive a USB copy of the records for \$25. (R. at 2) Miss Washburne then wrote a check for \$25 to Petitioner Firefly Systems, Inc., the provider of the product. (R. at 2-3) Dr. Frye then gave Firefly the records of Washburne's medical records. (R. at 2-3)

After digitizing Miss Washburne's records, Petitioner Firefly shipped the software to Dr. Frye, and Miss Washburne received the USB copy of her records. Petitioner generally instructs customers to check their records for accuracy, which Miss Washburne had not done and subsequently misplaced. (R. at 3)

In September 2008, Miss Washburne was in the state of Haven on a field trip sponsored by the school she worked for in Grace. On that day, Miss Washburne felt sick and was taken to the University Medical center in Capitol City, Haven. Miss Washburne's medical records were accessed via Petitioner's web portal, where copies of records were kept. (R. at 3) Doctors diagnosed Miss Washburne with an acute appendicitis, and removed her appendix.

Unfortunately, Petitioner's digital records for Miss Washburne were missing her penicillin allergy. Five minutes after administering penicillin, Miss Washburne began having respiratory problems. Doctors recognized this as an allergic reaction to the penicillin and

administered epinephrine. Miss Washburne recovered and was discharged from the hospital two days later. (R. at 4)

However, on her way home from the hospital, just after crossing back into Grace, Miss Washburne collapsed. She was pronounced dead at the scene. It was determined that Miss Washburne's death was due to her allergic reaction to the penicillin. (R. at 4)

Miss Washburne's family brought a products liability suit against Petitioner alleging that Petitioner's product was defective in not listing Miss Washburne's allergy. The trial court dismissed the initial claim under a Conflict of Laws analysis and Fed. R. Civ. Pro. 12(b)(6). On appeal, that decision was reversed. Petitioner now appeals the decision of the Court of Appeals.

MissWashburne's estate prays that this court will affirm the ruling of the Court of Appeals.

SUMMARY OF ARGUMENT

A true conflict exists between the substantive law of Grace and that of Haven because applying the different laws will achieve inconsistent results. Haven's choice-of-law analysis applies because the forum is in Haven. Under Haven's "most significant relationship test," Grace has the most significant relationship to the litigation based on the facts in the record and as a matter of policy. Thus, since Grace has the most significant relationship to the litigation, Grace's substantive law applies to the issue of whether Respondent has sufficiently stated a claim on which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6).

Miss Washburne has stated a claim for strict products liability upon which relief can be granted. Petitioner's product is defective under the substantive law of both the state of Grace and the State of Haven. Petitioner's product was manufactured defectively under the substantive law of the state of Grace, which applies the Restatement (Second) of Torts, because the product

failed to meet the safety standard that a consumer would expect from such a product. Miss Washburne established design and warning defect claims under Grace's substantive law because Petitioner's product failed to meet the consumer expectations test. Miss Washburne established a sufficient claim for manufacturing, design and warning defects under the substantive law of Haven, which applies the Restatement (Third) of Torts, because Petitioner's product departed from its intended design by inaccurately reflecting Miss Washburne's records, the risk of injury outweighed the costs of implementing a reasonably alternative design, and because Petitionerfailed to adequately warn Miss Washburne of the product's risks. Petitioner breached its implied warranty of merchantability when its software was not fit for ordinary use. Petitioner created an express warranty in its advertisements and breached that warranty when the product did not accurately digitize Miss Washburne's records as indicated.

Miss Washburne respectfully requests the Court to affirm the Circuit Court's decision.

ARGUMENT

I. THIS COURT HAS JURISDICTION OVER PETITIONER'S WRIT BECAUSE THE UNITED STATES SUPREME COURT HAS JURISDICTION OVER ALL APPEALS FROM A FEDERAL CIRCUIT COURT.

This Court has jurisdiction over Petitioner's petition for writ of certiorari pursuant to 28 U.S.C. § 1254, which states that cases in the courts of appeals may be reviewed by the Supreme Court by writ of certiorari granted upon the petition of any party in a civil case. The Court of Appeals decision to affirm the District Court's dismissal of the express warranty claim, and reverse the District Court's dismissal of strict products liability and implied warranty of merchantability claims is an appealable final order.

A dismissal for failure to state a claim on which relief can be granted, pursuant to Fed. R. Civ. P. 12(b)(6), is reviewed de novo. Review is based on a question of law and "is limited to the

contents of the complaint." Pencil St. Soap Co. v. United States, 787 F.3d 547, 549 (13th Cir. 1990). All factual allegations in the complaint must be accepted as true, and viewed in the light most favorable to the plaintiff. Christopher v. Harbury, 536 U.S. 403, 406 (2002); see also Erickson v. Pardus, 551 U.S. 89, 94 (2007). A complaint need not allege detailed factual allegations and may proceed even if recovery appears to be remote and unlikely. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007).

II. THE COURT OF APPEALS FOR THE THIRTEENTH CIRCUIT WAS CORRECT IN APPLYING THE STATE OF GRACE'S SUBSTANTIVE LAW TO GOVERN THE RESOLUTION OF THIS CASE UNDER THE STATE OF HAVEN'S CONFLICT OF LAWS ANALYSIS BECAUSE THE STATE OF GRACE'S SUBSTANTIVE LAW GOVERNS UNDER BOTH LEX LOCI DELICTI AND MOST SIGNIFICANT RELATIONSHIP ANALYSES.

Before any choice of law analysis can be done, there must actually be a conflict between the laws of the states interested. Oil Shipping B.V. v. Sonmez Denizcilik Ve Ticaret A.S., 10 F.3d 1015, 1018 (3d Cir 1993). Here, there is a conflict between the two states because Grace and Haven both apply different laws in products liabilities cases. Grace adheres to the Restatement (Second) of Torts: Products Liability, whereas Haven adheres to the Restatement (Third) of Products Liability. One example of a conflict between the two laws is that the Restatement (Third) requires a Plaintiff to show a reasonable alternative design in products liability cases, where the Restatement (Second) does not. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (1998).

Since the choice of law that applies will determine what the Plaintiff must include in the complaint, applying the different approaches is likely to reach an inconsistent result. Therefore, a true conflict exists between the two laws.

Haven's choice-of-law analysis shall determine which substantive law applies to this case. In cases brought under diversity of citizenship, a district court must apply the substantive

law and choice-of-law rules of the forum state. <u>Klaxon Co. v. Stentor Elec. Mfg. Co.</u>, 313 U.S. 487, 495-96 (1941). Otherwise, "the accident of diversity of citizenship would constantly disturb equal administration of justice in coordinate state and federal courts sitting side by side." <u>Day & Zimmerman, Inc. v. Challoner</u>, 423 U.S. 3, 4 (1975). Haven resolves conflicts of laws by applying the "most significant relationship" test under the Restatement (Second) Conflict of laws. Booker v. InGen, Inc., 241 Haven 17, 24 (2007).

A. Grace substantive law governs the resolution of this case under the most significant relationship test because Grace was the state in which Miss Washburne was domiciled, worked, had her primary care physician, formed her relationship with Petitioner, and in which the injury occurred.

The "most significant relationship" test says "[t]he rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which . . . has the most significant relationship to the occurrence" RESTATEMENT (SECOND) CONFLICT OF LAWS § 145(1) (1971). Factors to consider when determining which state has the "most significant relationship" include: 1) the place of the injury; 2) the place where conduct causing injury occurred; 3) the domicile, residence, nationality, place of incorporation, and place of business of the parties; 4) the place where the relationship between the parties is located; 5) any factors under § 6 of the restatement which the court may deem relevant. <u>Id.</u> at §145(2). When the contacts seem evenly balanced, the public policies of the concerned states must be analyzed to determine the most significant relationship. <u>Brewer v. Dodson Aviation</u>, 447 F.Supp.2d 1166, 1176 (W. D. Wash. 2006).

In <u>Robinson v. McNeil Consumer Healthcare</u>, the Court of Appeals for the Seventh Circuit held that the state in which the symptoms first appear "should be deemed the place of the injury." 615 F.3d 861, 866 (7th Cir. 2010). However, many cases have held that when the place of the injury is "fortuitous" it is given less weight when combined with the other factors in the test. In

Hitchcock v. United States, the Court of Appeals for the D.C. Circuit held that where a woman who reacted adversely to a rabies immunization while temporarily in Virginia, the state with the most significant relationship was D.C. because the "locus of the relationship was [D.C.]." 665 F.2d 354, 361 (D.C. Cir. 1981). Moreover, in Wessling v. Paris, the Kentucky Court of Appeals held that when all the interests involved, "other than the fortuitous place of the accident," are in one state, then that state will be deemed to have the most significant relationship to the litigation. 417 S.W.2d 259, 260 (Ky. 1967). However, when the contacts were too close to call, the Brewer court held that one state's public policies to deter tortious conduct of all manufacturers (both instate, and out-of-state) and protect its injured citizens were outweighed only by another state's policy-based legislation intended to "specifically govern the claims brought against its manufacturers." Brewer, 447 F.Supp at 1180-1181 (referring to Ohio's "Statute of Repose").

Grace has the most significant relationship to the litigation and therefore Grace's substantive law should apply. Miss Washburne contends that the injury in this case was the death resulting from the biphasic anaphylaxis. It can be argued, under Robinson, that Miss Washburne's injury occurred in Haven since her symptoms first appeared in there, i.e. the shot of penicillin that caused the reaction. However, this case is more analogous to Hitchcock and Wessling in that Miss Washburne's presence in Haven was merely fortuitous and all other factors point to Grace having the most significant relationship. It is true that Miss Washburne was in Haven for work-related activity and it was mere coincidence that the first time she had to utilize Petitioner's defective product was prior to an appendectomy. Moreover, like in Wessling, all other relevant factors under this test occurred in Grace.

Miss Washburne was domiciled, worked, and had her primary care physician all located in Grace. The relationship between the parties was formed in Grace when Miss Washburne

purchased Petitioner's product in Grace through her physician. This would not have happened had Petitioner not specifically made contact with Miss Washburne's doctor to establish a business relationship in Grace. Petitioner may argue that the relationship was formed in Haven because that is where Petitioner's principal place of business is located. However, the only relationship the parties had in Haven was the *first* time Miss Washburne had to utilize Petitioner's product at Haven's hospital. Unfortunately, it was also the last time she used Petitioner's defective product.

Miss Washburne contends that the injury suffered was the death that occurred in Grace, not the shot of penicillin administered in Haven. It is true that the first shot cause the initial anaphylaxis, but it was the biphasic anaphylaxis, i.e. the second allergic reaction that killed Miss Washburne, which occurred in Grace, despite the administration of the medicine in Haven. While not all of the facts leading up to litigation occurred in Grace, the events that occurred in Grace outweigh those that occurred in Haven. Therefore, Grace has the most significant relationship to the litigation and, therefore, Grace substantive law should apply, which is the RESTATEMENT (SECOND) OF TORTS § 402(A) (1977).

Conversely, even if the court finds that the states are "evenly balanced," Grace has a more significant relationship as a matter of public policy. Nothing in the record indicates that Haven has a Statute of Repose as in <u>Brewer</u>, but it is Miss Washburne's position that Grace has a strong interest in protecting its injured citizens from out-of-state manufacturers as a matter of public policy. Although Petitioner has its main place of business in Haven, Petitioner still took active measures to conduct business in Grace and, therefore, Grace law should apply to protect the consumers that Petitioner targets.

B. Grace substantive law governs the resolution of this case under lex loci delicti because the injury was Miss Washburne's ultimate death, which occurred in the state of Grace.

Petitioner argued in the District Court that Haven law should apply to this case under *lex loci delicti*. Under *lex loci delicti*, the state where the injury occurred is the law that applies. See e.g. Richards v. United States, 369 U.S. 1 (1962). *Lex loci delicti* is no longer good law based on the Haven Supreme Court's ruling in <u>Booker's</u> "most significant relationship" test. <u>Booker v. InGen, Inc.</u>, 241 Haven 17, 24 (2007). Nevertheless, if *lex loci delicti* is still good law, Grace law should apply because that is where the injury occurred.

Here, the injury was Miss Washburne's death which occurred in Grace. Petitioner argues that the injury was the initial penicillin shot administered in Haven. However, the Court of Appeals for the Seventh Circuit has held that "the injury is usually, but not always, the last act necessary to complete the tort." Consolidated R. Corp. v. Allied Corp., 882 F.2d 254, 256 (7th Cir. 1989). Furthermore, when a drug is taken in one state and the victim dies in another state, the injury is said to have occurred in the state where the victim died. Alli v. Eli Lilly & Co., 854 N.E.2d 372 (2006). Therefore, the trial court must apply the substantive law of "the state where the last event necessary to make an actor liable for the alleged wrong takes place." Id. at 376. Under this approach, the last event that occurred was Washburne's death. Therefore, since the last event occurred in Grace, according to the record, under *lex loci delicti* Grace law applies. However, *lex loci delicti* has been abandoned in many states, and even the circuit court has said that it is no longer good law in Haven.

Therefore, assuming *lex loci delicti* does not apply, Haven law should apply the "most significant relationship" test to determine which state's substantive law applies.

- III. THE COURT OF APPEALS FOR THE THIRTEENTH CIRCUIT WAS CORRECT IN DETERMINING THAT MISS WASHBURNE HAD SUFFICIENT STRICT PRODUCT LIABILITY CLAIMS FOR MANUFACTURING, DESIGN, AND WARNING DEFECTS AS WELL AS A SUFFICIENT CLAIM FOR BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY; THE COURT OF APPEALS ERRED IN AFFIRMING THE DISTRICT COURT'S DISMISSAL OF MISS WASHBURNE'S BREACH OF EXPRESS WARRANTY CLAIM.
 - A. <u>Miss Washburne has stated a sufficient claim for strict products liability on which relief can be granted regardless of the applicability of either Grace or Haven substantive law.</u>
 - 1. The Court of Appeals for the Thirteenth Circuit was correct in determining that Miss Washburne stated a sufficient claim for strict products liability on which relief can be granted under Grace substantive law because she has established that the manufacturer is liable in spite of exercising any care in manufacturing and selling the product.

Grace has adopted the RESTATEMENT (SECOND) OF TORTS § 402(A) in its entirety. <u>Turner v.</u> <u>Smith Bros., Inc.</u>, 30 Grace 144 (2006). This section reads:

- (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.

RESTATEMENT (SECOND) OF TORTS § 402(A) (1965). Under this section, it is the product at issue which makes the manufacturer liable despite exercising all possible care in making and selling the product. Barker v. Lull Eng'g, 573 P.2d 443 (Cal. 1978). For purposes of the Restatement, there are three types of defects: manufacturing, design, and warning defect. Turner, 30 Grace at 153.

a. The Court of Appeals for the Thirteenth Circuit was correct in determining that Miss Washburne stated a sufficient claim for strict products liability on which relief can be granted based on a claim for manufacturing defect under Grace substantive law because Petitioner's product failed to satisfy ordinary consumer expectations when it inaccurately and fatally misrepresented Miss Washburne's medical records.

Firefly's digital records were manufactured defectively. The "consumer expectation test" applies to determine whether there was a manufacturing defect. Id. Under this test, a manufacturer is strictly liable for injuries when a product fails to satisfy such ordinary consumer expectations as to safety in its intended or reasonably foreseeable operation. Barker v. Lull Engineering Company, Inc., 573 P.2d 443, at 454. This can be shown by circumstantial evidence, even if the specific defect is not identified. Id. Moreover, a manufacturer can be held liable for "any condition not contemplated by the ultimate consumer that will be unreasonably dangerous to the consumer." Dunn v. Zimmer, Inc., 2005 U.S. Dist. LEXIS 5344 at *19 (emphasis added). Whether a device is "simple" enough for an ordinary consumer to be able to reasonably contemplate unreasonable dangers is a matter of law to be determined by the court. Scaccianoce v. Hixon Mfg. & Supply Co., 57 F.3d 582 (7th Cir. 1995).

In <u>Dunn</u>, the District Court of Connecticut held that where a patient's replacement hip had failed because of faulty construction, the consumer expectation test did not apply because "such devices are highly complex and it is unlikely that the average consumer would be reasonably capable of determining product safety." <u>Dunn</u>, 2005 U.S. Dist. LEXIS 5344, at *21. In <u>Scaccianoce</u>, while the Seventh Circuit Court of Appeals did not give extensive guidance to determine whether a device is simple, the court held that when something requires "some degree of expertise . . . [that] takes it out of the class of 'simple' products." 57 F.3d at 586.

The product at issue in this case is Firefly's digital records of Miss Washburne's medical history. Following <u>Scacianoce's</u> reasoning, nothing in the record indicates that Petitioner's

records required any sort of expertise by its consumers. The facts clearly show that even though Petitioner sent doctors the digital copies, patients also received USB flash-drives with digital records. This shows that Petitioner wanted both the doctor and the patient to be able to use the product even though most ordinary patients have no medical expertise. Thus, Petitioner's product would likely be "simple" enough for ordinary consumer to contemplate the dangers.

An ordinary consumer would expect their digital medical records to accurately reflect their paper records. Specifically, one would expect that something as serious as one's allergies would not be inaccurate. However, Petitioner not only failed to list Miss Washburne's penicillin allergy, in fact, Miss Washburne's allergies were actually listed as "NONE" in the allergies field. From this, regardless of whatever specifically caused the allergy field to say "NONE", because a reasonable consumer would not expect something as serious as allergies to be blatantly inaccurate on their record, it can be inferred that the product was inherently defective, which in this case was fatal for the consumer. It is true that neither Miss Washburne, nor her physician double-checked the records for accuracy, but under this test, it is the product that is at issue, not any individual's conduct. The fact that the specific defect in this case has not been identified is irrelevant because circumstantial evidence is all that is required.

Thus, because it can be inferred that Petitioner's product was inherently defective by failing to list someone's allergies, the product failed to meet the safety standard that an ordinary consumer would come to expect from such a product. Therefore, Petitioner's product had a manufacturing defect.

b. The Court of Appeals for the Thirteenth Circuit was correct in determining that Miss Washburne stated a sufficient claim for strict products liability on which relief can be granted based on a claim for design and warning defects under Grace substantive law because Petitioner failed to implement a valid warning system informing both the seller and consumer of errors into its product.

The Circuit Court was correct in its ruling that Firefly's product had design and warning defects. For either an alleged design or warning defect, a combination of the consumer-expectations test and a risk-benefit analysis is applied. <u>Barker</u>, 573 P.2d at 443. When analyzing these types of defects, the product may perfectly resemble all others in the same line of products, but the product still may be inherently unsafe due to lack of safety devices or warning in its design. <u>Id</u>. at 453. The consumer expectations test is defined above. The risk-benefit analysis says that a product is defective if the consumer's injury "is attributable to a specific design feature of the product *and* the risks associated with the design outweigh its benefits." <u>Papike v.</u>

In this case, Petitioner designed a product that automatically inserted the word "NONE" in the allergies field, which was not checked for accuracy and which was not Petitioner's intended purpose, nor was it what an ordinary consumer would expect. Petitioner failed to implement a valid warning system that alerted consumers of potential errors. Under the consumer expectation analysis, it seems reasonable that a consumer would rely the seller to be accurate. Thus, it seems reasonable that an ordinary consumer would overlook the accuracy of their records, as Miss Washburne did in this case. The fact that Petitioner advised consumers to check for accuracy was not enough because there was no sense of urgency. If Petitioner had sufficiently warned people like Miss Washburne to check their records, then maybe Miss Washburne would have discovered Petitioner's error.

Applying a risk-benefit analysis, the risk of not having a system that incorporated a warning system regarding medical record omissions is high in the sense that something bad could happen as a result, which it did in this case. An incorrect input or an omission could result in misdiagnosis or mistreatment. In this case, it cost Miss Washburne her life. The facts indicate that IBM had a much more sophisticated "red flag" system where users' attention was drawn to potentially serious omissions like known allergies. Furthermore, the facts indicate that IBM's system is ten percent more costly than that of Petioner's. If this additional cost were passed on to all consumers, that means that consumers like Miss Washburne would have to pay an additional \$2.50 to increase the probability of accurate medical records. Therefore, the risk is clearly far greater than the benefit of having a less expensive system.

Therefore, Petitioner's product had both a design and warning defect.

2. Miss Washburne has stated a sufficient claim for strict products liability on which relief can be granted under Haven substantive law because she has established that Petitioner's product had a manufacturing defect, a defective design, and inadequate warnings.

The product defect must have actually caused harm to the plaintiff. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2, cmt. q; See also Haven Rev. Code § 1018.11. There must be a nexus between the defect and the injury, that shows, more likely than not (by a preponderance of the evidence) that the product was the actual causation. <u>Pafford v. Secretary of Dept. of Health and Human Services</u>, 64 Fed.Cl. 19, 29-30. (2005).

It is Miss Washburne's position that, if not for the inaccuracy in her medical record, she would not have been given penicillin. If Miss Washburne had not been given the penicillin, she would not have died from the consequential biphasic anaphylaxis. Because Miss Washburne would not have been given penicillin, and subsequently died from the allergy, if her record had been accurate, Petitioner's product actually caused Miss Washburne's injury.

The product defect must have proximately caused harm to the plaintiff. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. §2, cmt. q; See also Haven Rev. Code § 1018.11. "Proximate cause is an actual cause that is a substantial factor in the resulting harm." Toll Bros., Inc. v. Dryvit Systems, Incorporated, 432 F.3d 564, 568 (4th Cir. 2005).

Miss Washburne contends that the default "NONE" in place of a listed allergy, or an alternative default "unknown," was misleading. If not for the "NONE" in the allergy field of Miss Washburne's electronic medical record, the emergency room staff would have been aware that there was a possibility of medicinal allergies, rather than being affirmatively told there were none. Because the hospital could have been conscious of the possibility that Miss Washburne had a serious allergy if Petitioner's product had not automatically inserted the word "NONE" in her medical record, Petitioner's product proximately caused Miss Washburne's injury.

a. Miss Wasburne has stated a sufficient claim for strict products liability on which relief can be granted based on a claim for manufacturing defect under Haven substantive law because Petitioner's product departed from its intended design when it inaccurately reflected Miss Washburne's medical records.

Petitioner's product was manufactured defectively under Haven law. To prevail under her manufacturing defect claim, Miss Washburne must show that Petitioner's product departs from its intended design even though all possible care was exercised in preparing and marketing the product. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. §2(A) (1998). Miss Washburne bears the burden of proving the defect's existence; that the product was not manufactured according to its design specifications. Toms v. JC Penney Co., 304 Fed. Appx. 121, 124 (3d Cir. 2008). Under Haven law, Miss Washburne may prove the defect's existence by circumstantial evidence which would create an inference that a defect existed prior to sale. Marcus v. Valley Hill, Inc., 301 Haven 197 (2006).

In Gomez v. St. Jude Medical Diag Div., Inc., where the plaintiff had surgery to unclog an artery, a recently-developed puncture closing device was used to close the incision. 442 F.3d 919, 924 (5th Cir. 2006). Complications led to several more procedures and frequent medical care. Id. at 925. The plaintiff sued the manufacturer of the device, and relied on circumstantial evidence of defect and causation. Id. at 26. The court held that the circumstantial evidence could support an inference that the product was defective. Id. at 937. The court justified the conclusion by asserting that the law does not distinguish between circumstantial evidence and direct evidence. Id. at 933. Similarly, in this case, Miss Washburne is inferring that the product is defective based on circumstantial evidence. In **Toms**, the plaintiff sued under a manufacturing defect claim when her terrycloth bathrobe caught fire from her cigarette. 304 Fed. Appx. at 122. There, the court held that the plaintiff did not offer sufficient evidence on the manufacturing defect claim. Id. at 125. The court reached that conclusion because the plaintiff only provided the testimony of herself and her neighbor, and provided no evidence (such as a time frame, or the testimony of a witness with fire fighting experience) that the robe was unusually flammable, other than the fact that the robe caught fire. <u>Id</u>. at 126. The present case is unlike <u>Toms</u> because here Miss Washburne is providing circumstantial evidence which creates an inference that the product was defective, whereas the plaintiff in Toms merely presented an inference of a defect, without corroborating circumstantial evidence.

Miss Washburne contends that the intended design of Petitioner's software was to accurately reflect the patient's medical records with electronic access. The defect is that Petitioner's software did not accurately reflect Miss Washburne's medical records because of Petitioner's default mechanism of reflecting Miss Washburne's allergies as "NONE." In the case of medical records, misrepresenting an allergy is serious, and as for Miss Washburne, fatal if

omitted. The hospital relied on Miss Washburne's electronic medical record. Regardless of whatever specifically caused the allergy field to say none, because a reasonable consumer wouldn't expect something as serious as allergies to be blatantly inaccurate on their record, it can be inferred that the product was inherently defective.

The District Court observed that Petitioner's public policy arguments in favor of electronic medical record software held sway. Miss Washburne agrees that conversion to health information technology is in the interest of public policy. Miss Washburne argues however, that the interests of public policy are better served by reliable, accurate medical records, rather than by simply having electronic records. Petitioner's product does not accurately and reliably reflect patients' medical records. Petitioner's inaccurate and unreliable product harms, and does not serve, the interests of public policy.

b. Miss Washburne has stated a sufficient claim for strict products liability on which relief can be granted based on a claim for design defect under Haven substantive law because the risk of severe injury or death outweighed the cost of a reasonable alternative design that was available for a ten percent cost increase.

Miss Wasburne's defective design claim must stand because the dangerous risks as a result of Petitioner's design could have been significantly reduced at little cost. A product is defective when foreseeable risks of harm could have been reduced by the adoption of a reasonable alternative design. Additionally, the omission of a reasonable alternative design renders the product unsafe. Restatement (Third) of Torts: Prod. Liab. § 2 (B) (1998). A reasonable alternative design can be a product design other than the one used by the defendant that probably would have prevented or reduced the risk of Miss Washburne's injury without impairing the product's utility, and was economically and technologically feasible at the time the product was manufactured. Smith v. Louisville Ladder Co., 237 F.3d 515, 518 (5th Cir. 2001). In Smith, the plaintiff sued the manufacturer of a cable ladder under a defective design claim

after falling as a result of a hook that did not remain attached to the cable. <u>Id.</u> at 517-18. There, the court held that the plaintiff had not satisfied the reasonable alternative design requirement because the alternative that was proposed was merely a "preliminary concept," and not ready for manufacture. <u>Id.</u> at 519. Some courts have recognized that a reasonable alternative design is not always necessary to prove a product was defectively designed. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2, cmt. b (1998).

In the case of a design defect, the consumer is not usually knowledgeable enough to form an opinion on a reasonable expectation as to how safe the design of a product should be.

Consequently, a risk-utility balancing is necessary; society benefits not when products are excessively safe at a higher cost to the manufacturer, but when the optimal amount of product safety is achieved. Restatement (Third) of Torts: Prod. Liab. § 2, cmt. a (1998). In applying a risk-utility analysis, a court must identify the risk attributable to a specific design feature, then determine whether a reasonable person would find that the product's utility is outweighed by the danger, whether the danger was foreseeable or not. Krummel v. Bombardier Corp., 206 F.3d 548, 551 (5th Cir. 2000); Papike, 107 F.3d at 743. The Court of Appeals for the Seventh Circuit has expressed that if the probability of a particular risk is low, that is no defense if the costs of avoiding that risk are lower. Bammerlin v. Navistar International Transportation Corp., 30 F.3d 898, 902 (7th Cir. 1994). In some cases, "a plaintiff may not need to detail and quantify the risk and utility of a product where the product...in question is 'relatively uncomplicated and...such that a layman could readily grasp them." Krummel, 206 F.3d at 552 n.4.

A reasonable alternative design is evident in IBM's model of electronic medical records, which includes a multi-level warning system to prevent inaccurate reflections of a patient's medical records. IBM's warning system prevents the electronic record from omitting serious

information, such as allergies. A system that prevents serious omissions such as allergies would have reduced Miss Washburne's risk of injury, as the hospital would have accessed a record that was complete, including Miss Washburne's penicillin allergy. IBM was the first-to-market with their electronic medical records system. The utility of Petitioner's product would not be impaired by such an alternative design. Conversely, the utility would be improved because patients and medical practitioners alike could rely on medical records to be more complete. Because IBM's system was available before Petitioner's system, the technology for the reasonable alternative design was feasible at the time Petitioner designed and produced their product. The cost in implementing a better design is an increase of about ten percent of the cost of Petitioner's product, which was economically feasible in the market at the time the product was designed and manufactured. As a matter of public policy, when individuals' health relies on a product, producing a lower quality system for a lower cost is not in consumers' best interest. Because there was a reasonable alternative design that was technologically and economically feasible, and would have reduced the risk of Miss Washburne's injury, Petitioner's product was defectively designed.

Digitized medical records are relatively uncomplicated and do not require a particular level of expertise or specialization; a reasonable person understands how electronic medical records operate. In such a case as this, this Court may find that Miss Washburne is not required to examine the risk and utility in detail. Miss Wasburne purports that the defect in Petitioner's product design is the automatic insertion of the word "NONE" when an allergy field is left blank. The risk inherent in such a defect is an inaccurate listing of allergies, which can lead to minor, serious, or fatal injuries. As explained above, the cost of reducing such a risk is a ten percent increase in price plus additional training for operators. Miss Washburne had to pay Petitioner 25

dollars. Miss Washburne almost certainly would have happily paid an extra \$2.50 for a reduction in the probability that her medical record would omit her penicillin allergy and report that she had no allergies at all. A reasonable person would find that the risk of misrepresenting an individual's allergies outweighs the ten percent price increase for a digitized records system that provides an accurate medical record. Because a reasonable person could find that the risk inherent due to the defect in Petitioner's design reduced the product's utility, and was low in cost to improve, Miss Washburne has presented a sufficient claim for defective design.

c. Miss Washburne has stated a sufficient claim for strict products liability on which relief can be granted based on a claim for a warning defect under Haven substantive law because Petitioner could have reduced the risks of harm by reasonable warnings.

Miss Washburne contends that Petitioner did not adequately warn her of its product's risks. To establish a claim for a warning defect, a plaintiff must show that the foreseeable risks of harm could have been avoided or reduced by reasonable instructions or warnings, and that the omission of the warning renders the product not reasonably safe. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2(C) (1998). Subsection (c) adopts a reasonableness test for warning defects. Id. cmt. i. In a warning defect claim, the defendant's liability is "directly related to the adequacy of the warning provided." Donovan v. Centerpulse Spine-Tech Inc., 2010 WL 1269751, at *8 (W.D.N.Y. 2010). In Donovan, plaintiff sued the manufacturer of an implant system of spinal rods and screws after she experienced complications from the product. Id. at *1. There, the court held that plaintiff was adequately warned of the risks of the spinal implant system because the package insert gave detailed information regarding the conditions the plaintiff complained of. Id. at *9.

A warning defect is presumed where the defendant had a duty to warn the plaintiff and there was no adequate warning. <u>Magistrini v. One Hour Martinizing Dry Cleaning</u>, 109

F.Supp.2d 306, 312 (D. New Jersey 2000). A duty to warn arises where the manufacturer had constructive knowledge of the defect. Constructive knowledge contains two factors: 1) knowledge that the defendant should have known from reasonably available information, and 2) "knowledge that should have alerted a reasonably prudent person to act." Id. A "manufacturer satisfies its duty by warning of all potential dangers that it knew, or in the exercise of reasonable care, should have known to exist." Donovan, 2010 WL 1269751, at *8.

Here, Petitioner did not warn Miss Washburne of any dangers. A reasonably prudent person would have warned patients that their medical records could be inaccurate based on the system's default entry of "NONE" in the allergy field. In the exercise of due care, Petitioner should have known that the default entry of "NONE" when allergies are omitted from medical records creates the risk of injury due to exposure to allergens. Petitioner should have known these risks, and should have warned Miss Washburne of them, as well as of all potential risks; yet Petitioner did not warn Miss Washburne of any risks.

Miss Washburne contends that Petitioner did not adequately warn her of its product's risks. Petitioner may argue that it warned Miss Washburne when it instructed customers to verify electronic records before disposing of paper records. Because the paper medical records were returned to Miss Washburne's primary care physician, there is no indication in the record that Miss Washburne was directly instructed to review her records. Furthermore, it is Miss Washburne's position that an adequate warning would have included an explanation that an omission in the electronic record's allergy field yields a default entry of "NONE." Miss Washburne had been active in avoiding any exposure to penicillin throughout her life, and it can be reasonably inferred that because of this, had she been warned of the default "NONE," she certainly would have reviewed her electronic record to ensure that it accurately listed her allergy.

Because Petitioner should have known of its product's inherent risks, and did not adequately warn Miss Washburne of those risks, Miss Washburne has sufficiently set forth a warning defect claim.

- B. <u>Miss Washburne has stated a sufficient claim for breach of implied warranty of merchantability and for breach of express warranty under the Uniform Commercial Code.</u>
- 1. The Court of Appeals for the Thirteenth Circuit was correct in determining that Miss Washburne made a valid claim of a breach of the implied warranty of merchantability under Uniform Commercial Code § 2-314 because there are sufficient facts to indicate that Petitioner's lacked a basic degree of fitness for its intended use.

If this Court chooses to apply the substantive law of the state of Haven, and finds that there was no manufacturing defect according to the RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2(A), respondent may proceed with a claim of breach of implied warranty of merchantability under U.C.C. § 2-314. A manufacturing defect claim and an implied warranty of merchantability claim based on the same set of facts are exclusive of one another under the law of Haven. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2, cmt. n.

Under Grace's substantive law, the strict liability rule is not exclusive, and Miss Washburne may bring an implied warranty of merchantability claim in addition to a products liability claim. RESTATEMENT (SECOND) OF TORTS § 402A (1965); Basko v. Sterling Drug, Inc., 416 F.2d 417, 424 (2d Cir. 1969). The products liability rule followed in the state of Grace is not exclusive, and does not preclude liability on alternate grounds. RESTATEMENT (SECOND) OF TORTS § 402, cmt. a. Additionally, as the lower court correctly noted, personal injury damages are available for breach of implied warranty of merchantability under the Uniform Commercial Code. U.C.C. § 2-715(2)(b) (2003).

The contract between Miss Washburne and Petitioner suffices for an implied warranty of merchantability under the Uniform Commercial Code section 2-314. Any contract for sale of goods includes an implied warranty that the goods shall be merchantable, if the seller is a merchant with respect to goods of that kind. U.C.C. § 2-314(1) (2003). Under the Uniform Commercial code, a merchant is a person who deals in goods of the subject of the contract. U.C.C. § 2-104(1) (2003). In this case, Petitioner regularly markets such software systems as the one in this contract, therefore, they qualify as a merchant under the Uniform Commercial Code. Here, there was a sale of Petitioner's product; therefore there was an implied warranty that the product would be merchantable.

Petitioner's product was not merchantable; therefore there was a breach of the implied warranty of merchantability. Products that are merchantable must at least pass without objection under the contract description, and be fit for the ordinary purposes for which products of that description are used. U.C.C. §§ 2-313(2)(a)-(c) (2003). The Court of Appeals for the Eleventh Circuit has asserted that the implied warranty of merchantability provides for a minimum level of quality. Royal Typewriter Co. v. Xerographic Supplies Corp., 719 F.2d 1092, 1099 (11th Cir. 1983). Additionally, the Ninth Circuit has expressed that a breach of the implied warranty of merchantability occurs if the product lacks even the most basic degree of fitness for ordinary use. Birdsong v. Apple Inc., 590 F.3d 955, 958 (9th Cir. 2009). In Birdsong, plaintiffs sued defendant Apple claiming that the defendant's earbud headphones that come with the defendant's iPod were not merchantable because of the potential to cause hearing damage if used to play high volumes. Id. at 956-57. There, the court held that the defendants did not breach their warranty of merchantability, because the consumer of the iPod merely has the option of using the product in a risky manner, "not that the product lacks any minimum level of quality." Id. at 958.

Conversely, in this case, Petitioner did not allow Miss Washburne an option of the manner in which she used Petitioner's product. Miss Washburne had no control over whether the product was used in a risky or non-risky manner. It is Miss Washburne's position that the intended use of Petitioner's product was the accurate reflection of patients' medical records, including medical histories, as evidenced from Petitioner's business premise. Here, because the product incorrectly asserted that Miss Washburne had no allergies, when in fact she had a very serious allergy to penicillin, Petitioner's software lacked a basic degree of fitness for its intended use. Because Petitioner's product lacked a basic degree of fitness for its intended use, there was a breach of the implied warranty of merchantability.

2. The Court of Appeals for the Thirteenth Circuit erred in affirming the District Court's dismissal of Miss Washburne's breach of express warranty claim under Uniform Commercial Code §2-313 because Petitioner created an express warranty in its advertising which was broken when Miss Washburne's medical records were not accurately digitized as indicated.

Petitioner breached its express warranty under Uniform Commercial Code section 2-313 when its product did not conform to an affirmation of fact that became part of the basis of the bargain. Express warranties, by the seller of goods to an immediate buyer, are created by an affirmation of fact or promise made by seller. U.C.C. § 2-313(2) (2003). If the affirmation of fact becomes part of the basis of the bargain, this creates an express warranty that the goods will conform to that affirmation or promise. U.C.C. § 2-313(2)(a) (2003). Petitioner created an express warranty by affirmations it made in its advertising, which became part of the basis of the bargain for Miss Washburne, the immediate buyer.

Miss Washburne was an immediate buyer of Petitioner's product. An immediate buyer is "a buyer who enters into a contract with the seller." U.C.C. § 2-313(1) (2003). The Court of Appeals for the Eighth Circuit expanded on the definition of an immediate buyer by explaining

that an "indirect purchaser" is not an immediate buyer when there is an intermediary transaction with another, independent purchaser. <u>Campos v. Ticketmaster Corp.</u>, 140 F.3d 1166, 1169 (8th Cir. 1998). Here, Miss Washburne directly sent Petitioner a personal check, made out to Firefly, and Petitioner sent Miss Washburne a USB drive with a copy of her electronic medical record. Because Miss Washburne made a purchase directly through Petitioner, without an intermediary transaction with another, independent purchaser, Miss Washburne was an immediate buyer.

Petitioner made an affirmation of fact or a promise which served as the basis of the bargain with Miss Washburne. An advertisement containing an affirmation creates an express warranty. Cipollone v. Liggett Group, Inc., 893 F.2d 541, 547 (3d Cir. 1990). In Cipollone, a smoker claimed breach of express warranty based on defendants' advertisements that their cigarettes were "mild," or safe. Id. at 548. The court held that there was no breach of express warranty because plaintiff did not show that she relied on the advertisements. Id. at 569. Not every state has a reliance requirement. Cole v. General Motors Corp., 484 F.3d 717, 726 (5th Cir. 2007). In Cole, the court explained that some jurisdictions have a strict reliance requirement, some jurisdictions have no reliance requirement at all, and in some jurisdictions plaintiffs have a rebuttable presumption of reliance. Id. It is Miss Washburne's position that both the states of Grace and Haven have no reliance requirement for express warranties created by an advertisement. Here, Petitioner had been aggressively advertising its electronic medical records product in recent months. The affirmation contained in those advertisements was Petitioner's business premise of recording and digitizing patients' medical records, including personal medical histories. Miss Washburne's medical record was not digitized with an inclusion of her medical history; her record was digitized omitting her medical history of a serious allergy to a common medication. Because Miss Washburne's medical history was not digitized with her

medical record, as Petitioner expressed it would do in advertising with its business premise, there was a breach of express warranty.

CONCLUSION

Based on the above, Respondent respectfully requests that this Court affirm the Circuit Court's judgment.

Dated: February 9, 2011 Respectfully submitted,

Team #4
Counsel for Respondent

Estate of Zoe Washburne