No. XX-XX-XXXXX

IN THE SUPREME COURT OF THE UNITED STATES

April Term 2011

Firefly Systems, Inc.,

Petitioners

-V-

In re Estate of Zoe Washburn,

Respondent

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE THIRTEENTH CIRCUIT

BRIEF FOR PETITIONER

Team 11

Counsel for Petitioner

QUESTIONS PRESENTED

1. Under the State of Haven's conflict of laws analysis, does the State of Haven or the State of Grace's substantive law govern the resolution of this case?

2. Depending upon the application of Restatement (Second) of Torts §402A or Restatement (Third) of Torts: Products Liability §2, has Respondent stated a claim for strict products liability upon which relief can be granted, or does the claim require additional showing?

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STATEMENT OF THE CASE

I. FIREFLY'S PROVISION OF DIGITIZATION SERVICES AND RESPONDENT'S ALLEGED RESULTANT INJURY FROM USE OF THE SERVICE.

Firefly Systems, Inc. ("Firefly") is on the cutting edge of electronic medical records storage. R. at 3[1]. The premise of this Haven based company is simply to transfer patients' medical records to a digital medium allowing for easy access between physicians and hospitals in the event of an emergency. *Id*. To accomplish this, Firefly employs a system where employees input information from paper medical records into a digital form. *Id*. This record is then electronically shared with hospitals that partner with Firefly's service, as well as other non-participating hospitals through a secure web portal. *Id*. While Firefly's software is mass-produced, Firefly's service is customized to the individual medical records of each patient. *Id*. at 2.

The electronic medical records industry has seen a recent surge in competition, with companies like IBM developing a similar system. *Id*. at 3. While IBM's more expensive system relies on a "final check flag system" that halts a technician's progress when entering medical data to ensure accuracy, this feature requires additional training. In contrast, the more competitively priced and user-friendly Firefly system relies on a technician's manual "double-checking" to ensure accuracy of the data transfer and does not require additional training. *Id*.

In 2008, Firefly began marketing its digital medical records system to healthcare professionals nationwide. *Id*. at 2. Through this process, Firefly secured the business of Dr. Kaylee Frye. *Id.* Dr. Frye then notified her patients of her practice's conversion to the electronic system, indicating that patients could receive a USB flash-drive with a copy of their digital

[1] Unless otherwise indicated, all page references preceded by "R." are to the consecutively paginated "Record."

medical record for a price of twenty-five dollars. *Id.* Dr. Frye's patient, Zoe Washburne, a citizen of the State of Grace, took advantage of this offer and sent a twenty-five dollar check directly to Firefly. *Id*. at 2-3. Dr. Frye forwarded Washburne's paper medical record, containing reference to Washburne's penicillin allergy to Firefly. *Id*. at 3. Data transfer technicians completed the transfer and sent a USB flash-drive copy to Washburne. *Id*. at 3-4. Firefly then advised customers to verify the electronic records prior to destroying the paper copies. *Id*. at 3. It should be noted that the copy of Washburne's medical record on Firefly's server also contained this reference to Washburne's penicillin allergy. *Id*. at 4. In the event that Washburne did not have an allergy to penicillin, the default would have been to populate the "Known Allergy" field with "NONE." *Id.*

On September 10, 2008, Washburne experienced acute abdominal pain, causing her to feel feverish and sick to her stomach, while chaperoning a field trip in the State of Haven. *Id*. at 3. Washburne was taken to University Medical Center where she was rushed to the emergency room with pain so severe that she was non-responsive and unconscious. *Id*. Using Firefly's web portal access, hospital staff were able to retrieve Washburne's electronic medical record. *Id*. Washburne was diagnosed with appendicitis and Dr. Simon Tam, the surgeon on call, performed an appendectomy. *Id*.

Following the surgery, Washburne was administered penicillin, as is the protocol, to avoid post-surgical infection. *Id*. at. 4. Within five minutes, Washburne had an allergic reaction causing respiratory problems. *Id*. Hospital staff were unaware of her penicillin allergy, as the electronic record they possessed contained no entry in the field of "Known Allergies." *Id.* As a result of her allergic reaction the staff became aware of Washburne's penicillin allergy and were able to alleviate her symptoms. *Id.* The remainder of Washburne's hospital stay passed without

incident and she was discharged on September 12, 2008. *Id*. Upon driving into Grace with her family, Washburne collapsed. *Id*. Her parents were unable to revive her and emergency medical technicians pronounced her dead at the scene. *Id*.

II. PROCEEDINGS IN HAVEN STATE COURTS.

Washburne's estate filed this wrongful death claim in Haven against Firefly, alleging a breach of strict products liability based upon manufacturing, design, and warning defects, as well as breach of implied warranty of merchantability and express warranty. *Id*. The United States District Court for the District of Haven, deciding that the conflict of laws issue resolved in favor of Haven law, held that the strict products liability argument was without merit. *Id*. at 7-8. Also without merit were the estate's claims of breach of implied warranty of merchantability and express warranty. *Id*. at 9. The District Court granted Firefly's 12(b)(6) Motion to Dismiss for failure to state a claim. *Id*.

Washburne's estate appealed to the United States Court of Appeals for the Thirteenth Circuit. *Id.* at 10. That court reversed the lower court's finding that the substantive law of Haven applied and instead applied the substantive law of Grace. *Id*. at 11. In resolving the strict products liability question, the Court of Appeals held that Respondent had a viable claim and therefore reversed the lower court's grant of Firefly's Motion to Dismiss. *Id*. at 13. Also, on the issue of the breach of implied warranty of merchantability the Court of Appeals found that Washburne's estate did make a valid claim. *Id*. As for the issue of the express warranty, the Court of Appeals affirmed the district court's dismissal of the claim. *Id*. Firefly now appeals by writ of certiorari to the Supreme Court of the United States. *Id*. at 14.

SUMMARY OF THE ARGUMENT

The substantive law of Haven applies to this litigation. Since the forum state is Haven, the applicable conflict of laws rules are taken from the Restatement (Second) of Conflict of Laws, which applies the "most significant relationship" test. Through the process of analyzing each case pursuant to §§ 6 and 145 of the Restatement (Second) of Conflict of Laws, the ensuing result is that the unique facts of each case become vital to determining the applicable law. This qualitative approach ensures that on a case-by-case basis the facts that correlate to the substantive issue at bar and each state's interest in the litigation are given appropriate weight.

In the present case, when weighing the facts against the substantive issue of Firefly's liability, the result is that the State of Haven's interests outweigh those of the State of Grace. This issue of products liability is directly linked to Firefly's activity in Haven. Haven is Firefly's principal place of business, the place where the injury occurred and the locus of the conduct that led to that injury. The fact that the relevant conduct complained of in this litigation took place in Haven tips the balance in favor of Haven law being applied. Furthermore, Haven's own interest in regulating businesses within its borders, such as Firefly, also reflects the greater impact the outcome of this case will have on Haven, rather than on Grace. For these reasons, the United States District Court for the District of Haven correctly applied Haven law.

Since Haven is the applicable law in this action, Firefly prevails on Respondent's manufacturing defect claim because Respondent fails to state a claim on which relief may be granted. Therefore, the claim should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6). Although both lower courts manifest an understanding that the "product" under the purview of products liability law is the digital medical record, both lower courts have erred in their reasoning with respect to that point. The Tenth Circuit defines the term "product" as

meaning "any item or good that is personalty at the time it is conveyed by the seller to another party. It does not apply to a transaction that, by its nature, involves wholly or predominantly the sale of a service rather than a product." Here, Firefly was in the business of providing a service for individual customers by converting medical records, rather than the production and distribution of a manufactured product.

Additionally, the Second Circuit held that a product "may not include mere provision of . . . data supplied under individually-tailored service arrangements." The individually tailored service arrangement contemplated by the Second Circuit is the very arrangement that exists between Firefly and their customers. Accordingly, strict products liability does not extend to transactions which focus on the provision of services, but rather, to transactions which focus on the sale of goods.

If this Court finds that the medical record at issue constitutes a product, Respondent fails to overcome the burden of showing the product departed from its intended design even though all possible care was exercised by Firefly in preparing and marketing the product. As the District Court opines, the digital medical record was "intended to passively accept inserted information," and it did just that. Moreover, Firefly exercised the requisite care in digitally creating a version of Respondent's medical records by manually double-checking to ensure their accuracy. Arguably, the record left Firefly's control at the time it was uploaded onto Firefly's server. It is undisputed that the copy of the record on Firefly's server did contain the proper penicillin allergy warning. Having established that fact, Respondent has the burden of showing that the product was more dangerous than an ordinary consumer would expect. To that end, the medical record produced by Firefly worked exactly as its designers intended. With attention to the fact that it is a

medical record, the average consumer would be aware of the inherent risks for human error in that type of document, regardless of whether the record was in paper or digital format.

To prevail on a theory of defective design under Restatement (Third) of Torts: Products Liability §2, Respondent must demonstrate that the foreseeable risks of harm by the product could have been reduced by implementing a reasonable alternative design and that the alternative design is so important that it renders a product as is, unsafe. Risk utility balancing is used to determine whether an alternative design could have reduced the risk of injury. While the emphasis on imposing liability creates an incentive for manufacturers to achieve optimal levels of safety in designing and marketing products, this is not the standard by which liability is actually imposed. Instead, 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. Although IBM's system is an example of an alternative design, Respondent has failed to include this in their complaint, causing their design defect claim to fail.

Establishing a claim for a warning defect requires Respondent to show that the foreseeable risks of harm could have been avoided or reduced by reasonable instructions or warning, and that the omission of the warning renders the product not reasonably safe. Since warning of an obvious risk in most instances will not provide effective additional measures of safety, a product seller is not generally liable for failing to warn or instruct product users regarding foreseeable risks and risk avoidance measures. Firefly provided the only effective warning at their disposal and instructed their technicians to double check their entries, as well as instructed their customers to verify the electronic records prior to destroying the original paper copy. Furthermore, since it was unforeseeable that a medical record both parties agree was correct on Firefly's server would suddenly contain error when downloaded, Firefly should not be

held liable for failing to warn of that risk. Additionally, under a theory of "but for" causation, the lack of an alternative warning system informing the data technician that the allergy field was listed as "NONE" likely would not have changed the tragic result of this case. Without evidence establishing a warning defect, Respondent fails to bring a valid claim.

Even if this Court finds Grace substantive law to be applicable to the present action, Firefly continues to prevail because Respondent fails to state a claim on which relief may be granted. Grace follows Restatement (Second) of Torts which does not differentiate between manufacturing, design, and warning defects. In the same way that Restatement (Third) uses the consumer expectations test to analyze a manufacturing defect claim, Restatement (Second) applies the same analysis to a strict products liability claim. The consumer expectations test examines what an ordinary consumer would expect when using the product in an intended or reasonably foreseeable manner. Since an ordinary consumer using Firefly's service would be aware of possible inaccuracies in medical records conversion, the application of either Restatement (Second) or Restatement (Third) allows Firefly to prevail.

Finally, Respondent's additional claims of breach of implied warranty of merchantability and express warranty should be dismissed. Under Restatement (Third), two or more factually identical design defect or warning defect claims may not be submitted to the trier of fact in the same case under different doctrinal labels. A Restatement (Third) manufacturing defect claim and an implied warranty of merchantability claim rest on the same factual predicate. Since Respondent has offered no evidence of the existence of a manufacturing defect in Firefly's system, the claim of breach of implied warranty of merchantability necessarily fails and is rendered duplicative and may not be brought with the defect claims. Furthermore, express warranty is defined as a promise from the seller to the buyer that the goods shall conform to that

promise or description of the goods. Again, without any evidence that Firefly made any representation or promise to Respondent, this claim fails.

For the foregoing reasons, the District Court's grant of Firefly's Motion to Dismiss should be affirmed.

ARGUMENT

I. THE SUBSTANTIVE LAW OF HAVEN APPLIES UNDER THE "MOST SIGNIFICANT RELATIONSHIP" TEST OF THE RESTATEMENT (SECOND) OF CONFLICT OF LAWS.

The United States District Court for the District of Haven correctly held that the substantive law of Haven applies to this litigation. R. at 7. The prevailing rule in diversity cases, like the present case, is that a federal court must apply the conflict of laws rules of the forum state. *Klaxon Co. v. Stentor Electric Mfg. Co.*, 313 U.S. 487, 496 (1941). As such, the forum for this lawsuit is the State of Haven. R. at 6. Having recently abandoned the principle of *lex loci delicti* to resolve conflict of laws issues, Haven now follows the interest-weighing approach of the Restatement (Second) of Conflict of Laws. *Booker v. InGen.*, 241 Haven 17, 24 (2007).

Under the "most significant relationship" test of the Restatement (Second) of Conflict of Laws, the substantive law of Haven applies. The "most significant relationship" test creates a presumption in favor of applying the law of the state where the injury occurred, unless another state can claim a more significant relationship to the action. R. at 7. Section 145 of the Restatement (Second) of Conflict of Laws identifies the following as the factors to consider when determining which state's law should apply: "(a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicil [sic], residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered." Restatement (Second) of Conflict of Laws § 145 (1971).

Furthermore, § 6 of the Restatement (Second) of Conflict of Laws provides a set of principles by which each state's interest in the litigation may be evaluated. These principles include:

> (a) the needs of the interstate and international systems, (b) the relevant policies of the forum, (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue, (d) the protection of justified expectations, (e) the basic policies underlying the particular field of law, (f) certainty, predictability and uniformity of result, and (g) ease in the determination and application of the law to be applied.

Restatement (Second) of Conflict of Laws § 6 (1971). "Conflict-of-laws questions thus cannot be resolved by reciting general pronouncements; to determine which sovereign has the 'most significant relationship' to a particular issue, a court must instead examine the facts and circumstances presented in each particular case." *Digioia v. H. Koch & Sons, Div. of Wickes Mfg. Co.*, 944 F.2d 809, 812-13 (11th Cir. 1991). By analyzing the present case through the lens of §§ 6 and 145 of the Restatement (Second) of Conflict of Laws, the evidence indicates that the State of Haven has the "most significant relationship" to the matter.

The United States District Court for the District of Haven cited that their determination to apply Haven's substantive law was based on the facts that the injury to Respondent occurred in Haven, the conduct causing the injury occurred in Haven, the relationship between the parties was centered in Haven and that Firefly's principal place of business is in Haven. R. at 7. Conversely, the United States Court of Appeals for the Thirteenth Circuit found that Grace was the state with the "most significant relationship" based on the facts that Respondent was domiciled in Grace, worked in Grace, had her primary care physician in Grace and formed a contractual relationship with Firefly in Grace. *Id.* at 11. Given that both states have an equal number of interests in their favor, it is necessary to adopt a qualitative, rather than a quantitative approach when weighing those interests. *Gulf Consol. Services, Inc. v. Corinth Pipeworks, S.A.*,

898 F.2d 1071, 1075 (5th Cir. 1990). In applying this qualitative approach, the United States District Court for the District of Haven correctly identified Haven as the state with the "most significant relationship" to the substantive issue in this case. R. at 7.

While there is no Thirteenth Circuit or United States Supreme Court precedent on this question of conflict of laws, there is substantial case law from other United States Circuit Courts that deal with the application of the "most significant relationship" test. The Seventh Circuit has stated that "[t]he relative importance of all the alleged contacts, including the place of injury, must be independently evaluated on a case-by-case basis with respect to the particular issue involved, the character of the tort, and the relevant policies of the interested states." *Pittway Corp. v. Lockheed Aircraft Corp.*, 641 F.2d 524, 526-527 (7th Cir. 1981); *see also Digioia*, 944 F.2d at 814 (holding that the state of California had a stronger link to the particular issue of the products liability litigation and therefore its law should apply in a case where injury was caused by a cart that was negligently manufactured in California). The Fifth Circuit has also analyzed the "most significant relationship" test with an eye toward the conduct that is relevant to the substantive issue at the center of the case. *In re Air Disaster at Ramstein Air Base, Germany, on 8/29/90*, 81 F.3d 570, 577 (5th Cir. 1996).

In *In re Air Disaster at Ramstein Air Base*, an alleged manufacturing and design defect in the electrical system of a C-5A aircraft, originating with the manufacturer in Georgia, resulted in a crash on an Air Force base in Germany. *Id.* The Fifth Circuit found that Georgia law applied since "[v]irtually all of the relevant conduct complained of took place in Georgia…" *Id.* The court concluded that since the electrical defects were linked to manufacturing activities in Georgia, Georgia law applied. *Id.* Analogously, the case at bar deals with a situation where although Respondent's death occurred in Grace, the injury and conduct relevant to that result, the

administration of penicillin to Respondent, occurred in Haven. By the Fifth Circuit's logic, since it was Firefly's marketing and sale of its digitization service in Haven that resulted in Respondent's wrongful death claim, Haven's is the applicable law in this matter.

Later, the Fifth Circuit again turned to this concept of the "relevant conduct" at issue to make a determination of which state's law would apply in *McLennan v. Am. Eurocopter Corp., Inc.*, 245 F.3d 403, 426 (5th Cir. 2001). "While McLennan was injured in Canada, the relevant conduct that McLennan claims gave rise to his injuries, the marketing and manufacturing of the helicopter, took place in Texas, where AEC maintained its principal place of business." *Id.* Through this method of giving more weight to the § 145 factors that are most closely related to the "relevant conduct" that gave rise to the claim, the Fifth Circuit determined that Texas law would apply. Turning to § 6 of the Restatement (Second) of Conflict of Laws, the court stated that Texas law was applicable since "…Texas has a strong interest in enforcing its products liability laws against the manufacturers operating in the State." *Id.* Essentially, the Fifth Circuit demonstrates how the factors of §§ 6 and 145 of the Restatement (Second) of Conflict of Laws are considered in tandem by analyzing the unique facts of each case as they correlate to relevant policy issues associated with each state's interests. It is through this process that appropriate weight and deference is given to the state with the strongest tie to the central issue of the claim.

In applying this approach it is first necessary to identify the "relevant conduct complained of." *Gulf Consol. Services, Inc.*, 898 F.2d at 1075. In the present case, the issue is Firefly's alleged products liability in connection with Respondent's wrongful death claim. Specifically, the substantive issue in question is the manufacturing and design of Firefly's digital medical records. These alleged manufacturing and design issues are directly related to Firefly's activities in Haven. Much like *In Re Air Disaster at Ramstein Air Base* and *McLennan* where the

Fifth Circuit viewed the origin of any defects (i.e. the manufacturing sites of the product in question) as key to the resolution of the conflict of laws question, it is Firefly's activities in Haven that serve as the link between the substantive issue at the center of the litigation and the "relevant conduct complained of." In terms of relative weight to the other factors of § 145, the elements the District Court identified as compelling application of Haven law weigh more heavily when balancing the interests of Haven and Grace. Therefore, since Firefly's principal place of business is in Haven, and the location of the injury and the conduct that led to that injury occurred in Haven, these factors weigh more heavily in favor of applying Haven law.

Although Respondent's domicile and workplace are in Grace, those facts are not enough to overcome the significance of the facts weighing in favor of Haven. In *Saloomey v. Jeppesen & Co.*, 707 F.2d 671, 676 (2d Cir. 1983), two Connecticut residents died as a result of faulty maps mass-produced in Colorado. The Second Circuit determined that although "…both decedents were domiciled in Connecticut, that is not enough to justify the application of Connecticut law, given the strong impact of the Colorado contacts." *Id.* Those weightier Colorado contacts included that the map-making company was located in Colorado and also had its principal place of business there. *Id.*

Much like in the present case where the digital medical record is essential to the substantive issue, in *Saloomey* the faulty maps were fundamental to the underlying issue of whether the products were defective. The Second Circuit concluded that given that the maps were central to the litigation there could be no contention that "…application of Colorado substantive law to actions involving alleged defects in those charts was unforeseeable, unpredictable, or fortuitous." *Id.* The Fifth Circuit also proves to be instructive on this point stating, "[b]ecause both the case law and the Restatement instruct us to place more emphasis on

the place of the alleged misconduct, than on the residential preferences of scattered plaintiffs, the district court correctly concluded that Georgia law, [the location of the place of the alleged misconduct] should apply." *In Re Air Disaster at Ramstein Air Base*, 81 F.3d at 577.

Furthermore, when completing the "most significant relationship" test it becomes apparent that "[s]ome contacts are more important than others because they implicate state policies underlying the particular substantive issue." *Gulf Consol. Services, Inc.,* 898 F.2d at 1075. This issue of "state policies" is incidental to § 6 of the Restatement (Second) of Conflict of Laws and its focus on state interests. The function of § 6 is to determine which state has the most at stake in the litigation by looking to "the needs of the interstate and international systems, the relevant policies of the forum, the relevant policies of other interested states and particularly of the state with the dominant interest in the determination of the particular issue, and ease in the determination and application of the law to be applied," which all weigh more heavily when dealing with a products liability action. Restatement (Second) of Conflict of Laws §145 cmt b.

Since the present litigation looks to punish Firefly for their allegedly defective system, Haven as the location of Firefly's business and the site of the injury and the conduct that caused the injury has the greatest interest in applying its law. The present case can be distinguished from a case like *Guillory on Behalf of Guillory v. United States*, 699 F.2d 781, 786 (5th Cir. 1983), where the central issue was protection of a state's citizens, and not judicial oversight of the conduct of hospitals and physicians. The present litigation addresses issues of products liability and alleged defects in the manufacturing and warning systems of digital medical records, which are irrelevant to the activities that took place in Grace.

The Fifth Circuit understood the § 6 interests at stake in *Guillory on Behalf of Guillory*, where a man was overmedicated at a Texas hospital resulting in his death in Louisiana. *Id.* In

recognizing that Texas law would enforce the requirement that doctors exercise reasonable care, regardless of judicial supervision, the court was able to more appropriately identify Louisiana's state interest as integral to the issue presented to the court. *Id*. Through "…Louisiana's strong recognized interests in protecting its citizens and providing them with a just recovery, it becomes apparent that Louisiana law bears the most significant relationship to the occurrence in question." *Id.; see also Alumbaugh v. Union Pacific R. Co.*, 322 F.3d 520, 524 (8th Cir. 2003) (holding that Kansas had the greater governmental interest in regulating conduct within its borders in a case where the injury and conduct causing the injury both occurred in Kansas). In the same way, the present litigation is more concerned with Haven's ability to regulate the businesses within its borders, like Firefly, than with Grace's interest in providing recovery for Respondent's death.

Given the foregoing, the state with the "most significant relationship" to this litigation is the State of Haven. That being such, the Fifth Circuit recognizes that "[o]nly when the district court's view of applicable state law is 'against the more cogent reasoning of the best and most widespread authority' should this court reverse the judgment of the lower court." *Harville v. Anchor-Wate Co.*, 663 F.2d 598, 602 (5th Cir. 1981). Therefore, given the overwhelming evidence in favor of Haven having a greater interest in the litigation, this Court should overturn the United States Court of Appeals for the Thirteenth Circuit's finding that Grace substantive law applies.

II. RESPONDENT HAS FAILED TO STATE A CLAIM FOR STRICT PRODUCTS LIABILITY UPON WHICH RELIEF CAN BE GRANTED, WHEREBY ADDITIONAL SHOWING IS REQUIRED.

Federal Rule of Civil Procedure 12(b)(6) permits a court to dismiss all or part of an action for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6) (West

2011). When ruling on a defendant's 12(b)(6) Motion to Dismiss, a judge must accept all the factual allegations in the complaint as true. *Erickson v. Pardus,* 551 U.S. 89, 94 (2007). Additionally, a court must take the material allegations of the complaint as admitted and liberally construe them in favor of the plaintiff. *Jenkins v. McKeithen,* 395 U.S. 411, 421 (1969). A complaint in the pleading stage does not need to allege detailed factual allegations, rather, under Rule 8 of the Federal Rules of Civil Procedure the complaint only requires a "short and plain statement of the claim showing that the pleader is entitled to relief." *Bell Atl. Corp. v. Twombley*, 550 U.S. 544, 555 (2007); Fed. R. Civ. P. 8 (West 2011). In the case at bar, Firefly's rule 12(b)(6) Motion to Dismiss should be granted because Respondent has failed to state a claim for which relief may be granted.

A. Respondent Fails to State a Claim for Manufacturing Defect.

1. The Medical Record At Issue Is Not a "Product" For The Purposes Of Products Liability Law.

Historically, products liability law has focused on "products" as tangible objects that injure the consumer. *See Winter v. G.P. Putnam's Sons*, 938 F.2d 1033, 1034 (9th Cir. 1991). That is to say, categories of products that were the focus of frequent litigation included tires, automobiles, and insecticides, among many others. *Id.* Indeed, the law of products liability must evolve with innovations in technology. Therefore, as society progresses into an ever-increasing digital realm, courts will be charged with the responsibility of redefining the relationship that exists between a manufacturer and consumer. However, extending the breadth of Restatement (Third) of Torts: Products Liability §2(a) (1998) to include the medical record at issue would go against the established case law that has already redefined the term "product" for purposes of products liability law.

Under a manufacturing defect claim, the District Court opined that the focus shifts from the conduct of the manufacturer, to the product and the defects that existed at the time of sale. *See Barker v Lull Eng'g*., 20 Cal.3d 413 (Cal. 1978); R. at 11. Allowing for a shift in the analysis required both lower courts to define the product that would receive scrutiny under the Restatement (Second) of Torts §402A and Restatement (Third) of Torts: Products Liability §2 (hereinafter "Restatement (Second)" and "Restatement (Third)", respectively). Presumably, the courts' reasoning flows from the understanding that the "product" is the digitized medical record, while the actual transference of the record is an incidental service to the record's creation. R at 7, 11. However, both lower courts have erred in their reasoning with respect to finding that the electronic medical record constitutes a product for purposes of a products liability action. To that end, the United States Circuit Courts are persuasive on this issue and accordingly this Court can decide in favor of Firefly as to this issue.

Factually similar to the case at bar, the Second Circuit heard *Saloomey*, which involved geographical area charts used by airplane pilots in planning and executing their routes while in flight. *See* 707 F.2d at 672. Specifically, the area charts provided pilots with information crucial for correct instrument readings while en route to their destinations. *Id*. However, a fatal airplane crash resulted when the pilot relied on an unnoticed error in a chart's depiction of electronic altitude guidance procedures. *Id*. Notably, the charts provided to and depended on by the pilots were mass-produced with information that was gleaned from FAA regulations and merely displayed in a chart format. *Id.* at 676. Moreover, each chart that was distributed contained no individual tailoring or substantial change from any other chart distributed to other airliners. *Id.* At issue, was whether the aeronautical charts should be construed as products within the purview of products liability law. *Id*. Accordingly, the Second Circuit found it dispositive that the charts

were mass-produced, and received no individualized tailoring, in holding that the charts were in fact products, even though the distribution consisted of information rather than a traditional material object assembled by a manufacturer. *Id.* at 677.

Additionally, the heavy emphasis on the mass-production element of the charts in *Saloomey* resulted in a holding that charged manufacturers with the special responsibility of ensuring that the consumer of the charts was not injured by their product. *See Id.* at 676. With respect to that point, mass-production connotes an assembly-line type manufacturing setting where each product is indistinguishable from the next product in line. When a substantial number of products, virtually identical to one another, are released into the market, courts are interested in the safety of the product since the same defect has the probability of appearing over and over again in a mass-produced product. Here, even though the software that Firefly used to create the medical records was mass-produced and received no customization at any of the hospitals where it was in use, the individual medical record that Firefly created received patient-specific information, input by a Firefly employee. R. at 2. Instead of a mere reproduction of information provided by another agency, as in *Saloomey*, the medical records are individually-tailored to only those patients that take advantage of the digitization services that Firefly offers. *Id*.

The United States Court of Appeals for the Thirteenth Circuit and the United States District Court for the District of Haven correctly point out that both Restatement (Second) and Restatement (Third) apply to sellers of products. *Id.* at 7, 11. To that end, the Tenth Circuit defines the term product as "any item or good that is personalty at the time it is conveyed by the seller to another party. It does not apply to a transaction that, by its nature, involves wholly or predominantly the sale of a service rather than a product." *Alexander v. Beech Aircraft Corp.*, 952 F.2d 1215, 1220 (10th Cir. 1991). That being said, the medical record at issue should not be

construed as a "product" given the fact that Firefly's business is predominantly the sale of a service rather than a product. Above all else, Firefly is not engaged in the sale of medical records but rather the marketing of digitization services. R. at 2.

Unlike the Tenth Circuit, it was challenging for the Second Circuit to define what a "product" was for the purposes of products liability law, and instead that court stated with certainty what a "product" was not. "A product may not include mere provision of . . . data supplied under individually-tailored service arrangements." *Saloomey*, 707 F.2d at 677. With attention to that point, the individually-tailored service arrangement contemplated by the Second Circuit is the very arrangement that exists between Dr. Frye, Respondent, and Firefly. R. at 2. Firefly's role is distinguishable from that of the chart suppliers in *Saloomey,* because Firefly is not simply engaged in the business of amassing generic information from medical practitioners and subsequently hosting it on their servers.

Instead, Firefly's business is premised on the fact that they serve each individual customer, creating a medical record that is specific to one person. *Id*. at 2-3. Variations exist between each and every medical record Firefly is contracted to produce. Paper medical records by their very nature are unable to be mass-produced because no two patients are the same. Digitizing the records should not alter that reasoning. Ultimately, it is Dr. Frye and the Respondent who offer data on an individualized basis to Firefly in order to have a digital medical record produced.

"The doctrine of strict liability has not been extended to transactions whose primary objective is obtaining services or where the transaction's service aspect predominates and any product sale is merely incidental to the provision of the service." *In re Dow Corning Corp.*, 220 F.App'x. 457, 458 (9th Cir. 2007). "In determining whether a transaction is the sale of a product

or a service, courts have recognized 'that the *essence* of the transaction between the retail seller and the consumer relates to the *article sold*.'" *Id.* To that end, the Ninth Circuit refused to attach liability to a hair replacement provider for the purpose of products liability, because even though the patient was buying "new hair," it was actually the transplant services that were being sold to the consumer. *Id.* Analogous to the case at bar, even though Respondent ends up with a digital medical record, it is the transference of the record that Firefly is selling, not the record itself. Therefore, Firefly is engaged in the provision of a service and not the sale of products. Failing to establish that the medical record is in fact a "product" precludes Respondent from any relief based on strict products liability.

2. Even If The Medical Record Qualifies As a Product, Respondent Fails to Establish That It Was Defective At The Time It Left Firefly's Control, And Additionally That It Was The Proximate Cause Of Injury.

In the present action, Respondent has the burden of showing that the product departs from its intended design even though all possible care was exercised by Firefly in preparing and marketing the product. Restatement (Third) of Torts: Products Liability §2(a). As noted above, and by the lower courts, the "product" which receives scrutiny is the medical record as an end result, and not the software that assists in its creation. R. at 7, 11. The language of Restatement (Second) and Restatement (Third) reserves liability for instances in which the product is expected to and does reach the user or consumer without substantial change in the condition in which it is sold. Restatement (Third) of Torts: Products Liability §2(a). Therefore, it is incumbent upon Respondent to prove that the defect in the product was the proximate cause of the injury, and that the product contained the defect at the time it left Firefly's control.

Historically, "strict liability" was understood by courts to give consumers the ability to hold a manufacturer strictly liable for injuries, regardless of the manufacturer's exercised care or

negligence. *Id.* Thus, a manufacturer was potentially "on the hook" for monetary damages based solely on the fact that they were in the business of manufacturing and selling the product that caused injury. *Id.* As a result, analysis beyond establishing that fact was rarely necessary. *Id.* However, as courts were forced to grapple with imposing what at times seemed to be an unfair level of liability, practical limitations on the definition of strict liability arose from several jurisdictions.

The Eighth Circuit held that

> a manufacturer is not an insurer of the safety of his product, [however,] he has a duty to use ordinary care in its design, and in the selection of materials that go in it, in order to protect those who will likely use it from unreasonable risk of harm while it is being used for its intended purpose or while it is being used for any purpose which should reasonably be expected by the manufacturer.

Dulin v. Circle F Indus., Inc, 558 F.2d 456, 466-67 (8th Cir. 1977). In other words, the Eighth Circuit is not naïve to the fact that products may cause injury; however, it is choosing to provide manufacturers with protection from liability if enough forethought and care were exercised during the manufacturing process.

Applying this standard to the case at bar, Firefly was charged with the responsibility of transferring Respondent's medical records into a digital format. R. at 2. As the District Court opines, the digital medical record was "intended to passively accept inserted information," and it did just that. *Id.* at 8. The digital medical record was manufactured in a very deliberate manner. Firefly, being cognizant of the intended use of the medical records, designed the records in such a way that patient-specific information could be included. Just as the Eighth Circuit paints a picture of a manufacturer hand-selecting the materials that will go into the end product in order to ensure safety, Firefly engaged in similar precision and planning. Recognizing that there was room for error when the technicians manually entered patient information, Firefly's protocol was

to have their employees double-check their input. *Id.* at 4. To that end, the digital version of Respondent's medical record stored locally on Firefly's servers indicated the proper penicillin allergy warning. *Id*. Moreover, Firefly exercised the requisite care in digitally creating a version of Respondent's medical record by ensuring its accuracy. *Id.* By establishing that the allergy entry was correct, Respondent's argument that the product deviated from its intended design lacks persuasiveness.

Where the product can be said to have suffered a defect was in the hands of University Medical Center, when it was downloaded off the server and viewed on the hospital's hardware. *Id.* at 12. The Thirteenth Circuit Court of Appeals points out "it is unclear whether the defect was a result of an error on the part of the Firefly employee inputting the data, or whether a malfunction in the software caused an error that failed to display Washburne's allergy to Dr. Tam at University Medical Center." *Id*. However, if the record was correct on the local Firefly server, it would mean there was no error by the Firefly employee inputting the data, or the software that was used in its creation.

Arguably, the record left Firefly's control at the time it was uploaded onto Firefly's server. Just as there is a lapse in time between shipment and sale of a product, where the product sits on a shelf, there was a similar lapse in time between the uploading of the record by Firefly onto their server, and the downloading off the server by University Medical Center, where no more editing or processing took place. Upon being uploaded, the medical record was a "finished product." Therefore, it seems more plausible that the defective product was actually the hardware used by University Medical Center to access Firefly's records, which is not subject to this litigation. Because there is a gray area surrounding the time and cause of the defect, Respondent

fails to overcome the burden of showing definitively that the defect existed at the time the product left Firefly's control.

The Fifth Circuit imposed even greater limitations on liability by stating "the [manufacturer] is not obliged to design the safest possible product, or one as safe as others make or a safer product than the one he has designed, so long as the design he has adopted is reasonably safe." *Weakley v. Fischbach & Moore, Inc.,* 515 F.2d 1260, 1267 (5th Cir. 1975). *Weakley* involved a mill worker who was injured after electrical current surged through his body from an "isolator switch." *Id.* at 1268. Although plaintiff argued that evidence of such an injury and evidence of safer alternatives in the market should be sufficient to impose liability, the Fifth Circuit disagreed. *Id.* Instead, that court gave weight to the fact that the mill's safety procedures were intended to prevent such an injury. Although injury was not prevented in that instance, the presence of those safety procedures rendered the product reasonably safe. *Id.*

In essence, the court was recognizing that although the product might not be the safest on the market, safety procedures and other precautions are a suitable way of compensating for the lack of additional features. Generally speaking, a cross-section of most product markets will show differing specifications, qualities, and safety mechanisms used in different products. These variations allow for differences in price, purpose, and can provide the consumer with a product that is easier to use. Applying the Fifth Circuit's reasoning to the case at bar, although Firefly's product did not contain a "final check flag system," Firefly's procedure of having the data technicians, doctors, and patients "double-check" the record after its completion would be a suitable alternative, rendering the product reasonably safe for its intended use.

Whatever it may be, the Fifth Circuit recognizes that not every product on the market will be the same, but in that same breath, gives manufacturers a tangible standard to work with.

Manufacturers do not have to achieve extreme safety in their respective markets, but rather reasonable safety. *Id.* Accordingly, the definition of reasonable safety for purposes of Restatement (Third) of Torts: Products Liability §2(a) comes from the "consumer expectations test." Practically speaking, a product is required to be more dangerous than an ordinary consumer would expect it to be, before a court will attach liability. *Id.* Therefore, it is an objective test based on the typical, average, common expectations of a reasonable consumer. *See Jennings v. BIC Corp.,* 181 F.3d 1250, 1260 (11th Cir. 1999).

Inasmuch as a digitized version of an original medical record is thought to be part of a movement towards error-free records management, human involvement in the process makes it at the very minimum, reasonably foreseeable that there will be a limited level of error in the final digital version of the record. Although the United States Court of Appeals for the Thirteenth Circuit holds that Respondent would have the expectation that the electronic medical record will be an exact copy of the paper record, that court ignores the threat of human error inherent even in a paper record. R. at 12.

The threat of imperfect transcription is a problem that affects paper and digital medical records alike. By way of example, the advent of computerized menus and cash registers at fast food eateries may at one time have been implemented in an effort to reduce errors in customer ordering, however, in the same manner as the present case, merely digitizing a component of the process does not cure it of all faults. Regardless, it would be reasonable for Respondent to anticipate some inaccuracy in the downloaded medical record. Therefore, the product is no more dangerous than an ordinary consumer would expect it to be.

Although a tragic result, Respondent does not meet the burden of showing that the medical record was unreasonably dangerous. *See Halliday v. Sturm, Ruger & Co., Inc.,* 792 A.2d

1145, 1158 (Md. 2002). In a state court action, a mother brought a products liability claim against a gun manufacturer after the death of her son from a self-inflicted gun shot wound. *Id.* Because death was a result, the argument was made that the gun was unreasonably dangerous. *Id.* However, the court stated "regrettably, it [the firearm] worked exactly as it was designed and intended to work and as any ordinary consumer would have expected it to work." *Id.* Analogous to the case at bar, even though death resulted, this Court should not rush to impose liability against Firefly. The medical record produced by Firefly worked exactly as its designers intended. With attention to the fact that it is a medical record, the average consumer would be aware of the inherent risks for human error in that type of document, regardless of whether the record was in paper or digital format.

As the District Court concludes, "it cannot be said that [Firefly's] product was the proximate cause of [Respondent's] harm." R. at 8. Detrimental reliance on the "electronic record was a choice made by the treating hospital, in lieu of searching for [Respondent's] physician to check that doctor's records or memory concerning [Respondent]." *Id*. However, liability cannot be imposed on Firefly for an error that did not exist at the time it left their control, and was reasonably foreseeable by the consumer.

B. By Failing To Allege A Safer Alternative Design Respondent Has Failed To Overcome Its Burden Of Proof As Required By The Risk Utility Analysis.

Restatement (Third) states that a product is defective in design when the foreseeable risks could have been reduced or avoided by a reasonable alternative design, without which the product is rendered not reasonably safe. In contrast to manufacturing defects, design defects are predicated on a different concept of responsibility that requires risk-utility balancing. Respondent must show that the magnitude of danger from the product in question outweighs the costs of

avoiding that danger. *Arnold Webster v. Pacesetter, Inc.*, 259 F.Supp.2d 27, 31 (D.D.C. 2003). "The purpose of risk/utility analysis is to determine whether the risk of injury might have been reduced or avoided if the manufacturer had used a feasible alternative design." *McCarthy v. Olin Corp.,* 119 F.3d 148, 155 (2d Cir. 1997).

In order for a claim for design defect to be sustained, Respondent must present evidence of the existence of some alternative design that makes the product at issue unsafe. Essentially, Respondent is charged with the burden of proving whether the defect could have been designed away. This idea of alternative design provides a benchmark by which courts can measure the defectiveness of the product. For example, cases where plaintiffs sustained injuries from water vaporizers turned on whether the plaintiffs asserted a feasible alternative design. *See Blissenbach v. Yanko,* 107 N.E.2d 409 (Ohio Ct. App. 1951); *see also McCormack v. Hankscraft Co.,* 154 N.W.2d 488 (Minn. 1967). In *Blissenbach*, since the plaintiff offered no proof of an alternative design, their claim for defective design was dismissed. 107 N.E.2d at 411. Conversely, in *McCormack*, by offering specific proof of an alternative design, plaintiff was able to maintain a claim for defective design. 154 N.W.2d at 495.

Furthermore, the Sixth Circuit has stated, "[u]nder the Michigan risk-utility test…an expert who testifies that a product could have been designed differently, but who has never made or seen the alternative design he proposes, and therefore has no idea of its feasibility, utility, or cost, does not make out a *prima facie* case that a reasonable, practicable, and available alternative design was available." *Peck v. Bridgeport Machines, Inc.*, 237 F.3d 614, 618 (6th Cir. 2001). In *Peck,* an expert testified that there was an alternative design to a lathe, however he had never seen it used, nor did he know how expensive this alternative design would be to implement. *Id*. Absent this evidence the court found that there was no way to determine whether

the benefit of the alternative design outweighed the utility of the product. *Id*. Therefore, the plaintiff had not met its burden for bringing a design defect claim. *Id*.

Paralleling the reasoning in *Peck,* since there is no evidence in the Record that Respondent has asserted the existence of an alternative design, their design defect claim necessary fails. It is not enough for the lower courts to take judicial notice of the existence of IBM's system. Furthermore, taking into account that IBM's system is more difficult to use than Firefly's and that it requires additional training and has a higher operating cost, it becomes apparent that in urgent care situations, the benefit of having a system that is easy to use substantially outweighs the risk of inaccuracy. R. at 3. In the present case, neither lower courts, nor Respondent has suggested an alternative design. Failing to do so means that Respondent's claim must be dismissed.

It is necessary for Respondent to not only assert that a proposed alternative is feasible, but also that the alternative is safer. *Crespo v. Chrysler Corp.*, 75 F.Supp.2d 225, 228 (S.D.N.Y. 1999). New York State has recognized that "the requirement that the plaintiff prove that it is 'feasible to design the product in a safer manner,'…must mean safer to the relevant set of users overall, not just to plaintiff." *Id*. In *Crespo,* plaintiff asserted that there were at least three alternatives to the deployed airbag that killed a young child. *Id*. at 229. One of these alternatives included removing the airbag from the vehicle altogether. *Id*. Since the proposed alternative was not safer than the original design, and the plaintiff was never able to provide a reasonable estimate of the number of people beyond the deceased child whose lives would be saved, the court found that the design defect claim could not stand. *Id.* at 229, 231.

By this same token, it would arguably not be enough for Respondent to suggest that Firefly's services should be limited to only those hospitals that choose to partner with its service,

in place of allowing others to have access via the web portal. While this arrangement would have eliminated the possibility for error when Respondent's medical record was downloaded, it would cause innumerable injuries to other patients in similar situations by not allowing their treating doctors access to their medical records. Based on the New York analysis, Respondent has not presented a feasible alternative design that is safer.

Even if Respondent were to argue that IBM's system is an example of a feasible alternative design, their claim would continue to fail. It cannot be argued that IBM's design would have prevented Respondent's injury. In fact, both IBM and Firefly's systems have implemented protocol as a means of avoiding inaccuracies. R. at 3. IBM's system has a "final check flag system" which reviews information the operators input and warns of any potential errors or omissions in converting the patient's record from paper to digital format. *Id.* All Firefly employees are instructed to double check the data to ensure that the entries match the corresponding field on the paper record. *Id.* Just because Firefly's product lacks IBM's "final check flag system," does not mean it is unsafe. Arguably, no "final check flag system" could have prevented a faulty download at University Medical Center.

When the possibility of adding a "final check flag system" is analyzed under risk utility balancing, the risk of not providing a hospital with at least some form of a medical record is outweighed by the utility that Firefly's current system offers. Born out of one of Learned Hand's most famous opinions, a simple algebraic formula provides courts with a way of juxtaposing the risk and utility of a product in cases similar to the one at bar. Specifically, the formula is as follows: "if the probability be called P; the injury, L; and the burden, B; liability depends upon whether B is less than L multiplied by P: i.e., whether B [is] less than PL." *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947). Simply, the question posed by Hand was,

is a product's risk greater than its benefit or utility? *Id.* Today, this "risk utility" balancing is used in defective design cases as a way of providing courts with a method of measuring danger versus benefits. *Krummel v. Bombardier Corporation*, 206 F.3d 548, 551 (5th Cir. 2000).

Additionally, overly strict safety standards create a risk of imposing unnecessary financial burdens on manufacturers, whereas lax safety standards create financial as well as safety risks. *Bates v. Dow Agrosciences LLC,* 544 U.S. 431, 450 (2005). For a fair determination of liability, risk utility balancing must be done in light of the knowledge of risks and risk avoidance techniques reasonably adopted at the time of distribution. *Id.* The practicability of a manufacturer using such risk avoidance measures is gauged in terms of economic feasibility, overall design, and operation of the product. *See generally Glover v. BIC Corp.,* 6 F.3d 1318 (9th Cir. 1993).

Practically speaking, risk utility balancing is best illustrated by cases involving plaintiffs who were injured by airbags that were deployed during car accidents. In an example before the First Circuit, liability would only imposed if "the magnitude of the danger [of the airbag system] outweighed the usefulness and desirability of the product" to "the public as a whole." *Connelly v. Hyundai Motor Co.*, 351 F.3d 535, 541 (1st Cir. 2003). Ultimately, the court in *Connelly* found that "the benefit to the public of including the overly aggressive airbag system in the Sonata outweighed the danger caused by the airbag system (because the system saved many more lives than it took)*." Id. Connelly* stands for the proposition that although a product is not injury-proof, if the overall benefit of having the product exceeds the small risk that a few people might be injured, courts will not impose liability for a defective design. Applying the First Circuit's reasoning to the present action, the benefit of hospitals being able to utilize a digital version of any patient's medical records, rather than rely on nothing at all, outweighs the danger of a few

inaccurate medical records. As such, Respondent is unable to establish that there is any evidence to substantiate a design defect claim.

C. Under a Risk Utility Balancing Analysis, Respondent Has Failed To State a Claim For Inadequate Warning.

To establish a claim of warning defect, Respondent must show that the foreseeable risks of harm could have been avoided or reduced by reasonable instructions or warning, and that the omission of the warning renders the product not reasonably safe. Restatement (Third) Torts: Products Liability §2(c). To be adequate, a warning "must provide complete disclosure of the existence and extent of the risk involved. *Pavlides v. Galveston Yacht Basin*, *Inc.*, 727 F.2d 330 (5th Cir. 1984). A "warning must (1) be designed so it can reasonably be expected to catch the attention of the consumer; (2) be comprehensible and give fair indication of the specific risks involved with the product; and (3) be of an intensity justified by the magnitude of the risk." *Id.*

Manufacturers are under no duty to provide warnings about obvious dangers. *DG&G, Inc. v. FlexSol Packaging Corp. of Pompano Beach,* 576 F.3d 820, 824 (8th Cir.2009). If the user of a product knows or reasonably should know of a particular danger, strict liability will not result from failure to warn. *Id*. In *DG&G* the manufacturer of polyethylene bags used for bagging cotton was not strictly liable to a cotton gin operator for failing to warn that the bags were inappropriate for moisture-restored cotton. *Id.* The Eighth Circuit held that the operator knew or reasonably should have known of the specific danger of bagging cotton with excess moisture because the industry was well aware of the bags' shortcomings. *Id.* As applied to the present action, Firefly should likewise not be liable to Respondent because the obvious danger of human error in filling out a medical record reasonably should have been known by Respondent as well as by University Medical Center. Accordingly, Firefly warned both Dr. Frye and Respondent to verify the digital copy of the medical record prior to destroying the original paper copy. R. at 3.

Similarly, in a Seventh Circuit case a plaintiff sustained injuries after he climbed on a satellite dish attempting to clear it of snow. *Bilski v. Scientific Atlanta*, 964 F.2d 697, 698 (7th Cir. 1992). The court concluded that since the danger was obvious, "[t]he jury in this case could reasonably have concluded that the danger posed to [plaintiff] in climbing up on the satellite dish was 'common knowledge,' and that therefore [defendant] had no duty to warn him not to do it." *Id*; s*ee also Smith v. Hub Manufacturing, Inc.*, 634 F.Supp. 1505 (N.D.N.Y 1986) (holding that the danger of swimming pools is obvious thus rendering a warning to not leave children unattended redundant). *See also McMahon v. Bunn-O-Matic Corp.*, 60 F.3d 651 (7th Cir. 1998) (holding that everyone knows that hot coffee will burn if spilled on skin, so warning that it will cause third degree burns is not required). The First Circuit has held that a supplier has a duty to warn foreseeable users of dangers in the use of its product of which the supplier knows or should have known. However, according to the "sophisticated user" defense, there is no duty to warn an "end user" of a product's latent characteristics or dangers when the user knows or reasonably should know of those dangers. *Taylor v. American Chemistry Council*, 576 F.3d 16, 25 (1st Cir. 2009). Warning those who already appreciate a danger is superfluous and is unlikely to have a deterrent effect. *Id.*

Moreover, "state of the art" issues involve a manufacturer's ability to foresee a product danger, enabling the manufacturer to warn consumers of the danger. "State of the art" is defined as the best technology reasonably available at a given time. *Menne v. Celetox Corporation*, 861 F.2d 1453, 1472 (10th Cir. 1989). There is no evidence to show that Firefly did not act in conformity with the generally recognized and prevailing practices within the industry for the conversion of medical records to digital format. "Where scientific or medical evidence exists tending to show that a certain danger is associated with the use of a product, the manufacturer

may not ignore or discount that information in drafting its warning solely because it finds it to be unconvincing." *Id.* The Fifth Circuit found that a manufacturer was not liable for failure to warn of unforeseeable dangers when a plaintiff could offer no proof that a manufacturer knew or should have known that its asbestos-containing products were harmful. *Gideon v. Johns-Manville Sales Corp.,* 761 F.2d 1129, 1145 (5th Cir. 1985).

In the same vein, Firefly was not aware of any similar instances of incompatibility with respect to the downloading of medical records off of Firefly's server. The information was correct on their servers, therefore they had no reason to believe that it would not reach the retrieving hospital in the same condition. R. at 8. Firefly can not held liable for a hardware malfunction resulting from University Medical Center's computer system. It was unforeseeable that a medical record that both parties agree was correct on Firefly's server would suddenly contain error when downloaded. This type of danger is not only unforeseeable but also completely outside Firefly's control, that is to say, it was University Medical Center's own hardware that caused the defect in the medical record resulting in Respondent's injury.

It is indisputable that errors in electronic medical records are known risks when making the conversion from paper to digital format. Even paper medical records may contain mistakes that could lead to such a tragedy, as occurred in this case. When the purchaser of the product is recommended or prescribed by an intermediary who is a professional, the adequacy of the instructions must be judged in relation to that professional. *Arnold Webster,* 477 U.S. at 35. Firefly warns their customers to verify the electronic records, once returned, and before disposing of the original paper copies. R. at 3. Dr. Frye and Respondent had ample opportunity to review records to ensure accuracy of the digital medical record, per Firefly's warning. *Id.* Accordingly, had Dr. Frye and Respondent heeded Firefly's warning, both parties would have

been aware that the penicillin allergy was accurately noted on the original paper copy as well as the digital copy on Firefly's server. Since the inaccuracy only presented itself when it was downloaded off the server, any warning by Firefly would have been ineffective in preventing Respondent's death.

Furthermore, "but for" causation contemplates the benefit that an alternative warning system would have had on the injury that resulted. The lack of an alternative warning system informing the records transcriber that the allergy field was listed as "NONE" likely would not have changed the tragic result of this case. While an alternative warning system may decrease the likelihood that the allergy column was left in its default "NONE", under risk utility balancing the additional software installation, and validation costs that would have been incurred by Firefly outweigh the risks to the consumer. R. at 8. Both the Haven legislature and Congress have appropriated funds to encourage medical records cost saving through conversion to health information technology. *Id.* Legislatures have decided there is a need for a health care system which operates at lower costs, therefore it is a matter of public policy that reasonable measures to reduce health care costs should be encouraged. *Id*. Respondent has failed to allege a reasonable warning alternative; therefore, the pending warning defect claim should be dismissed.

D. Even If This Court Is to Find That Grace Law Applies, Respondent's Strict Liability Claim Would Still Be Dismissed.

Even if this Court chose to apply the substantive law of Grace, Firefly would continue to prevail, for the reason that the analysis of manufacturing defects under §402A of the Restatement (Second) of Torts, mirrors the analysis of manufacturing defects under the Restatement (Third). That is to say, Grace legislatures have adopted §402A of the Restatement (Second) of Torts in its entirety. R. at 10. Similarly to the Restatement (Third) of Torts: Products Liability §2(a), adherence to §402A allows a court to hold a manufacturer strictly liable for selling a defective

product even though the manufacturer exercised all possible care in the preparation and sale of the product. *See* Restatement (Second) of Torts §402A (1965). Therefore, the basis for bringing a manufacturing defect claim under Restatement (Third) of Torts: Products Liability §2(a) is grounded on the same premise that applies under Restatement (Second) §402A. *Reyes v. Wyeth Laboratories,* 498 F.2d 1264, 1272 (5th Cir. 1974). Where the Restatements differ as to products liability analysis is in the fact that the Restatement (Third) goes above and beyond a manufacturing defect and adds design and warning claims against the manufacturer. *Id.*

Given that Firefly prevails under the "higher standard" of Haven law, it necessarily follows that Firefly would prevail under the standard imposed by the State of Grace. Reiterating the analysis that took place under Restatement (Third) with respect to a manufacturing defect, Respondent fails to overcome the burden of showing that the defect in the product was the proximate cause of her injury, and that the product contained the defect at the time the product left Firefly's control.

III. RESPONDENT'S ADDITIONAL WARRANTY CLAIMS SHOULD BE DISMISSED.

A. Respondent's Independent Claim Based Upon Breach of Implied Warranty of Merchantability is Duplicative of Their Manufacturing Defect Claim and May Not Be Brought.

Liability for breach of implied warranty is generally based upon a product's inadequate condition or malfunction without regard to the seller's fault. *Garcia v. Edgewater Hosp*., 244 Ill.App.3d 894, 902 (Ill. App. Ct. 1993). Therefore, proof of the seller's negligence is not only unnecessary but also irrelevant. Just as strict liability in tort establishes that a product is not merchantable, so does the claim for breach of implied warranty of merchantability. Therefore, if one claim is brought the accompanying claim is moot. The heart of the warranty of merchantability is that a product is warranted to be "fit" for its "ordinary purposes." Uniform

Commercial Code §2-314(2). Under Restatement (Third), two or more factually identical design defect or warning defect claims may not be submitted to the trier of fact in the same case under different doctrinal labels. Restatement (Third) of Torts: Products Liability §2 cmt. n. These claims are based on the same risk utility analysis and would result in confusion or inconsistent verdicts. *Id.* This analysis further applies to manufacturing defects. Under Restatement (Third) a manufacturing defect claim and an implied warranty of merchantability claim rest on the same factual predicate.

In *Depositors Ins. Co. v. Wal-Mart Stores, Inc.* 506 F.3d 1092, 1095 (8th Cir. 2007) the plaintiffs were unable to establish a manufacturing defect in extension cords or lamp cords. Without this proof, their claim for breach of implied warranty of merchantability failed because essentially the warranty claim rested on whether a manufacturing defect existed. *Id*. By the same token, since Respondent has failed to present evidence that there was a manufacturing defect in Firefly's system, their claim for breach of implied warranty of merchantability is duplicative and may not be brought. Restatement (Third) of Torts: Products Liability §2 cmt. n.

B. Respondent Fails to State a Claim Based on Express Warranty.

Express warranties are affirmative assertions, made by the seller in connection with a sales transaction, that a product possesses certain characteristics of quality, construction, performance capability, durability, or safety. Uniform Commercial Code §2-313. This form of warranty stems from seller's words or other forms of communication rather than from any inherent characteristic of the product itself. Under the Uniform Commercial Code §2-313, express warranties may be created by an affirmation of fact or promise relating to goods, any description of the goods which is made part of the basis of the bargain, or by any sample which is made part of the bargain.

In *Seitz v. Brewers' Refrigerating Mach. Co.*, 141 U.S. 510, 519 (1891) this Court held that there was no express warranty that the refrigerator in question would "…cool 150,000 cubic feet of atmosphere to 40° Fahrenheit." This Court stated

> [t]his is not the case of an alleged defect in the process of manufacture known to the vendor, but not to the purchaser…but of a purchase of a specific article, manufactured for a particular use, and fit, proper, and efficacious for that use, but in respect to the operation of which, in producing a desired result under particular circumstances, the buyer found himself disappointed.

Id. Similarly, Respondent's express warranty claim fails due to the fact that she was not promised anything, nor did Firefly represent anything to her. It was Dr. Frye, and not Firefly, who informed Respondent about converting her medical records to an electronic format. R. at 9. As a result, the express warranty claim should be dismissed.

CONCLUSION

For the aforementioned reasons, Firefly respectfully requests that this Court affirm the United States District Court for the District of Haven's grant of Firefly's Motion to Dismiss. Specifically, that the substantive law of Haven applies, resulting in a reversal of the United States Court of Appeals for the Thirteenth Circuit's decision with respect to strict products liability and implied warranty of merchantability claims, and affirm with respect to the dismissal of the express warranty claim.

Respectfully submitted,

Team 11