IN THE

# Supreme Court of the United States

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FIREFLY SYSTEMS, INC.,

Petitioner,

v.

*IN RE* ESTATE OF ZOE WASHBURNE,

Respondent.

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ON WRIT OF CERTIORARI TO THE

UNITED STATES COURT OF APPEALS FOR THE THIRTEENTH CIRCUIT

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**BRIEF FOR RESPONDENT**

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Counsel for Respondent

Team 2

## QUESTIONS PRESENTED

**I. Whether the State of Grace has the most significant relationship to this products liability litigation, such that the conflict-of-laws issue should be resolved by applying Grace substantive law.**

**II. Whether Respondent has stated a claim for strict products liability upon which relief can be granted.**

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## STANDARD OF REVIEW

Determining which state's substantive law applies to resolve a conflict-of-laws issue is a question of law reviewed *de novo*. *F.W.F., Inc. v. Detroit Diesel Corp.*, 308 F. App'x 389, 390 (11th Cir. 2009); *see also Beard v. J.I. Case Co*., 823 F.2d 1095, 1097 (7th Cir. 1987).

Whether or not Respondents have stated a claim upon which relief can be granted is a question of law reviewed *de novo*. *Reger Dev. LLC v. Nat'l City Bank*, 592 F.3d 759, 763 (7th Cir.), *cert. denied*, 130 S. Ct. 3507 (2010).

## STATEMENT OF THE CASE

Prior to her death, Zoe Washburne ("Ms. Washburne"), was a middle school teacher at River Middle School, located in Grace. (R. at 1.)[1] Ms. Washburne's parents, who also live in Grace, discovered when she was a child that she was allergic to penicillin. (R. at 1, 3.) In late 2008, Ms. Washburne's primary care physician, Dr. Kaylee Frye ("Dr. Frye"), sent her a letter advising that Dr. Frye's practice was converting to an electronic medical records system. (R. at 1.) The letter indicated that although there were several companies offering these services, Dr. Frye's practice would use a system designed, marketed, and sold by Firefly Systems, Inc. ("Firefly"), a Delaware corporation with its principal place of business in Haven. (R. at 1.) Dr. Frye's letter stated that Ms. Washburne could pay a twenty-five dollar fee to receive a USB flash drive containing a copy of the new electronic medical record created by Firefly. (R. at 1.)

Ms. Washburne subsequently wrote a personal check for twenty-five dollars, payable directly to Firefly. (R. at 1-2.) It was at that point that Dr. Frye sent a paper copy of Ms. Washburne's medical record to Firefly so Firefly could use the information to create a new electronic medical record. (R. at 2.)

[1] All facts discussed are from the official record on appeal, and cited as "(R. at [page].)" Since the pages of the record on appeal are not numbered, for purposes of this brief, the first page of the district court opinion is page one.

After Firefly created the electronic medical record, Firefly shipped the software to Dr. Frye, and shipped a USB drive containing the electronic medical record to Ms. Washburne. (R. at 2.) Ms. Washburne received the USB drive, but never had the opportunity to review the contents and at some point misplaced the USB drive. (R. at 2.)

Firefly's software is mass-produced, and the company does not offer customization or tailoring of the program to different medical providers. (R. at 1.) Instead, Firefly opted to advertise aggressively with hospitals nationwide. (R. at 2.) Firefly's business involved Firefly employees transferring medical information from paper records to the new electronic record created by Firefly. (R. at 2.) This included all aspects of a patient's medical history: personal and family past medical histories, charts, notes, and records of past and present procedures. (R. at 2.) The electronic medical record would then be stored securely on Firefly's servers. (R. at 2.) The computers of hospital systems participating in Firefly's network were integrated directly with Firefly's servers. (R. at 2.) Non-participating hospitals and providers could access a copy of the electronic medical record through a secure web portal operated by Firefly. (R. at 2.)

On Wednesday, September 10, 2008, Ms. Washburne traveled into Haven as a chaperone on a field trip sponsored by her school. (R. at 2.) While there, she began to experience severe abdominal pain and nausea and was transported to University Medical Center, a local hospital. (R. at 2.) By the time Ms. Washburne arrived at the hospital, she was unconscious and nonresponsive. (R. at 2.) Using Ms. Washburne's driver's license, the staff at the hospital was able to obtain Ms. Washburne's electronic medical records from Firefly through its web portal. (R. at 2.) However, the electronic medical record retrieved by the hospital from Firefly's web portal was missing any reference to Ms. Washburne's allergy to penicillin. (R. at 3.) In fact, that record contained nothing in the "Known Allergies" field. (R. at 3.) Firefly's software is designed to place the word "NONE" in the "Known Allergies" field if

Firefly's data entry clerk enters no allergies for a patient. (R. at 3.) It is unclear why the "Known Allergies" field in the electronic medical record obtained from Firefly's secure web portal was blank. (R. at 3.) However, both the paper record provided to Firefly from Dr. Frye and the copy of the record stored locally on Firefly's servers contained the allergy. (R. at 3.)

The staff at the emergency room determined Ms. Washburne had appendicitis. (R. at 2.) The surgeon on call, Dr. Simon Tam ("Dr. Tam"), arrived sometime thereafter, verified the staff's diagnosis of appendicitis, and determined that Ms. Washburne's appendix had to be removed immediately in surgery. (R. at 2.) After surgery, as is common practice, Dr. Tam administered penicillin to avoid post-surgical infections. (R. at 3.) About five minutes after the penicillin was administered, Ms. Washburne experienced respiratory problems consistent with a penicillin allergy. (R. at 3.) The staff administered epinephrine, which alleviated Ms. Washburne's respiratory problems. (R. at 3.) The staff realized at this point that Ms. Washburne was allergic to penicillin, but no other problems arose during her hospitalization. (R. at 3.)

Ms. Washburne recovered quickly and the hospital discharged her on Friday, September 12. (R. at 3.) Ms. Washburne met her parents and began to ride back with them to their home in Grace. (R. at 3.) Some time after crossing into Grace, Ms. Washburne collapsed, and despite attempts by her parents to revive her, emergency medical services personnel pronounced her dead upon their arrival at the scene. (R. at 3.) It was determined later that the second reaction, resulting in Ms. Washburne's death, was due to biphasic anaphylaxis, a relatively rare secondary reaction linked directly to the original allergic reaction Ms. Washburne experienced in the hospital. (R. at 3.) Biphasic anaphylaxis can occur up to 72 hours after the original allergic reaction, even though the person had no further exposure to the allergen. (R. at 3.)

The only safety precautions regarding Firefly's software involved two instructions. (R. at 2.) The first was merely an admonition to Firefly employees to ensure the information they put in the electronic record matches that of the paper record. (R. at 2.) The second instruction was to new customers directing them to check the electronic records before they destroy the paper copies. (R. at 2.) In contrast, Firefly's largest competitor, IBM, which was the first to sell an electronic medical records system, includes a built-in "flag" system. (R. at 2.) Although the IBM system costs about ten percent more than Firefly's, IBM's system includes a so-called "final check flag system." (R. at 2.) Though the system requires some additional training of data entry clerks, it automatically reviews the data entry clerks' input and warns the clerks of potential problem areas—including omissions or errors—in converting the paper record to an electronic record. (R. at 2.) These "flags" are color-coded to correspond, apparently, to the seriousness of the result of the potential error. (R. at 2.) For example, a yellow flag appears for omissions or errors which do not affect a patient's safety, such as eye and hair color. (R. at 2.) However, a red flag is used to denote an error which could be serious, like allergies and family histories. (R. at 2.) If a red flag appears, the data entry clerk cannot continue with the creation of the electronic record before confirming the information in the flagged field was entered correctly. (R. at 2.) Firefly's system had no such safety mechanism to catch potentially life-threatening omissions. (R. at 2.)

## SUMMARY OF THE ARGUMENT

District courts, sitting in diversity, apply the conflict-of-laws rules of the state in which they sit. Haven courts have adopted the approach of the Restatement (Second) of Conflict of Laws (1971), which provides that the court will apply the law of the state with the most significant relationship to the issue before the court. The most significant relationship is determined by looking to the principles in the Restatement, considered in light of the relevant contacts each interested state has with the litigation. In

this case, Grace has the most qualitative contacts with the parties regarding these products liability issues, and consideration of the relevant principles weighs heavily in favor of applying Grace law. Accordingly, Grace has the most significant relationship to the issues and Grace substantive law should be applied in this case.

A complaint need only include a short, plain statement of the claim that entitles the pleader to relief. If a plaintiff fails to make such a statement, a court is permitted to dismiss the case upon a defendant's motion. When ruling on such a motion, however, courts must accept all the factual allegations in a complaint as true, and the facts are viewed in the light most favorable to the plaintiff. Respondent has established that the product differed from its intended design and was thus unreasonably dangerous; that there was a reasonable alternative design and that consumers would expect the product to be more safely designed; and that the failure to provide additional warnings rendered the product unreasonably safe and such additional warnings would have reduced or avoided the harm. Given the liberal pleading standard, and the requirement to accept all facts alleged as true, Respondent has stated valid claims under both Grace and Haven substantive law.

## ARGUMENT

### I. GRACE SUBSTANTIVE LAW CONTROLS BECAUSE GRACE HAS THE MOST SIGNIFICANT RELATIONSHIP TO THE CASE.

Federal courts hearing diversity cases apply the conflict-of-laws rules of the state in which they sit to determine which state's substantive laws to apply to a case. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 495-96 (1941). Haven courts have adopted the approach of the Restatement (Second) of Conflict of Laws (1971), which provides that the court will apply the law of the state with the most significant relationship to the issue before the court. *Booker v. InGen, Inc.*, 241 Haven 17, 26 (2007). The most significant relationship is determined by looking to the principles in the Restatement, considered in light of the relevant contacts each interested state has with the litigation. Restatement

(Second) of Conflict of Laws §§ 6, 145(2) (1971). Since Grace has the most qualitative contacts with this case, and consideration of the principles weighs heavily in favor of applying Grace law, Grace substantive law should apply.

**A. Grace has the most qualitative contacts with the case.**

To determine which state has the most significant relationship to the incident, the court looks to certain contacts between the parties and the forum state, and the parties and other interested states. Restatement (Second) of Conflict of Laws § 145(2) (1971). In addition, "it is the significance, not the number, of § 145(2) contacts that governs the choice of law inquiry." *Rosenthal v. Ford Motor Co*., 462 F. Supp. 2d 296, 303 (D. Conn. 2006). The contacts to be considered are: (1) the place where the injury occurred; (2) the place where the conduct causing the injury occurred; (3) the domicile/residence and place of business of the parties; and (4) the place where the relationship between the parties is centered. *Id.*; Restatement (Second) of Conflict of Laws § 145(2) (1971).

**1. The place of injury should be accorded no weight in the analysis.**

When a state abandons the doctrine of *lex loci delicti* and adopts instead the "most significant relationship" test of the Restatement (Second) of Conflict of Laws, a proper conflict-of-laws determination should rest on sections six and 145, unless that state expressly adopts the presumption set out in section 146. Application of section 146 without a state's express adoption of that section would, in effect, resurrect the previously abandoned doctrine of *lex loci delicti*. Furthermore, where the place of injury is fortuitous, a court should give the place of injury no weight in its conflict-of-laws analysis.

**a. Where a state abandons *lex loci delicti* in favor of the most substantial relationship test and does not expressly adopt the section 146 presumption, the place of injury should not receive foundational importance.**

The place of injury should be only one factor to consider in the conflict-of-laws analysis because Haven abandoned the doctrine of *lex loci delicti*. When a state abandons *lex loci delicti*, which provides

that the law of the state of injury controls, and adopts the most substantial relationship test set out in the Restatement (Second), but does not expressly adopt the place-of-injury presumption under section 146, a court applying that state's conflict-of-laws rules should rest its analysis solely on the most substantial relationship. *Jones v. Winnebago Indus.*, *Inc*., 460 F. Supp. 2d 953, 966-67 (N.D. Iowa 2006); *see also Linden v. CNH Am. LLC*, No. 3:09-cv-00019-JEG, 2010 WL 4840435, at *3 (S.D. Iowa Jan. 26, 2010) (place of injury not heavily weighted in contacts analysis since Iowa abandoned *lex loci delicti* rule for conflict-of-laws factors analysis). This was precisely the analysis and conclusion reached in *Jones*, where the district court concluded that since the Iowa Supreme Court had expressly rejected *lex loci delicti*, had not expressly adopted section 146, and had formulated the test as the most significant relationship as determined under sections six and 145, the place-of-injury "presumption" would not be applied. *Jones*, 460 F. Supp. 2d. at 966-67; *cf. In re Derailment Cases*, 416 F.3d 787, 794-95 (8th Cir. 1995) (noting Nebraska expressly adopted 146 to determine which law to apply to personal injury claim). Moreover, though the place where the injury occurred is a factor in determining which state's substantive law to follow, "it does not warrant undue weight in product liability cases." *Rowe v. Hoffman-La Roche Inc*., 892 A.2d 694, 703 (N.J. Super. Ct. App. Div. 2006), *rev'd on other grounds*, 917 A.2d 767 (N.J. 2007).

*Jones* is directly applicable in this case. Here, the district court erred in determining the analysis begins with a presumption that the substantive law to be applied is that of the state of injury. (R. at 6.) Though the court mentioned that presumption as falling under "well-settled Haven law," no authority in the record or otherwise supports such an assertion. (R. at 6.) To the contrary, the only authority in the record regarding Haven conflict-of-laws rules is *Booker v. InGen, Inc.*, 241 Haven 17 (2007), which adopted the most significant relationship test. (R. at 6.) Given that Haven abandoned *lex loci delicti* in favor of the most significant relationship test, it follows that an application of either section 146 or

section 175 to create such a presumption would run contrary to the intent of the Supreme Court of Haven in adopting the most significant relationship test. Accordingly, the place of injury should be only a potential factor in the choice-of-laws analysis rather than the presumptively controlling determination.

**b. Where the place of injury is fortuitous, it should not be given any weight in the conflict-of-laws analysis.**

Ms. Washburne's injury in Haven was fortuitous, and should not be given any weight in the contacts analysis. The place of injury is fortuitous when it could occur anywhere. *See Rowe*, 892 A.2d at 703. "Where a product causes injury to a victim while that victim is traveling in a jurisdiction away from his state of residence, the locus of injury in that particular state might be said to be fortuitous." *Elvig v. Nintendo of Am., Inc*., 696 F. Supp. 2d 1207, 1211 (D. Colo. 2010); *accord Hitchcock v. United States*, 665 F.2d 354, 361 (D.C. Cir. 1981); *Baroldy v. Ortho Pharm. Corp.*, 760 P.2d 574, 578-79 (Ariz. Ct. App. 1988); *Rowe*, 892 A.2d at 703; *see also* Restatement (Second) of Conflict of Laws § 145 cmt. e (1971) ("[T]he place of injury will not play an important role . . . when the place of injury can be said to be fortuitous . . . ."). Finally, in evaluating the importance of contacts for products liability claims, "the place of injury is much less important than the place where the conduct that caused the injury occurred." *Linden*, 2010 WL 4840435, at *3 (citing Restatement (Second) of Conflict of Laws § 145 cmt. e (1971)).

In the cases above, the injuries were held to be fortuitous since they could have occurred anywhere, and only occurred in those particular places because the plaintiff was a diplomat injured while en route back to Washington, *Hitchcock*, 665 F.2d at 361, traveling with her husband on temporary military assignment, *Baroldy*, 760 P.2d at 578-79, or had purchased a mobile product which had been sold nationally, *Rowe*, 892 A.2d at 703.

Similarly, the injury here could have occurred anywhere because it involved a mobile product accessible from and at any location. Ms. Washburne's injury in Haven is completely fortuitous because

her appendicitis could have manifested itself in Grace before the field trip, after the field trip, or in some other jurisdiction later. Thus, the place of injury should not be given weight in the determination of which state's substantive law to apply, and this Court should not consider the place of injury as favoring the application of Haven law.

**2. The conduct causing the injury occurred in Grace when the product was advertised in, marketed in, sold in, and shipped into Grace.**

Since the product was advertised, marketed, sold, and sent to Grace, and applying the law of the state of manufacture is unfair, the conduct causing the injury occurred in Grace. In a products liability case, the place where the conduct causing the injury occurred is often not the place where corporate decisions were made, but instead is where the product was marketed and sold. *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 458 (E.D. La. 2006). The court in *In re Vioxx* held that, although all corporate decisions were made in the defendant's state, the conduct causing injury occurred in the plaintiff's state because the product was advertised in, marketed in, shipped into, and sold in the plaintiff's state. *Id.* Additionally, "applying the law of the place of manufacture would be unfair because it would tend to leave victims under compensated as states wishing to attract and hold manufacturing companies would raise the threshold of liability and reduce compensation [to victims]." *Phillips v. Gen. Motors Corp.*, 995 P.2d 1002, 1012 (Mont. 2000).

Here, the fact that Firefly's corporate decisions occurred in Haven is not dispositive in determining where the conduct causing the injury occurred. The facts of *In re Vioxx* are indistinguishable from the instant case on this point, since the electronic medical record at issue in this case was advertised in, marketed in, shipped into, and sold in Grace. Also, as in *Phillips*, applying Haven law would protect a corporation operated in Haven by raising the threshold of liability and potentially reducing compensation to the victim. Thus, the conduct causing the injury in this case occurred in Grace.

### 3. The relationship between the parties is centered in Grace because Firefly marketed and sold its product in Grace.

The relationship between the parties is centered in Grace because the product's marketing and sale was in Grace. Where a manufacturer of a mass-produced product affirmatively markets and sells the product in a state, through an intermediary in that state, the relationship between the parties is centered in that state. The relationship between the parties is a contact courts consider in conflict-of-laws analyses. Restatement (Second) of Conflict of Laws § 145(2) (1971). In products liability cases, the relationship between the parties is determined by looking to the state in which the plaintiff was referred to the product, purchased the product, and used the product. *In re Vioxx*, 239 F.R.D. at 458. Moreover, while plaintiffs probably do not know the state(s) in which a corporation is incorporated or has its principal place of business, the corporation "consciously [chose] to advertise and market [the product] throughout the United States," leading to the sale of its product in Grace. *Id.*; *see also Rosenthal*, 462 F. Supp. 2d at 303.

In this case, the district court limited the scope of the relationship to the particular issue. (R. at 6.) The district court was not clear about which particular issue it was addressing, but that fact is irrelevant because the particular issue deals with the significance of each factor, not how each factor is determined. Restatement (Second) of Conflict of Laws § 145(2) (1971); *see also id.* cmt. b. A correct application of this factor shows the relationship between Firefly and Ms. Washburne is centered in Grace, the state where Ms. Washburne resided. In *In re Vioxx*, the court concluded that the relationship between a manufacturer and the plaintiffs was centered in each plaintiff's state because the drug manufacturer consciously marketed the products in each plaintiff's state, and because the drug was prescribed, sold, and consumed in each plaintiff's state. Similarly to *In re Vioxx*, Washburne was referred to Firefly's product in Grace through her doctor's office in Grace, purchased the product in Grace, and used the product in Grace. Additionally, Firefly consciously chose to market its product to

both Ms. Washburne and Dr. Frye in Grace. Thus, the relationship between the parties is centered in Grace.

**4. Ms. Washburne's residence in Grace outweighs Firefly's principal place of business in Haven because the aggregation of contacts is in Grace.**

Since Ms. Washburne's residence in Grace is grouped with other contacts in Grace, this factor weighs in favor of applying Grace law. When the manufacturer of a defective product has its principal place of business in one state, and the victim of the defective product resides in another state but has other section 145 contacts with that state, the substantive law of the victim's state of residence should be applied. As part of the contacts analysis, courts consider the domicile/residence and place of business of the parties. Restatement (Second) of Conflict of Laws § 145(2) (1971). However, where the parties are not grouped in the same state, this factor in and of itself is not heavily weighed. *Jones*, 460 F. Supp. 2d at 970-71. Instead, it should only favor one party when the location of that party is grouped with other contacts under the Restatement. *Id.*

In *Jones*, the plaintiff's residence in Idaho was grouped only with the place of injury, which was fortuitous. *Id.* at 971. In contrast, the defendant's place of business in Iowa was grouped with the location of the conduct causing injury. *Id.* The court in *Jones* concluded this factor weighed in favor of applying Iowa law because the defendant's place of business was grouped with other contacts in that state. *Id.*

In this case, Ms. Washburne was domiciled in Grace and Firefly's principal place of business is in Haven. (R. at 1, 6.) At first blush, it appears this factor favors neither party. However, as in *Jones*, a more careful look at the location of the parties in light of the other contacts suggests this factor should be weighed in favor of applying Grace law. Though Firefly's principal place of business is in Haven, Ms. Washburne's residence in Grace is grouped with Grace being the center of the relationship and the place where the conduct causing the injury occurred. Conversely, Firefly's principal place of business in

Haven is grouped solely with the fortuitous place of injury. Thus, this factor militates in favor of applying Grace law.

Since the relationship between the parties is centered in Grace, the conduct that caused the injury occurred in Grace, and the residence and place of business of the parties favors application of Grace law, an analysis of the contacts supports application of Grace substantive law.

**B. The application of the principles relevant to tort law weighs heavily in favor of applying Grace substantive law.**

Once a court has analyzed the contacts between the parties, it then turns to the policy considerations underlying the conflict-of-laws determination, which should be considered in the light of the contacts discussed above. Restatement (Second) of Conflict of Laws § 145(1) (1971); *id.* § 6(2). In a tort action, the factors of relatively greater importance are: (1) the relevant policies of the forum state; (2) the relevant policies of other interested states; (3) the ease of determination and application of the law to be applied; and (4) the needs of the interstate and international system. Restatement (Second) of Conflict of Laws § 145 cmt. b (1971). The remaining factors are of "relative insignificance" in a tort claim, but include: (5) the protection of justified expectations; (6) basic policies underlying the particular field of law; and (7) certainty, predictability, and uniformity of result. *Id.* In this case, the application of the factors relevant to this tort action weighs heavily in favor of applying Grace law. *Id.*

**1. Haven law should not apply because it protects manufacturers of defective products from tort liability by raising the threshold, shifting the risk of injury onto the consumer instead of placing the burden of consumer protection properly on the manufacturer.**

Haven's policies are contrary to the goals of the tort system and Haven substantive law should not be applied. Where a state's policies run counter to the policies underlying the field of law in the case, that state's policies weigh against application of that state's substantive law. "If . . . the defendant would enjoy a special immunity for his conduct under the local law of the state of injury (the forum state

here), it is not clear that the interests of this state would be furthered by application of its rule." Restatement (Second) of Conflict of Laws § 146 cmt. e (1971). This is because, in a products liability action, the purpose of a state's tort law is to deter the manufacture and sale of defective items. *Muncie Power Prods., Inc. v. United Tech. Auto., Inc.*, 328 F.3d 870, 878 (6th Cir. 2003). Even if the defendant does not enjoy a "special immunity" *per se*, an increased threshold of liability weighs against application of that state's substantive law. *Rosenthal v. Ford Motor Co.*, 462 F. Supp. 2d 296, 305 (D. Conn. 2006).

Firefly argues that both the federal government and Haven have public policies that favor digitizing and modernizing patient medical records, and have allocated funds to further that public policy. According to Firefly's argument, this strong public policy weighs in favor of applying Haven law because Haven has expended funds in support of that public policy. This public policy is laudable; however, application of Haven law, which raises the threshold of liability, would not further that public policy because it impliedly supports manufacturers who erroneously digitize records and expose patients to great danger. Rather, application of Grace law best supports this public policy because it encourages manufacturers to build safe and accurate electronic medical records.

Additionally, even though Haven's adoption of the Restatement (Third) of Torts does not create a so-called special immunity under the Restatement, "it does theoretically serve as an immunity by protecting defendants against [some] product liability claims based on strict liability." *Id.* Because it shifts the burden onto consumers rather than manufacturers, this treatment of defendants encourages manufacturers to institute less stringent quality control and thereby place defective products into the stream of commerce. Thus, because the policy of Haven is to protect defendants by raising the threshold of liability, this factor weighs against the application of Haven substantive law in this products liability litigation.

**2. Grace law should apply because it demonstrates a strong policy of protecting consumers from defective products and compensating victims for injuries sustained from defective products.**

Grace substantive law should apply because the policies of Grace hold manufacturers strictly liable for defective products. In a products liability case, where the goal is compensation and deterrence, the state laws that hold manufacturers strictly liable should be favored. Products liability cases are designed to compensate victims, deter wrongful conduct, encourage prompt warnings to consumers about defects, and make the responsible parties bear the cost of injury. *Phillips v. Gen. Motors Corp.*, 995 P.2d 1002, 1012 (Mont. 2000). Additionally, public policy favors making manufacturers of defective products responsible for the injuries they cause. *See Rosenthal*, 462 F. Supp. 2d at 305-06; *see also* Aaron Arnold, Note, *Rethinking Design Defect Law: Should Arizona Adopt the Restatement (Third) of Torts: Products Liability?* 45 Ariz. L. Rev. 173, 194 (2003). Where a state has a strong public policy protecting a certain group, that public policy weighs even more in favor of applying that state's substantive law. *See Rousselle v. Plaquemines Parish Sch. Bd.*, 633 So. 2d 1235, 1244 (La. 1994).

Applying Grace law ensures that costs to Grace residents due to injuries sustained from product defects "are fully borne by the responsible parties[,]" and will also deter future sales of defective products in Grace while encouraging manufacturers "to warn [Grace] residents about defects in their products as quickly and as thoroughly as possible." *Phillips*, 995 P.2d at 1012. One of the central purposes of Grace's product liability scheme is to prevent injuries to Grace residents caused by defective products. In contrast to Haven, Grace has a direct interest in the application of its product liability laws because Ms. Washburne, a Grace resident, was injured. Though it is arguable that Haven has an interest in deterring wrongful conduct of its corporations, Haven's substantive law belies that interest by raising the threshold of liability in its adoption of the Restatement (Third); in any event, Grace's interest is much more direct since the interest is to vindicate the injury of its own citizen.

In addition to Grace's direct interest in protecting its citizens from defective products, "public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them . . . ." Arnold, 45 Ariz. L. Rev. at 194 (quoting Restatement (Second) in arguing that Restatement (Third) should not be adopted because it departs from this policy). This reasoning is consistent with *Rosenthal*, where the court held that Connecticut's adoption of strict liability served a clear purpose of holding manufacturers accountable for defective products, and North Carolina's failure to adopt strict liability did not serve that purpose. *See Rosenthal*, 462 F. Supp. 2d at 305-06. Similarly, Grace's adoption of strict liability demonstrates a strong policy of holding manufacturers accountable for defective products, while Haven's higher threshold for liability does not.

Finally, Ms. Washburne was injured by a defective product while she was acting within the scope of her duties as a middle school teacher on a field trip from Grace. Grace's interest in protecting the interests of its school teachers engaged in their official duties at the time of injury—and through them ensuring the protection of the students—weighs very heavily toward applying Grace law. *See Rousselle*, 633 So. 2d at 1244 (strong public policy of protecting teachers sufficient state interest to justify impairing contractual obligations). Accordingly, Grace policies weigh heavily in favor of applying Grace law.

**3. Grace substantive law should control because its ease in application streamlines judicial administration and reduces the confusion of juries.**

Because Grace substantive law is all strict liability, it is easier to apply and should control. Where one state's substantive law has two standards for products liability, and another state's substantive law has only one standard, the law with one standard should apply. Generally, this factor is not especially relevant in tort litigation because the defendant is either liable or not liable, and because the substantive law is usually not particularly complex. *Jones v. Winnebago Indus., Inc.*, 460 F. Supp.

2d 953, 974 (N.D. Iowa 2006). However, where a court is faced with substantive laws that can be difficult to apply, this factor weighs in favor of the law that is easier to apply. *See id.*

Unlike the simple cap on damages or contributory negligence issue in *Jones*, application of Haven substantive law would require the judge and jury to navigate two different legal standards of liability in at least three discrete causes of action—manufacturing, design, and warning defects. *Cf. Jones*, 460 F. Supp. 2d at 974. But by applying Grace law, the court only has to apply one, simple standard. Application of Grace law is favored here because the liability standards in the Restatement (Second) of Torts are all the same—strict liability—and the Restatement (Third) has both a strict liability standard (for manufacturing defects) and a negligence standard (for design/warning defects), which would be more difficult for both a judge and jury to apply. Accordingly, this factor, to the extent it is relevant, favors applying Grace law.

**4. The needs of the interstate system do not weigh in favor of the application of either state's substantive law.**

This factor does not weigh in favor of applying either state's substantive law. Application of the Restatement (Second) as a whole properly balances the needs of the interstate and international system. This factor is designed to promote interstate harmony and commerce. Restatement (Second) of Conflict of Laws § 6 cmt. d (1971). However, this factor deals not with which state's substantive law to apply, but rather which state's conflict-of-laws rules further the needs of the interstate system. *Id.*; *Jones*, 460 F. Supp. 2d 953 at 972-73; *Phillips*, 995 P.2d at 1009.

In this case, Haven's conflict-of-laws rules follow the Restatement's approach by looking to the state with the most significant relationship. Accordingly, this factor does not weigh in favor of applying either state's law in this case.

**5. The protection of justified expectations carries little weight, but still favors applying Grace substantive law because parties should expect the law of the state of sale to control.**

Grace substantive law should control because parties should expect the law of the state of sale to control. When a manufacturer consciously markets and sells a product in a particular state, the law of the state of sale should control a products liability action because both the manufacturer and customer should expect that law to control. This factor often carries little weight in tort litigation because the parties may have acted without considering what law may apply, unlike in contracts cases where parties often contemplate litigation in a particular place. Restatement (Second) of Conflict of Laws § 6 cmt. g (1971). However, "because the central event upon which a products liability claim is normally based is the sale of the goods, injured parties would expect that the law of the place of sale should govern with respect to injuries caused by those defects." *Rosenthal*, 462 F. Supp. 2d at 305 (citation omitted). Sellers of defective products also should expect to be haled into court in the state where the plaintiff bought the product, especially where the seller "consciously [chose] to advertise and market" the product in that state. *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 458 (E.D. La. 2006).

In this case, Ms. Washburne bought the USB drive in Grace, and Dr. Frye ordered the records digitized in Grace. (R. at 1-2.) Ms. Washburne and Respondent would thus expect Grace law to govern. *See Rosenthal*, 462 F. Supp. 2d at 305. Additionally, Firefly should expect to be haled into court in Grace since it consciously chose to market and sell its product there. *See In re Vioxx*, 239 F.R.D. at 458. Thus, to the extent it is applicable, this factor weighs in favor of applying Grace law because the product was sold in Grace.

**6. The basic policies underlying tort law, and the certainty, predictability, and uniformity of results do not favor either state's substantive law.**

In a products liability case such as this one, the basic policies underlying the field of tort law do not weigh for or against application of either state's law. *See Jones*, 460 F. Supp. 2d at 975. Similarly,

certainty, predictability, and uniformity of result are "not necessarily realistic concerns in a case involving a 'mobile' product, . . . because '[c]onflicting laws are a result of the combination of a mobile society and America's federal system . . . .'" *Id.* (citation omitted). This case, like *Jones*, is a products liability case and involves a product that is mobile. Accordingly, these factors do not weigh in favor of applying either state's substantive law.

Considering all of the factors and contacts, Grace law should apply. The policies of Haven protect manufacturers and fail to adequately compensate victims or further the public policy behind accurate electronic medical records. Conversely, the policies of Grace fully compensate victims, hold manufacturers strictly liable, and ensure electronic medical records are accurate. Additionally, Grace law is easier to apply since it has only one standard of liability where Haven law has two standards. Moreover, Grace law should apply because the parties should expect the law of the state of sale to control. Finally, the needs of the interstate system, policies underlying tort law, and certainty and predictability do not weigh against application of Grace law. Since all of the relevant contacts favor application of Grace law, and the factors weigh in favor of applying Grace law, Grace substantive law should apply.

## II. RESPONDENT HAS ALLEGED SUFFICIENT FACTS TO STATE A CLAIM FOR STRICT PRODUCTS LIABILITY UPON WHICH RELIEF CAN BE GRANTED.

A complaint need only include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). This statement, however, must include facts which establish a cause of action rather than just "labels and conclusions[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Twombly*, 550 U.S. at 570). A motion to dismiss pursuant to Rule

12(b)(6) provides for dismissal for a complaint's "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6).

However, when ruling on a motion to dismiss, courts must accept all the factual allegations in a complaint as true. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). Furthermore, the facts alleged are viewed in the light most favorable to the plaintiff. *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). Additionally, the rules of civil procedure promulgate and encourage liberal pleading standards. Civil Form 11 in the appendix provides that a negligence claim can be asserted simply by alleging that "the defendant negligently drove a motor vehicle against the plaintiff." Fed. R. Civ. P. app. at Civil Form 11. Federal Rule of Civil Procedure 84 states plainly that the forms in the appendix "suffice under these rules[.]"

Though this Court, in *Iqbal* and *Twombly*, required something more than "code pleading," in this case sufficient facts are alleged to survive a motion to dismiss. Given the generally liberal pleading standard, the nature of the causes of action at issue, and the requirement to accept all facts alleged as true, Respondent has stated valid claims for manufacturing, design, and warning defects under both Grace and Haven substantive law.[2]

### A. Respondent has stated valid strict liability claims under the Restatement (Second) of Torts, which is incorporated into Grace substantive law and is controlling.

Respondent's manufacturing, design, and warning defect claims satisfy the standards of Grace substantive law. Grace substantive law, which is controlling in this case, provides that products liability claims are to be analyzed using the Restatement (Second) of Torts. *Turner v. Smith Bros., Inc.*, 30 Grace 144 (2006); (R. at 5, 10.) Grace courts use the consumer expectation test for manufacturing defect claims, and use the same test for design and warning defect claims when the information related to the

[2] The record on appeal does not include the complaint. Accordingly, all facts from the opinions of the district court and court of appeals are assumed to have been alleged in the complaint.

defect is easy to understand and not scientific or technical in nature. Respondent has stated valid claims for manufacturing, design, and warning defects under this standard.

**1. Respondent has stated a valid claim for a manufacturing defect under strict products liability because the electronic medical record did not conform to its specifications and was unreasonably dangerous.**

Respondent has stated a valid manufacturing defect claim because the electronic medical record did not conform to its specifications. Under the Restatement (Second), a seller of a defective product "unreasonably dangerous to the [customer]" is strictly liable for injuries and property damage caused by the product. Restatement (Second) of Torts § 402A (1965). This is true "even though [the seller] has exercised all possible care in the preparation and sale of the product." *Id.* at cmt. a. Whether a product is defective or unreasonably dangerous is determined by a consumer expectation test. *Turner*, 30 Grace at 153; *see also Cooper v. Old Williamsburg Candle Corp.*, 653 F. Supp. 2d 1220, 1224 (M.D. Fla. 2009) (noting that product has manufacturing defect when it fails to perform according to ordinary consumer's expectations); Restatement (Second) of Torts § 402A cmts. g, i (1965); *accord Simonetta v. Viad Corp.*, 197 P.3d 127, 135 (Wash. 2008) (manufacturer liable when product unsafe to extent beyond that reasonably contemplated by ordinary consumer). "The question in manufacturing defect cases is whether the product as produced conformed with the manufacturer's specifications." *Camacho v. Honda Motor Co.*, 741 P.2d 1240, 1247 (Colo. 1987); *see also Williams v. Genie Indus., Inc.*, No. Civ.A. H-03-4579, 2005 WL 1606927, at *4 (S.D. Tex. July 5, 2005) (manufacturing defect where "the product functioned improperly").

Here, since the product[3] was an electronic medical record accessed from Firefly by University Medical Center (R. at 2.)—which was supposed to be an exact duplicate of Ms. Washburne's paper

[3] Though it does not appear to be in dispute, it is worth noting that the electronic medical record is a "product" for purposes of strict liability analysis since it acts as a substitute for a physical record, was put on a USB drive in tangible form and mailed to Ms. Washburne, and consisted of

medical record—and it omitted any reference to her allergy to penicillin, there can be little doubt that the product failed to conform to its specifications and that it functioned improperly. *See Camacho*, 741 P.2d at 1247; *Williams*, 2005 WL 1606927, at *4. Since it is reasonable that an ordinary consumer would expect that an electronic medical record would replicate exactly the paper medical record, any substantive alteration (such as an omission about life-threatening allergies to medication) makes the electronic medical record unreasonably dangerous and Firefly strictly liable. *Turner*, 30 Grace at 153; *Cooper*, 653 F. Supp. 2d at 1224. At the very least, sufficiently plausible allegations have been pled to survive Firefly's 12(b)(6) Motion to Dismiss; therefore, Respondent has stated a claim for a manufacturing defect.

**2. Respondent has stated a valid claim for a design defect under both the consumer expectation and risk-utility tests used in Grace products liability actions.**

Respondent has shown a design defect under both the consumer expectation and risk-utility tests. In determining whether or not a design defect exists, Grace courts use a combination of the consumer expectations test and the risk-utility test. (R. at 11.)[4] The tests are not mutually exclusive, and use of each depends on the circumstances of the individual case. *Biosera, Inc. v. Forma Scientific, Inc.*, 941 P.2d 284, 287 (Colo. App. 1996). A consumer expectation test is generally appropriate, and should be used where the information presented is not highly scientific and technical in nature. *Id.*; *accord Kokins v. Teleflex, Inc.*, 621 F.3d 1290, 1297 (10th Cir. 2010). The design defect at issue in this case is

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medical information which was relied upon by physicians. *See generally Isham v. Padi Worldwide Corp.*, No. 06-00382 DAE-BMK, 2007 WL 2460776, at *8-9 (D. Haw. Aug. 23, 2007) (discussing what constitutes a product or service, and recognizing that false information contained in such technical guides as aeronautical charts constitutes a "product" for purposes of strict products liability in part because it represented that it contained all necessary information); *see also Am. Online, Inc. v. St. Paul Mercury Ins. Co.*, 347 F.3d 89, 89 (4th Cir. 2003) (using, in a different context, products liability language that software was "defectively designed and/or unreasonably dangerous").

[4] The court of appeals said "Haven Courts" but appeared to mean "Grace courts" because discussion revolved around application of Grace substantive law.

the failure to incorporate into the software a flagging system to alert a data entry clerk or health care providers that a field has potentially been overlooked.

**a. Respondent has sufficiently pled a design defect under the consumer expectation test, which is appropriate in this case, because the defective product's dangerous nature and the remedial safety measures available are apparent.**

Respondent has stated a claim for design defect under the consumer expectation test of the Restatement (Second). Where the design defect allegation revolves around a confirmation procedure in transferring information from a paper medical record to an electronic medical record, a consumer expectation test applies. The consumer expectation test provides that a product is defectively designed when it "fails to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable by the manufacturer . . . ." *Agrofollajes, S.A. v. E.I. Du Pont De Nemours & Co.*, 48 So. 3d 976, 997 (Fla. Dist. Ct. App. 2010). In cases where the information is not complex, and a trier of fact could easily determine what safety features a reasonable consumer would expect, the consumer expectations test is appropriate. *Biosera*, 941 P.2d at 287. In *Biosera*, the issue was whether a refrigerator used to preserve stem cells was defective because the switch was placed in a way that it could easily be turned off by accident. *Id.* The court determined that the consumer expectations test was appropriate because the danger and the efficacy of alternative designs were easy to understand. *Id.* However, in cases involving more complex or scientific information, a risk-utility test is required. *Kokins*, 621 F.3d at 1299. In *Kokins*, the issue was whether the steering cable on a motor boat was defectively designed. *Id.* at 1293. The court held that the risk-utility test was required because the testimony addressed, among other things, the "measures taken to keep water from entering its inner core, and the chemical and physical properties of two different kinds of steel." *Id.* at 1299.

This case involves a concept that is neither complex nor overly scientific or technical in nature. Unlike *Kokins*, this case does not involve technical, scientific information about the chemical properties of metals or complicated information regarding the ways the product could fail. *Id.* at 1299. Instead,

this case involves a question of whether a simple flagging system would have alerted a user that data were missing in a particular field. A trier of fact could easily conclude that the absence of a flagging system for important fields in the medical record renders the electronic record unreasonably dangerous. *See Biosera*, 941 P.2d at 287 (trier of fact could easily use consumer expectation test for power switch defect). Accordingly, Respondent has stated a claim for design defect under Grace's consumer expectation test, and any factual dispute regarding this issue should be resolved at trial.

**b. Respondent has also sufficiently pled a design defect under the risk-utility test because the risk of patient death as a result of a defective product outweighs any utility of the product.**

Even though a consumer expectations test is appropriate, and Respondent has stated a claim for a design defect under the consumer expectations test, Respondent has also stated a claim under a risk-utility test. When an electronic medical record's design fails to ensure the accuracy of critical information like allergies, the risk of patient death outweighs any benefit of the electronic medical record. A product is defectively designed under the risk-utility test when "the risks of a challenged design outweigh its benefits." *Kokins*, 621 F.3d at 1294; *see also Prasol v. Cattron-Theimeg, Inc.*, No. 09-10248, 2010 WL 4982899, at *3-4 (E.D. Mich. Dec. 2, 2010); *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 260-61 (Ill. 2007) (discussing certain factors that can be considered in the analysis).

The facts indicate that a reasonable alternative design was already in operation in a competitor's product—namely, the flagging system incorporated by IBM. (R. at 2.) IBM's product incorporated this additional software safety feature, apparently at a cost of two dollars and fifty cents more than Firefly's product (ten percent more than the twenty-five dollars paid by Ms. Washburne). (R. at 2.) In fact, the *Calles* court recognized the importance of these same factors: the "availability of a substitute product[,]" the "manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness[,]" and the ability of the manufacturer to "[spread] the loss by setting the price of the product . . . ." *Calles*, 864 N.E.2d at 260-61. Thus, Respondent has shown that the reasonable

alternative design satisfies the risk-utility test because its additional cost can easily be passed to the consumer without a drastic increase in price.

Moreover, the risk associated with not incorporating the design is exactly what occurred in this case: a patient's unnecessary and avoidable death. The *Calles* court stressed that the safety aspects of the product and the seriousness of the injury are significant concerns in a risk-utility analysis. *Id.* Applying a risk-utility analysis, Respondent has stated a claim and shown that the dangers associated with the current design are severe, while cost savings are minimal, and that a reasonable alternative design existed. *See Prasol*, 2010 WL 4982899, at *3-4 (recognizing reasonable alternative design to industrial remotes' protective shield, which required only a small amount of material to build, cost only five to ten dollars per unit, and would have prohibited the accident that occurred); *Calles*, 864 N.E.2d at 260-61. Since Respondent has alleged sufficient facts to support a design defect under both the consumer expectation and risk-utility tests, Firefly's Motion to Dismiss was properly denied in the court of appeals.

**3. Respondent has stated a valid claim for a failure to warn under strict products liability because Firefly's failure to warn customers, health care providers, or its data entry employees of the danger of errors made the product unreasonably dangerous.**

Firefly's failure to warn Ms. Washburne and health care providers accessing her electronic record that it may contain errors makes Firefly strictly liable for Ms. Washburne's injury. Liability attaches because of inadequate warnings when a product, even though perfectly designed and manufactured, is still not "reasonably safe when placed in the hands of the ultimate user without first giving an advance warning concerning the manner in which to safely use the product." *Braaten v. Saberhagen Holdings*, 198 P.3d 493, 498 (Wash. 2008) (quoting *Teagle v. Fischer & Porter Co.*, 570 P.2d 438 (Wash. 1977)). In a failure-to-warn case, a showing of a specific defect is not required where a plaintiff can show the product "was rendered unreasonably dangerous by the absence of adequate

warnings . . . ." *Kendall v. Bausch & Lomb, Inc.*, No. CIV. 05-5066-KES, 2009 WL 1740002, at *4 (D.S.D. June 17, 2009). Specifically, a failure to warn regarding software errors that affect a product's function has been recognized as a valid products liability claim. *See Wendorf v. JLG Indus., Inc.*, 683 F. Supp. 2d 537, 540 (E.D. Mich. 2010) (discussing liability for failure to warn of software malfunction affecting operation of product).

Here, the record indicates only that Firefly provided a warning associated with the USB record, instructing the customer to verify the contents before destroying paper records. (R. at 2.) This does not, however, alert the user about the potentially fatal result that can occur if an error in transferring information occurs in a part of the record such as allergies to medication. Rather, Firefly's warning was aimed at preventing a premature destruction of paper records, and was not aimed at alerting the customer of potentially dangerous errors in the electronic record.

Additionally, Firefly's product failed to warn the data entry clerk that a potential omission had occurred, and failed to warn either the customer (Ms. Washburne) or health care providers accessing the electronic medical record that there might be an error in electronic transmission of the medical record despite an accurate copy on the Firefly server. *See Wendorf*, 683 F. Supp. 2d at 540. This failure to warn made the product unreasonably safe. Because the rules of civil procedure allow for liberal pleading, this Court should deny Firefly's Motion to Dismiss for failure to state a claim based on warning defects.

**B. Even if the Court determines Haven law applies, Respondent has stated valid claims for relief under Haven law, which incorporates the Restatement (Third) of Torts.**

The Restatement (Third) of Torts distinguishes between manufacturing, design, and warning defects. Since the standard for manufacturing defects under the Restatement (Third) is essentially the same as the standard under the Restatement (Second), Respondent has stated a claim for a manufacturing defect. Respondent has also stated a claim for a design defect by showing a reasonable

alternative design and, alternatively, showing a design defect by inference. Finally, Respondent has stated a claim for a warning defect by showing that the foreseeable risk of harm—in this case, death—could have been prevented by an adequate warning, and that the failure to include the warning rendered the product unreasonably dangerous. Under Haven law, in addition to the Restatement (Third) requirements, a plaintiff making a products liability claim must also show that the product was both the actual ("but for") and proximate cause of the plaintiff's harm. Haven Rev. Code § 1018.11. Respondent has pled facts sufficient to show actual and proximate causation, and has stated valid claims for manufacturing, design, and warning defects under the Restatement (Third).

**1. Respondent's manufacturing defect claim satisfies the Restatement (Third) because the product departed from its intended design and caused injury, making Firefly strictly liable.**

As long as the product at issue—in this case the electronic medical record—departs from its intended design, Firefly will be strictly liable under the Restatement (Third) as well as the Restatement (Second) for injury caused by that departure. *Isham v. Padi Worldwide Corp*., No. 06-00382, 2007 WL 2460776, at *6 (D. Haw. Aug. 23, 2007) (holding that "[t]he theory of strict liability [under the Restatement (Third)] comports with the Restatement (Second) of Torts § 402A . . . ."). When an electronic medical record does not replicate exactly the paper medical record, it has departed from its intended design and the manufacturer is strictly liable for injuries caused by that error. All that need be shown to establish strict liability for a manufacturing defect under the Restatement (Third) is the state of the harmful product itself, and that the design was different. *Depositors Ins. Co. v. Wal-Mart Stores, Inc.*, 506 F.3d 1092, 1095 (8th Cir. 2007).

In this case, the facts indicate that the design was for the electronic medical record to match exactly the paper record, which included an allergy to penicillin, and that the electronic record did not include any information regarding allergies, not even the default "NONE." These facts alone satisfy the

requirements of the Restatement (Third) by showing either that a software malfunction failed to include any information about Ms. Washburne's allergies in the electronic medical record, or that the data entry clerk erred in inputting the allergy information. In either case, the manufacture of the product was defective in that it failed to conform to the product's design: an exact copy of Ms. Washburne's paper medical records. *Cf. Depositors*, 506 F.3d at 105 (summary judgment for defendant where plaintiff failed to show intended design or how product departed from that design). Therefore, Respondent has pled facts sufficient to allege a manufacturing defect under the Restatement (Third).

**2. Respondent's design defect claim satisfies the Restatement (Third) standard by showing a reasonable alternative design, and Respondent has sufficiently pled a defect by inference.**

The Restatement (Third) permits a plaintiff to show a design defect by showing a reasonable alternative design or, where the defect is one that does not normally occur in the absence of a defect, by inference. Since Respondent has shown both a reasonable alternative design and that the defect is one that does not normally occur in the absence of a defect, Respondent has satisfied both of the alternative methods of stating a claim for a design defect under the Restatement (Third).

**a. Respondent has sufficiently pled a reasonable alternative design in the IBM product.**

As discussed in Part II(A)(2)(b) above, under a risk-utility analysis, Respondent has shown that a reasonable alternative design existed. If a reasonable alternative design would have reduced the foreseeable risk of harm at reasonable cost, the manufacturer is strictly liable when the omission of that design renders the product not reasonably safe. Restatement (Third) of Torts: Prod. Liab. § 2 cmt. d (1971). A court ruling on a motion to dismiss for failure to state a claim must take as true all facts alleged, including those supporting an allegation of a reasonable alternative design. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *see also Christopher v. Harbury*, 536 U.S. 403, 406 (2002); Fed. R. Civ. P. 12(d).

Though the district court held a reasonable alternative design had not been alleged in the complaint, it appears as though the district court's determination rested on its conclusion that the alternative design was alleged but was not a reasonable one. (*See* R. at 7) (determination made after discussion of reasonableness). This is a question of fact that should be reserved for summary judgment or trial; in the pleading stage, where Respondent alleges that a particular design is a reasonable alternative, that fact, and all reasonable inferences drawn therefrom, must be taken as true in ruling on a motion to dismiss. *Erickson*, 551 U.S. at 94; *see also Christopher*, 536 U.S. at 406; Fed. R. Civ. P. 12(d) (motion to dismiss limited to complaint, and treated as motion for summary judgment if the court considers material outside the complaint). Taken as true, the alternative design alleged is reasonable because it was practicable and inexpensive to incorporate. Therefore, Respondent has alleged a reasonable alternative design.[5]

In any event, Respondent has shown that the risk of the system as it stands involves errors in transferring records which could lead to patient death. Since the approach of the Restatement (Third) follows the same risk-utility analysis in determining a design defect as courts applying the Restatement (Second), the failure to include the alleged alternative design, or any alternative design, made Firefly's software unreasonably dangerous. Restatement (Third) of Torts: Prod. Liab. § 2(b) cmt. a (1998).

**b. Respondent has sufficiently pled a defect by inference, which does not require showing a reasonable alternative design, because Ms. Washburne's injury is not one that would normally occur in the absence of a defect**.

Because Ms. Washburne's injury, in the context of this case, is one that would usually not occur without a defect in the electronic medical record, Respondent has stated a claim for defect by inference. The Restatement (Third) permits an inference of a defect without the need to show a reasonable

[5] Alternatively, if the district court considered material outside the complaint, such as evidence proffered by Petitioner, the motion should have been treated as one for summary judgment, and should have been stayed pending discovery by Respondent. *See* Fed. R. Civ. P. 12(d).

alternative design when the incident that harmed the plaintiff "was of a kind that ordinarily occurs as a result of a product defect" and "was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution." Restatement (Third) of Torts: Prod. Liab. § 3 (1998); *id.* at reporter's note cmt. c ("Plaintiff need not prove that the product departed from its intended design or that a reasonable alternative design could have been adopted."); *see also Phillips v. Cricket Lighters*, 841 A.2d 1000, 1019 n.13 (Pa. 2003) (recognizing inference can be drawn in certain design defect cases). Thus, where an injury is likely to occur only when a product defect exists, a plaintiff can state a claim for a design defect by inference without having to prove a reasonable alternative design or that the defect was what actually caused the injury. *See Am. Contractors Indem. Co. v. United States*, 570 F.3d 1373, 1377 (Fed. Cir. 2010); *Arnold v. Krause, Inc.*, 233 F.R.D. 126, 131-32 (W.D. N.Y. 2005) (allegation that ladder collapsed while plaintiff used it properly, and that subsequent inspection showed broken hinge, was sufficient to allow design defect inference).

The record indicates the paper record was correct, the record on the Firefly server was correct, and the record provided to Dr. Tam was incorrect. (R. at 3.) The error, then, can fairly be characterized as one that was of a kind that ordinarily occurs as a result of a defect, and was not solely the result of causes other than product defect. *See Cricket Lighters*, 841 A.2d at 1019 n.13. In *Arnold*, the plaintiff was injured when the ladder he was standing on collapsed. *Arnold*, 233 F.R.D. at 131-32. The court held that this allegation, combined with the allegation that an inspection of the ladder showed a broken hinge, was sufficient to allow a design defect inference and preclude summary judgment. *Id.* at 132. Like *Arnold*, the record does not indicate the electronic medical record was being used or accessed improperly. Also like *Arnold*, a subsequent investigation revealed the record accessed by Dr. Tam did not include the penicillin allergy. (R. at 3.) This is sufficient to state a claim for design defect by inference. *Arnold*, 233 F.R.D. at 132. Though there may be a factual dispute as to the actual cause of

the error, resolution of that dispute should be reserved for proceedings occurring after discovery, such as summary judgment or trial. *Am. Contractors*, 570 F.3d at 1377. Respondent's claim has alleged a defect by inference without the need to show reasonable alternative design, and has alleged facts sufficient to survive Firefly's 12(b)(6) Motion to Dismiss.

**3. Respondent has sufficiently pled a failure-to-warn claim under the Restatement (Third) because Ms. Washburne's death was foreseeable and Firefly failed to provide reasonable warnings to necessary parties.**

Respondent's failure-to-warn claim satisfies the Restatement (Third) standard. A product "is defective because of inadequate . . . warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller . . . and the omission of the . . . warnings renders the product not reasonably safe." Restatement (Third) of Torts: Prod. Liab. § 2 (1998). "Depending on the circumstances, [the warnings requirement] may require that instructions and warnings be given not only to purchasers, . . . but also to others who a reasonable seller should know will be in a position to reduce or avoid the risk of harm." *Id.* at cmt. i. Where an electronic medical record is to be used by the patient and health care providers, the manufacturer is required to warn all parties of potential errors.

This case is of the kind anticipated by the drafters of the Restatement. It is entirely foreseeable in this context that a data entry clerk, in creating an electronic medical record, might fail to include information from the paper record that is necessary to avoid serious injury or death to the patient. A software warning to the data entry clerk to confirm portions of the electronic record which are likely to cause injury if incorrectly inputted would likely reduce or eliminate such injury. As evidenced in this case, the failure to provide this warning resulted in the product being unreasonably safe to Ms. Washburne because the record failed to include her allergy information. A warning to the data entry clerk would have required the clerk to double check the information and would have avoided such a costly mistake.

Additionally, Firefly could easily have incorporated a warning to health care providers accessing the electronic medical record that the record itself may contain an error, or that there may be an error in transmission from Firefly servers. The danger associated with the omission of such a warning is evidenced in this case by Ms. Washburne's death.

A warning to Ms. Washburne and health care providers that there might be an error in the record or its transmission would have alerted all parties to confirm the accuracy of the electronic record before relying on it, avoiding a costly mistake. Thus, Respondent has alleged facts sufficient to survive Firefly's 12(b)(6) Motion to Dismiss.

**4. Respondent has sufficiently pled factual and proximate causation under Haven law by alleging facts supporting the conclusion that Ms. Washburne's death was a direct result of defects in Firefly's product.**

Having satisfied the requirements of the Restatement (Third), Respondent must still show factual and proximate causation. Haven Rev. Code § 1018.11. In a products liability action, both factual and proximate cause are determined by generally applicable tort rules of causation. Restatement (Third) of Torts: Prod. Liab. § 15 (1998). "The basic rules governing causation in products liability litigation are the same as those governing tort law generally." *Id.* at reporter's note cmt. a. Moreover, plausible allegations regarding causation are sufficient to survive a motion to dismiss because the defense of causation is generally improper in a motion to dismiss. *See Sanders v. City of Fresno*, No. CIV F 05-0469 AWI SMS, 2006 WL 1883394, at *16-18 (E.D. Cal. July 7, 2006) (causation sufficiently pled where plaintiff alleged Taser use was excessive and caused victim to be placed on a gurney, and victim's heart stopped shortly thereafter).

"Conduct is a factual cause of harm when the harm would not have occurred absent the conduct . . . ." Restatement (Third) of Torts: Phys. & Emot. Harm § 26 (1998). The applicable test is commonly referred to as the "but-for" test; that is, "an act is a factual cause of an outcome if, in the absence of the act, the outcome would not have occurred." *Id.* at cmt. b. In this case, if the electronic medical record

had been accurate and shown Ms. Washburne's allergy to penicillin, her reaction and subsequent death would not have occurred. Thus, it is a factual cause of her harm.[6]

In addition to showing factual cause, Respondent has shown proximate cause. When an electronic medical record contains an error which results in injury to the patient because of reliance on the record by medical personnel, the manufacturer of the electronic medical record is liable for the harm caused by the medical personnel, even if subsequent medical treatment constituted negligence. This is because "[a]n actor whose tortious conduct is a factual cause of harm to another is subject to liability for any enhanced harm the other suffers due to the efforts of third persons to render aid reasonably required by the other's injury . . . ." Restatement (Third) of Torts: Liab. for Phys. & Emot. Harm § 35 (1998). This statement of the rule is a reiteration of the rule announced in Restatement (Second) of Torts § 157 (1965). Restatement (Third) of Torts: Liab. For Phys. & Emot. Harm § 35 cmt. a (1998). "[W]ith respect to an action by the injured party against the original tortfeasor, the original tortfeasor is . . . liable for the entire harm to the plaintiff, including the original injury and any foreseeable enhancement of the injury by medical negligence." *Lewis v. Samson*, 35 P.3d 972, 985 (N.M. 2001) (citations omitted). Additionally, "[w]hen a person causes an injury to another which requires medical treatment, it is foreseeable that the treatment, whether provided properly or negligently, will cause additional harm." *Id.* If plausible allegations are pled regarding proximate causation, a motion to dismiss should be denied. *See Sanders*, 2006 WL 1883394, at *16-18 (motion to dismiss denied where facts, taken as true, establish causation).

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[6] Contrary to the district court's assumptions about foreseeable error in referring to medical files, and its subsequent conclusion that Firefly's error could not have been a factual cause, Respondent is not required to show the erroneous medical record was the *only* cause of harm, but rather that it was *a* cause of the harm. Restatement (Third) of Torts: Liability for Phys. & Emot. Harm § 26 cmt. l (1998) (emphasis added); *see also id.* § 27 (multiple sufficient causes doctrine allows for liability for tortious conduct that would have caused harm even if another actor's tortious conduct would have been sufficient individually to cause harm).

In this case, the only possible argument that Firefly is not the proximate cause of Ms. Washburne's injury must be premised on allegedly negligent medical treatment by the hospital's failure to hold and observe Ms. Washburne for a second reaction for a full 72 hours after the first reaction. (R. at 2-3.) The hospital's conduct is irrelevant because even if it is negligent, "[Firefly] will not be heard to complain of foreseeable medical negligence precipitated by the initial tortious injury in defense of [its] own liability to the injured party." *Lewis*, 35 P.3d at 985; *accord* Restatement (Third) of Torts: Phys. & Emot. Harm § 35 (1998). In *Sanders*, the court held that the plaintiff alleged causation sufficient to survive a motion to dismiss where the allegations were that police used a Taser excessively, which caused the victim's heart to stop shortly after the victim was placed on a gurney. Like *Sanders*, the allegations here are that the defects in Firefly's product caused Ms. Washburne's injury through her allergic reaction, all of which must be taken as true. This is sufficient to survive a Rule 12(b)(6) motion to dismiss.

## CONCLUSION

Grace's contacts with the case and the principles underlying tort litigation support application of Grace law. Thus, Grace law should apply because Grace has the most significant relationship to the litigation. Additionally, Respondent's allegations, taken as true, satisfy the standards of both the Restatement (Second) of Torts used by Grace and the Restatement (Third) of Torts used by Haven. Accordingly, Respondent has alleged facts sufficient to survive a motion to dismiss for failure to state a claim upon which relief can be granted. For the reasons discussed above, Respondent respectfully requests this Court affirm the decision of the United States Court of Appeals for the Thirteenth Circuit.

Respectfully submitted,

/s/ Team 2

Team 2
Counsel for Respondent