No. XX-XX-XXXXX

In the

Supreme Court

of the United States

March Term, 2011

Firefly Systems, Inc.,

Petitioner,

v.

***In Re* Estate of Zoe Washburne,**

Respondent.

On Writ of Certiorari
to the United States Court of Appeals
for the Thirteenth Circuit

Brief for the Petitioner

Team # 5 P
Counsel for the Petitioner

Questions Presented

I. Does Haven law apply when (a) the factors under § 6(2) of the Restatement (Second) Conflict of Laws indicate that Haven's state interests in the outcome of the dispute outweigh Grace's; and (b) all of the relevant factors under § 145(2) of the Restatement (Second) Conflict of Laws indicate that Haven has the most significant relationship to the dispute?

II. Does Fed. R. Civ. P. 12(b)(6) require the dismissal of a strict products liability claim when the Respondent (a) plead no facts showing how the product was manufactured in a defective manner; (b) failed to identify an alternative design or present facts that show the Petitioner's product is not reasonably safe because it failed to incorporate an alternative design; (c) failed to identify alternative warnings or instructions, or show that the product's instructions were inadequate; and (d) failed to show that the product was the but-for and proximate cause of injury?

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Opinions Below

The opinion of the United States District Court for the District of Grace is unreported but appears in Appendix A. The decision of the United States Court of Appeals for the Thirteenth Circuit is also unreported and appears in Appendix B.

Statutes Involved

This case involves the interpretation of the Health Information Technology for Economic and Clinical Health Act of 2009, 42 U.S.C. § 300jj-11 *et. seq*. (2009). The relevant provisions of the Health Information Technology for Economic and Clinical Health Act of 2009 are attached as Appendix C. This case also involves the interpretation of Fed. R. Civ. P. 12(b)(6). The relevant provisions of Fed. R. Civ. P. 12(b)(6) are attached as Appendix D. This case also involves the interpretation of Haven Revised Code § 1018.11. The following Restatements of the Law are also considered in this matter: Restatement (Second) of Conflict of Laws §§ 6, 145 (1971); Restatement (Second) of Torts § 402A (1965); and Restatement (Third) of Torts: Products Liability § 2 (1998).

Statement of the Case

A. Statement of the Facts

The Petitioner, Firefly Systems, Inc., ("Firefly" or "Petitioner"), is a software company incorporated in the state of Delaware, but its primary place of business is based in Haven. (R. at 2). In 2008, Zoe Washburn ("Respondent") received a letter from her primary care physician indicating that her paper medical records would be converted to an electronic system designed by

Firefly. *Id*. In the letter her physician indicated that converting to electronic health records ("EHR") would benefit every patient because it would allow records to be easily transferred to other physicians at neighboring hospitals. *Id*. Her physician also noted that EHRs are beneficial because doctors from out of town can quickly access these records in the event of an emergency. *Id*.

In response to her primary care physician's request, the Respondent agreed to the conversion and sent a personal check payable for twenty-five dollars to Firefly in order to obtain a copy of her EHR on a USB flash-drive. *Id*. at 3. Once Firefly received approval to convert the records it sent the primary copy to her physician, and a USB flash-drive copy to the Respondent. *Id*. When the Respondent received her copy of the electronic medical record she failed to review it to ensure its accuracy even though Firefly provided explicit instructions that told each customer to review the record for errors. *Id*. The Respondent eventually lost the copy of her EHR, and there is no evidence that she made any further attempts to ensure its accuracy. *Id*. at 3. These actions are unusual because the Respondent had a known penicillin allergy and she took active steps throughout the course of her life to ensure that her doctors knew about this problem. *Id*. at 2.

On Wednesday, September 10, 2008, the Respondent experienced abdominal pain while chaperoning a field trip with her students in Capitol City, Haven. *Id*. at 3. Her fellow teachers took her to University Medical Center (UMC) in Capitol City where she became unconscious and was treated for appendicitis. *Id*. During her treatment at UMC the doctors accessed the Respondent's online EHR and, for reasons that are not entirely clear, it lacked information regarding her penicillin allergy. *Id*. at 4. Without contacting her primary care physician to confirm the record's accuracy, the on call surgeon at UMC removed the Respondent's appendix

and administered penicillin to prevent a post-surgical infection. *Id*. Several minutes after receiving the penicillin the Respondent began experiencing respiratory problems that were common for those allergic to penicillin. *Id*. The doctors responded to this reaction by searching Firefly's web EHR portal, learning of the Respondent's allergy and administered epinephrine which completely alleviated the symptoms. *Id*. Following this, the Respondent suffered no further problems, and she left the hospital on September 12. *Id*.

When the Respondent left, the staff at UMC failed to inform her that she could still suffer a secondary allergic reaction up to 72 hours after her initial reaction. *Id*. Because of this failure the Respondent did not receive any medication that could have helped her cope with any further reactions. *Id*. While traveling home, this oversight proved to be fatal for the Respondent when she suffered a second reaction that resulted in her death. *Id*. Despite the reckless actions taken by the UMC staff, the Respondent's estate filed suit against Firefly, seeking recovery for her wrongful death. *Id*.

B. Course of Proceedings and Disposition in the Courts Below

Following the Respondent's death, her estate filed suit against Firefly claiming: (1) breach of express warranty; (2) breach of implied warranty of merchantability; and (3) strict product liability based upon a manufacturing, design, and warning defect. *Id*. The Respondent's estate filed the complaint in the Peterson County Court of Common Pleas located in Haven, and Firefly removed the cause to federal court based on diversity of citizenship under 28 U.S.C. § 1332. *Id*. On March 18, 2009, Firefly filed a motion to dismissed under Fed. R. Civ. P. 12(b)(6) ("R. 12(b)(6)") for failure to state a claim upon which relief can be granted. *Id*.

In its motion to dismiss, Firefly indicated that Haven law applied in this case under *lex loci delicti*, and the most significant relationship test established under § 145(2) of the Restatement (Second) Conflict of Laws.[1] *Id*. Since the Respondent's estate filed suit in Haven, the district court followed Haven's conflict of laws doctrine in accordance with this Court's decision in *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 481 (1941). *Id*. at 6. Using this approach, the district court rejected the *lex loci delicti* argument, and applied the most significant relationship test because the Supreme Court of Haven adopted this as its conflict of laws test in its decision in *Booker v. InGen, Inc.*, 24 Haven 17 (2007). *Id*. Following the standards set forth in the most significant relationship test, the district court concluded that Haven law governed this matter because: (1) Haven is where the injury occurred; (2) it is where the relationship between the parties is centered and; (3) it is where Firefly maintains its principle place of business. *Id*.

After resolving the conflict of law issue, the district court analyzed the Respondent's claim under the Restatement (Third) of Torts: Product Liability (1998). *Id*. at 7. Using the factors outlined in Restatement (Third) the district court concluded that: (1) the there was no manufacturing defect in Firefly's software; (2) that Firefly was not the proximate cause of the Respondent's injury and; (3) that the Respondent failed to show a reasonable alternative design in their complaint as required under Restatement (Third). *Id*. at 7-8. The district court also concluded that the Respondent's warning defect claim could not survive a R 12(b)(6) motion to dismiss because it failed to allege a reasonable warning defect in its complaint. In addition, the district court also concluded that the Respondent's implied and express warranty claims failed. *Id*. at 9. The implied warranty claim failed because it is a duplicative under Restatement (Third)

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[1] The two laws that conflict in this matter are Restatement (Third) of Torts: Product Liability § 2 (1998), which Haven uses to govern strict product liability claims, and Restatement (Second) of Torts § 402A (1965), which Grace uses to govern strict product liability claims.

when filed along with a manufacturing defect claim, and the express warranty claim failed because Firefly never made any representations directly to the Respondent. *Id*. As a result of these findings, the district court dismissed the Respondent's complaint and the Respondent filed an appeal with the United States Court of Appeals for the Thirteenth Circuit. *Id*. at 10.

In its conclusory opinion, the Thirteenth Circuit held that Grace law governed this case, even though the only evidence supporting the application of Grace law is the fact that the Respondent lived and worked in Grace. *Id.* at 11. Without weighing each state's interests in this matter, or any facts that closely tie Haven to the outcome of this litigation, the Thirteenth Circuit applied Grace law. Under the factors listed in Restatement (Second) of Torts, the Thirteenth Circuit concluded that the Respondent pled sufficient facts to survive a R. 12(b)(6) motion to dismiss with regards to the strict product liability and implied warranty of merchantability claims. *Id*. at 12. The Thirteenth Circuit affirmed the district court's decision with regards to the express warranty claim, but it remanded the other claims for further determination.

Firefly appealed the Thirteenth Circuit's decision that Grace law applied in this matter and that the Respondent's strict product liability claims were sufficient to stated in order for relief to be granted. The Supreme Court of the United States granted certiorari to consider these two issues.

C. Standard of Review

The appropriate standard of review for a court's dismissal of a complaint pursuant Fed. R. Civ. P. 12(b)(6) is *de novo*. *Reger Development, LLC v. National City Bank*, 592 F.3d 759 (7th Cir. 2010) (noting that *de novo* is the appropriate appellate standard of review for a district court's ruling on a R. 12(b)(6) motion to dismiss). Even though a *de novo* review of this type

requires the court to construe a complaint in the light most favorable to plaintiff, it is only required to accept the complaint's well-pleaded facts as being true. *Id*. Because the Petitioner's complaint lacks any well-pleaded facts, this Court should reverse the Thirteenth Circuit's decision to dismiss under R. 12(b)(6).

Summary of the Argument

This case presents two issues that have been subjected to conflicting opinions in the courts below. First, the Thirteenth Circuit incorrectly reversed the district court when it held that Grace law applied to this suit. Second, the Thirteenth Circuit incorrectly held that the Respondent's complaint alleged facts that are sufficient for strict products liability claims. These issues are addressed in turn.

The United States Court of Appeals for the Thirteenth Circuit incorrectly concluded that Grace law applies in this case. According to the Restatement (Second) of Conflict of Laws a court must not only consider the relevant contacts each state has with an action, but must also weigh each state's interest in the outcome of the case before deciding which state law applies in a particular suit. In this matter, the Thirteenth Circuit failed to conduct an analysis regarding which state maintained the greatest interest in the outcome of this case. Instead, it concluded that Grace law should apply, but it did so without providing any explanation as to why the facts that favor the application of Grace law outweigh the facts favoring the application of Haven law. *Id*. at 11. Because of this hasty decision, crucial facts that favor the application of Haven law were overlooked. Specifically, had Thirteenth Circuit properly followed the steps set forth in § 6(2) and § 145(2) of the Restatement (Second) of Conflict of Laws it would have concluded that

Haven's state interests outweigh Grace's, and that the facts of this case support the application of Haven law.

The Respondent also failed to plead sufficient facts for any of the three types of product liability claims in Haven. First, no facts have been plead to show that Firefly's software departed from its intentional design; a requirement for manufacturing defect claims in Haven. Second, the Respondent's design defect claim does not allege a safer alternative design exits, show how Firefly's system was not reasonably safe, or show how implementation of a competitor's double check system would prevent the type of harm involved. Finally, the Respondent has not alleged that Firefly's instruction telling customers to verify the accuracy of their EHR is inadequate, nor has she presented any facts that would show Firefly is liable for a warning defect claim in Haven.

While it is the Petitioner's position that Haven law should apply in this case, the Respondent's product liability complaint also fails under Grace law. First, no facts show that Firefly's system is actually defective or that it is unreasonably dangerous under Grace law. Second, the Respondent has not shown that Firefly's system fails the consumer expectations test, the risk-utility test or a combination of the two tests. Finally, the Respondent has not presented any facts that would show that the risk involved in Firefly's system outweigh its utility.

Furthermore, the Respondent's complaint also fails to show that an error in Firefly's system is the but-for and proximate cause of her death as is required under both Haven and Grace law. The Respondent died as a result of biphasic anaphylaxis and not the initial allergic reaction to penicillin. UMC's failures to warn the Respondent of the potential for biphasic anaphylaxis and provide her means to address such a reaction are significant cause factors in her death. It cannot be shown that she would not have died but for the error in Firefly's system. Finally, the long term benefits and utility of EHR systems such as Firefly's outweigh their risks.

Extending liability to Firefly in this case would overlook the benefits and utility of EHRs, and would chill the development of this much-needed medical system. Therefore, this Court should reverse the Thirteenth Circuit's decision with regards to the strict product liability claims.

Argument

I. Haven Law Is The Appropriate Choice Of Law To Govern This Matter.

According to Restatement (Second) Conflict of Laws § 145(2), the state that maintains the most significant relationship to the lawsuit is the state that should have its laws govern the matter. Restatement (Second) Conflict of Laws § 145(2) (1971). To make this determination a court must consider the following factors: (1) the place of the injury; (2) the place where the conduct causing the injury occurred; (3) the domicile, residence, nationality, place of incorporation, and place of business of the parties; (4) the place where the relationship between the parties, if any, is located; and (5) any factors under § 6(2) of the Restatement (Second) Conflict of Laws which the court deems relevant. *Id*. Under § 6(2) of the Restatement (Second) Conflict of Laws, the additional relevant factors the court may consider: (a) the needs of interstate and international systems; (b) the relevant policies of the forum; (c) the relevant polices of the interested states and the relative interests of those states in the determination of the particular issues; (d) the protection of the justified expectations; (e) the basic policies underlying the particular field of law; (f) certainty, predictability and uniformity of the result; and (g) ease in the determination and application of the law to be applied. Restatement (Second) Conflict of Laws § 6(2) (1971).

Haven law should govern because its state interests in the outcome of this litigation outweigh the interests of Grace, and under the factors in § 145(2) of the Restatement (Second)

Conflict of Laws, Haven maintains the most significant relationship to this matter. Specifically, the state of Haven's interests outweigh the state of Grace's because under the factors set forth in § 6(2) of the Restatement it maintains a greater interest in compensating tort victims for torts committed inside its border, regulating tort actions against businesses inside its border, and controlling the liability of businesses based inside its border. (R at 2-4). Furthermore, under the factors set forth in § 145(2) of the Restatement, Haven maintains a more significant relationship to this litigation because the initial injury occurred in Haven, the manufacturer assembled the product in Haven, the manufacturer is based in Haven, and the alleged product defect occurred in Haven. *Id.* Therefore, because these factors heavily favor applying Haven's law in this matter, this Court should reverse the Thirteenth Circuit's decision on this issue.

A. Haven's State Interests Outweigh Grace's State Interests.

In order to conduct a proper choice of law analysis under the Restatement, a court must not only consider the factors included § 145(2), but also those in § 6(2). Although no factor in §6(2) carries more weight than the others, it is essential to consider the factors in this section in order to ensure that the proper state's laws are applied. In this matter, both the district court and court of appeals failed to consider the factors outlined in §6(2). This oversight by both courts is significant because each court's decision ignored facts that indicate Haven maintains a greater state interest in this matter.

In *Mitchell v. Lone Star Ammunition*, the United States Court of Appeals for the Fifth Circuit was asked to decide whether Texas's state interests outweighed North Carolina's in a strict liability, implied warranty, and negligence action brought by Marines injured by defective ammunition. 913 F.2d 242 (5th Cir. 1990). In its decision, the court concluded that Texas's interests outweighed North Carolina's because the defective ammunition was manufactured in

Texas. *Id*. at 244. Based on this crucial fact, the court held that Texas maintained a paternalistic interest in the protection of its consumers and the conduct of businesses within its borders. Therefore its interests outweighed those of North Carolina even though the Marines were injured by the ammunition in North Carolina. *Id*. at 250. The court further reasoned that Texas's expansive legislation on tort liability for defective products bolstered its interest in the matter, and that these significant state interests justified the application of Texas law. *Id*.

This interpretation of the factors in §6(2) is not limited to the Fifth Circuit. Numerous courts made have reached similar holdings in their choice of law analysis. *See MG ex rel KG v. AI Dupont Hosp. for Children*, 393 Fed. App'x 884 (3d Cir. 2010) (ruling that Delaware law applied and that it maintained a greater state interest because the plaintiff was injured at a Delaware hospital even though the she lived in New Jersey); *Rosenthal v. Ford Motor Company*, 462 F. Supp. 2d 296 (D. Conn. 2006) (holding that because a Connecticut company sold the product, Connecticut maintained a greater state interest than North Carolina even though the injury occurred in North Carolina); *Lewis-DeBoer v. Mooney Aircraft Corporation*, 728 F. Supp 642 (D. Colo. 1990) (finding that Texas's interests in a wrongful death action outweighed Colorado's because the product that caused the wrongful death was designed, marketed, and sold by a Texas company); *Tillett v. JI Case Company*, 756 F.2d 591 (7th Cir. 1985) (concluding that Wisconsin law applied in a wrongful death action and that its interests in the matter outweighed Indiana's because the manufacturer maintained its business headquarters in Wisconsin).

In this matter both the United States District Court and the United States Court of Appeals for the Thirteenth Circuit neglected to conduct a § 6 analysis that weighed each state's interests. (R. at 2-14). Although both courts recognized that a conflict of law existed between the states with regards to the Restatement (Third) of Torts and the Restatement (Second) of

Torts, neither court examined each state's underlying policies of adopting those particular laws. *Id*. Because of this oversight, key facts that favor the application of Haven law were missed. Specifically, neither court considered the fact that the petitioner's principle place of business is located in Haven, that the software in question was manufactured in Haven, that the alleged data entry error occurred in Haven, nor why the Haven legislature took steps to adopt the Restatement (Third) of Torts. (R. at 2-5). Furthermore, Haven's interests outweigh Grace's because it reserves the right to correct the wrongs committed by either Firefly or UMC within its border. The previous decisions support the conclusion that the state that maintains the most interest in a matter is the one that is home to the manufacturer's primary place of business, is where the product was manufactured, or is where the incident that led to the ultimate injury occurred. In this matter all of these facts favor the application of Haven law, however each court below neglected to analyze these factors as mentioned under § 6 of the Restatement (Second) of the Conflict of Laws. As a result, the courts failed to recognize Haven's significant state interests in this matter and the additional reasons that favor the applying Haven's law.

Because of the oversight committed by both the United States District Court for the District of Haven, and the United States Court of Appeals for the Thirteenth Circuit, key facts that weigh in favor of applying Haven's law were missed. Neither court conducted a § 6 analysis regarding which state maintained a greater interest in this matter. Therefore, facts such as the petitioner's primary place of business, the location where the alleged data entry occurred, the location of the initial injury, and the forum state's legislative policy governing the issues were not considered even though all of these facts weigh in favor applying Haven's law. *Id*. As a result of this oversight by both lower courts, this Court should reverse the Thirteenth Circuit's decision on the conflict of law issue.

B. Haven Maintains the Most Significant Relationship to this Matter.

In addition to the factors included under § 6(2) of the Restatement, the factors listed in § 145(2) also favor the application of Haven law. Specifically, the injury in question initially occurred in Haven, the plaintiff's primary interactions with the product occurred in Haven, Haven is the location where the conduct that caused the injury occurred, and Haven is the manufacturer's primary place of business. (R. at 2-4). Based on these facts, and the decisions reached by other courts presiding over similar matters, this Court should reverse the Thirteenth Circuit's decision on the conflict of law issue.

In *Robinson v. McNeil Consumer Healthcare*, the United States Court of Appeals for the Seventh Circuit faced a similar set of facts when it considered whether Virginia or Illinois law applied in a products liability action where a plaintiff was injured after taking a children's pain reliever medicine. 615 F.3d 861, 865 (7th Cir. 2010). In that matter, the plaintiff asked the court to apply Illinois law because Illinois is where she suffered the full extent of her injuries. *Id*. However, the defendant claimed that Virginia law should apply because the plaintiff was prescribed the product in a Virginia hospital, used the defective product in Virginia and suffered her initial injury in Virginia. *Id*. The court agreed with the defendant, and held that Virginia law should apply in the matter because the events that occurred in Virginia are the events that gave rise to the primary issue in the case. *Id*. The court also noted that a plaintiff should not use an injury's latency period to move to another state in order to ask for the application of another state's law that may be more favorable to their cause. *Id*. at 866. The court conceded that

although it may be unusual for a plaintiff to take such actions, it is not unheard of and a court must consider these factors in its decision in order to prevent obvious forum shopping.[2] *Id*.

Other courts considering conflict of law issues that involved a plaintiff being injured by a product in one jurisdiction, and continuing to suffer injuries in another jurisdiction reached the same conclusion. *See Montgomery v. Wyeth*, 580 F.3d 455 (6th Cir. 2009) (holding that Tennessee law applied in a products liability action where the plaintiff suffered her initial injuries in Tennessee even though she purchased the product that caused her injury through a third party distributer in Georgia); *Bremer Aviation, Inc. v. Hughes Helicopter, Inc.*, 621 F. Supp. 290 (E.D. Pa. 1985) (ruling that New York law applied in a negligence and strict product liability action where the aircraft was sold to the plaintiff in Pennsylvania but crashed in New York); *Westerman v. Sears, Roebuck and Company*, 577 F.2d 873 (5th Cir. 1978) (concluding that Florida law applied in an implied warranty action since the plaintiff primarily used and interacted with alleged defective product in Florida).

In this case, the district court properly weighed the factors listed under § 145(2) of the Restatement and found that Haven law applied. (R. at 6). Based on the facts in this matter, and the supporting case law, the district court ruled correctly. Specifically, it noted that the plaintiff in this matter suffered her initial injury in Haven, and that the injury only exacerbated when she arrived in Grace. *Id*. Additionally, the Respondent's primary interaction with the Firefly's product occurred in Haven even though she initially purchased it through a third party in her state. *Id*. at 3. Furthermore, both the alleged data entry error, and the administration of penicillin occurred in Haven, making it the location where the conduct that led to her injuries occurred. *Id*.

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[2] The court specifically referenced DES and asbestos cases as instances where plaintiffs suffer injuries well after their initial contact with the defective product. The court noted that cases in which the initial injury can exacerbate over a period of time are cases that favor applying the law of the state where the initial injury occurred.

at 4. Based on the totality of these facts, in addition to Haven's substantial state interest in the matter, the district court properly concluded that Haven law applied. *Id*. at 7.

The Thirteenth Circuit ignored the facts weighed by the district court and applied Grace law simply because the Respondent resided in Grace and received the alleged defective product through a third party in that state. *Id*. at 11. Furthermore, the Thirteenth Circuit ignored Haven's state interests in the matter and concluded that Grace law should apply even though only one of the five factors listed under § 145(2) of the Restatement favored its use. *Id*. Based on these omissions, this Court should reverse the Thirteenth Circuit's decision on the conflict of law issue.

In conclusion, the factors outlined in § 6(2) and § 145(2) of the Restatement (Second) of Conflict of Laws favors the application of Haven's law. While the decisions of both the district court and the court of appeals omitted key aspects that must be considered under a conflict of law analysis, the district court did weigh all of the factors under § 145(2) and correctly concluded that Haven law applies. The Thirteenth Circuit failed to weigh crucial facts in this matter and it made the improper conclusion that Grace law applied even though the only factors favoring the application of Grace law are the Respondent's residence and location of her primary care physician.[3] *Id*. at 2-4. Therefore, this Court should reverse the Thirteenth Circuit's holding that Grace law applies in this matter.

II. The Respondent Failed to State a Strict Products Liability Claim Under Either Haven or Grace Law.

Even though Firefly showed that Haven law is the appropriate law to be applied in this matter, an overriding issue is the fact that the Respondent's complaint fails to state a strict

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[3] The plaintiff's primary care physician is not a party in this suit.

products liability claim upon which relief can be granted in either jurisdiction. This Court has held that a complaint must contain enough facts to support the grounds for a particular claim, and that a complaint which provides mere legal conclusions is insufficient to survive a R. 12(b)(6) motion to dismiss. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007). In this case, the district court correctly pointed out that the Respondent's complaint failed to allege any facts that showed how Firefly's system departed from its design and did note allege a reasonable alternative design or reasonable alternative warning. (R. at 8). Even if the claim is analyzed under Grace law, the Respondent has still not shown that Firefly's system was unreasonably dangerous or that any risks inherent with its design outweighed the medical benefits it provides to the community.

An equally important issue that must also be addressed regardless of which jurisdiction's substantive law applies is the causation of the Respondent's harm. It is undisputed that the Respondent's death occurred as a direct result of biphasic anaphylaxis coupled with the inability to get emergency medical help in a timely fashion. (R. at 4). There are no facts to suggest that the Respondent was provided any information regarding the recognition and treatment of biphasic anaphylaxis after being dismissed from the hospital. (R. at 2-14). It would be error to attribute the but-for or proximate cause of the Respondent's death to the absence of a penicillin allergy being listed in the electronic medical record when the UMC staff failed to inform her of the dangers associated with biphasic anaphylaxis when she left the hospital. Therefore, this Court should reverse the Thirteenth Circuit's decision regarding the R. 12(b)(6) motion to dismiss.

A. The Respondent Failed to Plead Sufficient Facts for Any Type of Strict Products Liability Claim in Haven.

The state of Haven adopted the Restatement (Third) of Torts: Products Liability (1998). (R. at 7). Therefore, a strict products liability claim can proceed under three different theories: (1) manufacturing defect, (2) design defect, or (3) inadequate warning. Restatement (Third) of Torts: Products Liability § 2 (1998). A plaintiff may not cumulate weak claims under these separate theories to make a stronger, overall strict products liability claim. *Cheshire Med. Ctr. v. W.R. Grace & Co.*, 49 F.3d 26, at 32 (1st Cir. 1995). However, evidence pertaining to one particular claim can used in evaluating the establishment of another. *Id.* In this case, the Respondent failed to plead any facts that show Firefly's EHR system departed from its intended design. (R. at 8) (citing Restatement (Third) of Torts: Products Liability §2(a)). Furthermore, the Respondent's complaint does not allege a reasonable, alternative design. (R. at 8) (citing Restatement (Third) of Torts: Products Liability §2(b)). Finally, the Respondent's complaint does not allege facts showing that alternative warnings or instructions beyond the explicit directive provided by Firefly would have reduced the foreseeable risks of harm. Because the Respondent's complaint has failed to satisfy the pleading burdens for all three strict product liability theories in Haven, the district court properly dismissed it pursuant to R. 12(b)(6).

1. Firefly's system did not depart from its intended design.

In order to establish a manufacturing defect claim, a plaintiff must show that a product departed from its intended design. Restatement (Third) of Torts: Products Liability § 2 cmt. c. Common examples of manufacturing defects include products that are physically flawed, damaged or incorrectly assembled. *Id.* The Eighth Circuit stated that a manufacturing defect

only exists when the item is considered substandard when compared to other identical units from the assembly process. *Depositors Ins. Co. v. Wal-Mart Stores, Inc.*, 506 F.3d 1092, 1095 (8th Cir. 2007) (citing *In Re Temporomandibular Joint Implants Prods. Liab. Litig.*, 97 F.3d 1050 (8th Cir. 1996). Therefore, a manufacturing defect claim is predicated upon a showing that a product has departed from its intended design.

In *Depositors Ins. Co.*, a plaintiff brought suit against the manufacturers of a lamp cord that was believed to be the cause of a house fire. *Id.* at 1094. The plaintiff failed to present evidence on the intended design of the cord, how the cord departed from that design and how the cord in question differed from the other cords produced by the manufacturer. *Id.* at 1095. Accordingly, the Eighth Circuit upheld the trial court's granting of summary judgment on the manufacturing defect claim. *Id.* In deciding an asbestos case, the Fifth Circuit pointed out that the chrysotile asbestos in question was no different than other chyrsotile asbestos produced by the manufacturer and therefore a manufacturing defect claim could not be sustained. *Cimino v. Raymark Industries, Inc.*, 151 F.3d 297 (5th Cir. 1998).

In this matter, Firefly's EHR software was designed to insert the word "none" in the known allergies field when no allergies are input for a patient. (R. at 4). A determination of whether this default is safe should not be a consideration in the manufacturing defect analysis. *See Cheshire Med. Ctr.*, 49 F.3d at 32. Here, the Respondent pleads no facts that show Firefly's EHR software departed from its intended design, and as the district court correctly held, the manufacturing defect claim could not survive a R. 12(b)(6) motion to dismiss. (R. at 8). Even if the passive inclusion of "none" in the known allergy field of Firefly's software departed from Firefly's intended design, the Respondent has failed to satisfy her burden to plead facts showing this.

2. The Respondent failed to plead facts sufficient to support a design defect claim.

In order to establish a design defect claim, a plaintiff must show that the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design, and that the omission of the alternative design renders the product not reasonably safe. Restatement (Third) of Torts: Products Liability § 2(b) (1998). As correctly pointed out by the district court, balancing product risks and utility is necessary to determine a reasonable expectation of safety in design. *Id.* cmt. a. Comment (a) of the Restatement further explains that a reasonably safe product still carries with it elements of risk that the consumer cannot be further protected against. *Id.* Comment (a) goes on to state that in the interest of fairness and efficiency, most courts agree that the balancing of risks and benefits in a product's design the knowledge of risks and risk-avoidance techniques reasonably available at the time of distribution must be considered. *Id.*

A prerequisite to the risk-utility balancing evaluation is having a reasonable alternative design to the product in dispute to serve as a standard of comparison. *Id.* cmt. d. Furthermore, minimal facts evidencing how the omission of the reasonable alternative design renders the product in question not reasonably safe must be present. *Id.* cmt. f. In this particular case, the Respondent's complaint fails to allege any alternative design and provides no facts from which a risk-utility balancing evaluation can take place. Therefore, the district court was correct to dismiss the Respondent's design defect claim pursuant to R. 2(b)(6).

a. The Respondent's complaint does not allege a reasonable, alternative design.

To establish a prima facie case of defect, the plaintiff must prove the availability of a feasible alternative design that would have reduced or prevented a plaintiff's harm. *Id.* Comment (f) of the Restatement states that the plaintiff has the burden pleading what other technology is available as an alternative design. *Id.* Illinois has adopted a similar standard to Haven with respect to showing a safer alternative design. *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, at 45 (Ill. 2002). In *Hansen*, the plaintiff filed a defective products claim for an intravenous catheter that was inadvertently disconnected and caused the patient to receive an embolism and die. *Id.* at 37. While the pleaded facts were not exhaustive, the plaintiff in this case pointed to a particular alternative design for the catheter connections that would have prevented inadvertent disconnection and was therefore able to proceed with a design defect claim. *Id.*

In another case the Fifth Circuit permitted a design defect claim to survive a summary judgment motion where the plaintiff alleged a specific alternative design that may have prevented the harm he suffered. *Malen v. MTD Products, Inc.*, 628 F.3d 296, at 308 (7th Cir. 2010). In *Malen*, the plaintiff's foot was severely injured when he got off his riding lawn mower in attempt to dislodge it from the curb. *Id.* at 299. The plaintiff was able to point to a retrofit service kit produced by MTD which would have operated as a fail-safe and prevented his injury from occurring. *Id.* at 308. By pleading this fact, the plaintiff's claim survived a motion for summary judgment. *Id.*

Unlike the cases presented, and contrary to the requirements of the Restatement, the Respondent has failed to even allege an alternative design in her complaint. (R. at 8). This

Court established that a plaintiff has the burden of pleading facts that make a cause of action plausible and not merely conceivable. *Twombly*, 550 U.S. at 570. In this particular case, the district court correctly ruled that the Respondent failed to meet the necessary burden of alleging a reasonable alternative design, and this Court should accordingly reverse Thirteenth Circuit's decision.

b. Firefly's system is reasonably safe when evaluated through a risk-utility analysis.

The utility and need for EHR systems such as Firefly's has been well-publicized for over a decade and is imperative to patient safety, improved efficiency in the medical community, and the lowering of health care costs in the U.S. In 2008, it was reported that medical errors resulted in an estimated 98,000 deaths per year. Sharona Hoffman & Andy Podgurski, *Finding A Cure: The Case for Regulation and Oversight of Electronic Health Record Systems*, 22 Harv. J.L. & Tech. 103, 105 (Fall 2008) [hereinafter *Finding A Cure*]. In addition to the deaths, medical errors also cost an estimated $29 billion each year. *Id.* It is believed that EHR systems could reduce the amount of deaths and costs associated with medical errors, and promote efficiency within the medical community. *Id.* In an earlier article published in the Berkeley Technology Law Journal, EHR systems were credited with improving the quality of patient care, accuracy of treatment decisions, achieving cost savings and promoting clinical research. Sharona Hoffman & Andy Podgurski, *E-Health Hazards: Provider Liability and Electronic Health Records Systems*, 24 Berkeley Tech. L.J. 1523, 1526 (Fall 2009) [hereinafter *E-Health Hazards*].

In 2004, President George W. Bush proposed plans to ensure the computerization of every American's health records within 10 years, and to create a National Health Information Network. *Finding a Cure*, *supra*, at 106. A little over five years later as part of the 2009

American Recovery and Reinvestment Act, the Health Information Technology for Economic and Clinical Heath Act (HITECH Act) was passed to facilitate the creation of a nation-wide health information technology infrastructure. American Recovery and Reinvestment Act, Pub. L. No. 111-5, §3001(b)(1-3), 123 Stat. 115, 23 (2009). Part of the HITECH Act's strategic plan is for every person in the United States to utilize a certified electronic health record by 2014. 42 U.S.C.A. § 300jj-11 (West 2011). The HITECH Act contemplates certification of technologies and systems to comply with standards that are to be developed in the future. *Id.* Technologies such as those developed by Firefly are the types of advancements that will fit into the HITECH Act's auspices and help accomplish its goals and objectives.

Even though the utility of EHR systems such as Firefly's is tremendous, the utility comes with some risks. There is noteworthy evidence of medical errors and tragedies that have occurred through the use of various types of EHR systems produced by a variety of vendors. *See, e.g., E-Health Hazards*, *supra*, at 1526-1528. In the current, early development stages of EHR systems, authorities expect that medical errors will occur as technology is more fully implemented and unanticipated problems are identified and resolved. *See Finding A Cure*, *supra*, at 120 (citing William W. Stead, *Rethinking Electronic Health Records to Better Achieve Quality and Safety Goals*, 58 Ann. Rev. Med. 35, 37 (2007)). Despite these inherent risks, the prospects of improving patient safety, increasing efficiency in the medical community and lowering health care costs justify the continued pursuit of developing and refining EHR systems. *See*, *e.g.*, *Finding a Cure*, *supra*, at 165. As pointed out by Hoffman and Podgurski, the appropriate forum from which to regulate and control the development EHR systems is through the legislature and regulations; not the courts. *Id.* The long-term benefits of EHR systems tip the scale in favor of pursuing the utility of EHR systems rather running from their risks.

Having established the overall utility of EHRs, the issue becomes whether Firefly's system presented risks that an alternative design would have reduced. Even though the Respondent did not allege a particular alternative design to Firefly's, the design can be compared to IBM's. (R. at 3). IBM's system provides final check flags that warn operators of any potential errors or omissions while converting the patient's record from paper to electronic format. *Id.* The IBM system requires operators to confirm potential omissions before proceeding with further data input. *Id.* This check system does provide an additional reminder to the software user, however the ability to confirm the potential omission is left strictly to the discretion of the user. There is no mechanism to detect if the user's disregard of the flag is consistent with the patient's paper record. It is possible that a user of the IBM system could ignore a flag reminder just like a user of Firefly's system could ignore a default "none" in the allergy field.

The additional reminder in the IBM system comes with additional costs and considerations. IBM's system is ten-percent more costly than the system offered by Firefly; a notable increase for a company competing in a booming industry such EHR systems. *Id.* Furthermore, the IBM system is not as simple to operate as Firefly's and requires additional training. *Id.* The increased training required to operate the IBM system represents indirect costs that are passed on to the consumer. Finally, the fact that the IBM system is more difficult to operate than Firefly's allows at least an inference that other errors not contemplated by the flag check system could occur in a patient's EHR created by IBM. Therefore, even though the IBM software provides its employees an additional reminder, there is no guarantee that this system will actually prevent the type of harm the Respondent sustained. Furthermore, issues such as increased costs and complexity of interface are risks that must be considered when evaluating the utility of the IBM system.

Comment (d) provides that a broad range of factors may be considered in determining whether an alternative design is reasonable, and whether its omission renders a product not reasonably safe. *Id.* at cmt. d. Some of the factors include the magnitude and probability of the foreseeable risks of harm, the instructions and warning accompanying the product, as well as the advantages and disadvantages of the product as designed. *Id.* Iowa has adopted § 2 of the Restatement and examines design defects in the same fashion as does Haven. *Wright v. Brooke Group Ltd.*, 652 N.W.2d 159 (Iowa 2002). In *Parish v. ICON Health & Fitness, Inc.*, the Iowa Supreme Court noted the utility of the trampoline when it was faced with analyzing its risks and potential alternative designs. 719 N.W.2d 540 (Iowa 2006). The plaintiff in this case offered no particular alternative design, and the court reasoned that the exercise benefits outweighed the risks and therefore the trampoline was reasonably safe even though an alternative design was omitted. *Id.* at 545. Like this case, the plaintiff in *Parish* did not allege an alternative design and was requesting the court to hold that the trampoline was not reasonably safe. *Id.*

When the factors of Comment (f) of the Restatement are applied in a risk-utility balancing test it is clear that Firefly's system is reasonably safe even in the absence of a check flag system. Therefore, because the Respondent's complaint has failed to allege any alternative design, or plead any facts that show Firefly's system is not reasonably safe, the district court correctly dismissed the Respondent's complaint.

3. The Respondent failed to plead any facts to support a warning defect claim.

The final category of product defect claims available in Haven is warning defects. The Restatement extends liability for warning defects when the foreseeable risk of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or

warnings, and the omission of the instructions or warning renders the product not reasonably safe. Restatement (Third) of Torts: Products Liability § 2(c) (1998). In this case, omission of instructions or warning is not at issue because Firefly provided customers a copy of their EHR and instructed them to verify its accuracy. (R. at 3). Like the design defect claim, the Respondent failed to allege any reasonable warning or instruction alternatives in her complaint. (R. at 8). Therefore, the adequacy of the instructions provided by Firefly is the only issue left for dispute.

Reasonableness is the standard by which the adequacy of warnings and instructions are measured. Restatement (Third) of Torts: Products Liability § 2 (c), cmt. i. (1998). Reasonable instructions and warnings inform persons how to use products safely and alert them about existence of risks so they may avoid harm when using the product. *Id.* Furthermore, the ability of a plaintiff to imagine a better warning in the aftermath of an incident does not establish that the warning or instruction provided with the product was inadequate. *Id.*

Florida evaluates strict product liability claims in accordance with the Restatement (Third) and *Scheman-Gonzalez v. Saber Mfg. Co.*, provides further guidance on distinguishing and determining the adequacy of instructions and warnings. 816 So. 2d 1133, 1139 (Fla. Dist. Ct. App. 4th Dist. 2002). In this case, the plaintiff was injured while attempting to mount an improperly sized tire to an automobile rim. *Id.* The only warning available to plaintiff was a label that gave the particular size of rim upon which the tire should be mounted. *Id.* The court found that this label provided usage instructions rather than warning about potential harm. *See Id.* at 1139-1140. The court further explained that warnings should make apparent the potential harmful consequences and that sufficiency and reasonableness of a warning or instruction are considered in light of whether a party knows of a particular danger. *See Id.*

When the Respondent's warning defect claim is evaluated through the parameters of the Restatement and in light of the standards clarified by Florida, it is apparent that the instructions provided by Firefly systems were reasonably adequate. The Respondent was well aware of her allergy to penicillin and had taken steps for many years to inform health care professionals of the allergy. (R. at 2). One of the most fundamental and obvious purposes of having an EHR is to provide unfamiliar health professionals with ready information about pertinent medical history in order to avoid obvious risks of harm. Accordingly, it is arguable that EHR systems vendors such as Firefly may be excused altogether from having to provide a warning or instruction. Nonetheless, Firefly provided specific instructions to verify the accuracy of an EHR with the sole and obvious purpose of preventing health care providers from obtaining inaccurate information. Therefore, because the Respondent's complaint has failed to allege any alternative instructions or facts showing that Firefly's instruction is unreasonably inadequate, her warning defect claim should be dismissed.

B. The Respondent Failed to Plead Sufficient Facts for a Strict Products Liability Claim in Grace.

Even if this Court finds that Grace law applies, the Respondent's complaint still fails to state a strict products liability claim upon which relief can be granted. Grace courts have adopted Section 402A of the Restatement (Second) of Torts (1965) in its entirety. *Turner v. Smith Bros., Inc.*, 30 Grace 144 (2006). In order to establish liability for a defective product under Section 402A, the plaintiff has the burden of proving that a product is in a defective condition that is unreasonably dangerous to the user or consumer. Restatement (Second) of Torts §402A(1) (1965). Even though Section 402A makes no distinction between manufacturing, design and warning defect claims, Grace analyzes strict products liability claims

according to these categories. *Turner*, 30 Grace at 153. The consumer expectation's test, which is similar to Section 402A's definition of an unreasonably dangerous product, is used when analyzing a manufacturing defect claim. (R. at 12). For design and warning defect claims, Grace utilizes a combination of the consumer expectations test and a risk-benefit analysis. *Id.* Regardless of whether the Respondent's claim is treated as either a manufacturing, design or warning defect, the Thirteenth Circuit's analysis is conclusory and the Respondent has plead no facts to show Firefly's system deviated from its design or that its utility is outweighed by its risk.

In contradiction of the authority it relied upon to determine liability for a manufacturing defect, the Thirteenth Circuit incorrectly concluded that a manufacturing defect must be present. In *Barker v. Lull Eng'g Co.*, the California Supreme court stated that a product is defective from manufacturing when it differs from a manufacturer's intended result. 20 Cal.3d 143, 149 (Cal. 1978). In *Escola v. Coca Cola Bottling Co.*, that court analyzed reusable, glass soda pop bottles and whether the particular bottle that injured the plaintiff deviated from the manufacturer's testing process. 24 Cal.2d 453 (Cal. 1944). The Thirteenth Circuit's reliance upon this authority to guide their analysis of a manufacturing defect warrants the same analysis that would take place under Haven law; determining whether a particular product deviates from its intended design. Firefly's software operated as it was designed and it insert a default "none" when no information was entered into a particular field. As with Haven law, the Respondent has plead no facts to show Firefly's software deviated from its intended design and therefore her manufacturing defect claim should be dismissed in Grace.

In analyzing design and defect warning cases, Grace uses a combination of the consumer expectation test along with the risk-benefit analysis. (R. at 12) (citing *Barker*, 20 Cal.3d at 413)). Even within the authority that Thirteenth Circuit relied upon to formulate its analysis of design

and warning defect cases, the weighing of the extent of the risks and the advantages posed by alternative designs is inevitable in many design defect cases. *See Barker*, 20 Cal.3d at (citing *Self v. General Motors Corp.*, 42 Cal. App. 3d 1 (Cal. App. 2d Dist. 1974) (*overruled by Soule v. General Motors Corp.*, 8 Cal. 4th 548 (Cal. 1994) (on the issue of prejudicial jury instructions relative to causation)). In this case, the Thirteenth Circuit's opinion does not consider any benefits offered by Firefly's EHR system. (R. at 12-13).

In *Mikolajczyk v. Ford Motor Co.*, the Illinois Supreme Court stated that when sufficient evidence is presented to show that the jury should engage in a risk-utility analysis, the broader risk-utility test should be utilized and the consumer expectation test should become one factor in a broader analysis. *Id.* at 556. The Respondent has alleged no facts which would indicate that, even if Grace followed the Illinois posture, her case would prevail under a consumer expectations' test. It has already been shown that the Respondent's design defect claim should fail under Haven law because the utility and benefits of an EHR system like Firefly's are tremendous. Therefore, in the absence of any pleading by the Respondent that Firefly's system fails the consumer expectation test, her design defect claim under Grace law should also be dismissed.

In another strict products liability case that involved the issue of combining the consumer expectation test with risk-benefit test, the Illinois Supreme Court found that a product could be deemed safe under the consumer expectations test, however it may fail under the risk-benefits analysis. *Calles v. Scripto-Tokai Corp.*, 224 Ill. 2d 247 (Ill. 2007). In *Calles*, a child died as a result of a home fire she started while using a butane lighter. *Id.* at 252. The Illinois Supreme Court stated that the butane lighter performed in accordance to the consumer expectations, however when considering the child as a foreseeable user, it's risk-utility was an issue for the

jury to decide and thus affirmed the appellate court's decision in reversing summary judgment. *Id.* at 265.

Two important distinctions can be made between *Calles* and the Respondent's case. First, the court in *Calles* was considering a child as a reasonably foreseeable user of the product. Contrastingly, the Respondent is a well-educated adult who is aware of the risk associated with the product in question which is actually intended to protect against that particular harm. Furthermore, she failed to heed a provided instruction that accompanied the product. Second, and of central importance to the procedural posture of the Respondent's case, is the fact that the plaintiff in *Calles* offered affidavits of expert witnesses, provided information on the costs to add child safety features to the lighters, and provided information that the lighter manufacturer was aware of the danger posed by children using their products in previous home fires. *Id.* at 252. The Respondent in this case has offered no information to show that Firefly's system fails the consumer expectation test or the broader, risk-utility analysis.

In *Turner v. International Harvester Co.*, the issue of the consumer expectations test with respect to a particular consumer was addressed. 133 N.J. Super. 277 (Law Div. 1975). In *Turner*, an owner of a used pickup truck was killed when the cab of the truck suddenly dropped on him while he was underneath it making a repair. *Id.* at 292. In analyzing whether the truck was an unreasonably dangerous product, the court stated that a product may be analyzed as it affects a particular purchaser or user instead of how it may affect the general public. *Id.* In this case, the injured purchaser was familiar with the hazards and processes of repairing a truck, and this familiarity with the risks became a consideration for the court. *See Id.* Accordingly, in determining whether Firefly's system was unreasonably dangerous, the Respondent's familiarity with her penicillin allergy along with evidence of her previous actions to warn medical

professionals of her allergy should be considered when determining if Firefly's system was unreasonably dangerous.

When the Thirteenth Circuit evaluated the design and warning defect aspects of the Respondent's claim, it erroneously treated a Firefly Systems' employee as a consumer or user. This error has caused Firefly's system's lack of a flag warning system to be mischaracterized as a failure to warn. (*See* R. at 13). Comment (l) of Section 402A defines the types of individuals to which the title "user" or "consumer" should be extended. Restatement (Second) of Torts § 402 A cmt. l. In discussing employees who use products, Comment (l) clearly distinguishes employees of a final purchaser or ultimate buyer as possibly being considered users or consumers; but not the employees of the seller. *Id.* With Firefly's system, the patients are the final purchasers, and the medical professionals who review the information for the patient's benefit are the users of the information service provided by Firefly. Firefly's software is merely a tool used to generate or deliver an EHR in a useable format to the patient and medical professional. Any type of warning system which calls attention to an allergy field being left in its default state during EHR creation would appear only to a Firefly employee. Therefore, the Thirteenth Circuit erroneously and in conclusory fashion stated that the lack of a flag warning system constituted a failure to warn on Firefly's part.

In addition to erroneously concluding that Firefly had failed to provide users of their product with a warning, the Thirteenth Circuit failed to consider the warning instructions provided to Firefly customers. (R. at 12-13). Comment (j) of Section 402A states that when a warning is given, a seller may reasonably assume that it will be read and heeded. *Id.* cmt j. Furthermore, Comment (j) states that when a product has a warning that makes the product safe for use if followed, the product is not in defective condition nor is it unreasonably dangerous. *Id.*

Firefly provided instructions to its customers to review their prepared EHR in order to verify its accuracy once they received it. (R. at 3). In this case, the Respondent, who was well aware of her penicillin allergy and had previously warned medical professionals of her allergy, did not heed the warning and lost the flash-drive that contained her EHR. (R. at 2-3). Therefore, because warning instructions were provided to the Respondent and she failed to heed them, the Thirteenth Circuit should not have concluded that Firefly's system was unreasonably safe.

In this case, the Respondent has failed to plead any facts that would support a strict products liability claim in Grace. The respondent has failed to allege that the risk associated with Firefly's system, when considered in light of the warning instructions given and the utility that EHR systems provide, makes it unreasonably dangerous and therefore defective. Accordingly, the Thirteenth Circuit was incorrect when it reversed the district court's dismissal of Respondent's complaint.

C. The Respondent Failed to Show That Firefly's System is a But-for and Proximate Cause of Harm.

Two important elements of a strict products liability claim that must be proven in either Haven or Grace, are that the alleged defective product is the but-for and proximate cause of harm. A Haven products liability statute establishes this requirement. Haven Rev. Code § 1018.11. This requirement is also true in jurisdictions that may lack such a statute but have adopted Section 402A. *E.g.*, *Peck v. Ford Motor Co.*, 603 F.2d 1240 (7th Cir. 1979). The Respondent has failed to show that Firefly's system is either a but-for or proximate cause of the condition that caused the Respondent's death; biphasic anaphylaxis. Contrary to the district court's characterization of biphasic anaphylaxis as being relatively rare, medical research shows that such secondary anaphylactic reactions occur rather frequently. E. Brazil & A.F.

MacNamara, *"Not So Immediate" Hypersensitivity – The Danger of Biphasic Anaphylactic Reactions*, 15 J. of Accid. Emerg. Med. 252, 252 (1998). Furthermore, medical research suggests that persons who experience an initial anaphylactic reaction should undergo inpatient observation for a minimum of 24 hours, and should only be discharged from a hospital after being educated in the recognition and treatment of biphasic anaphylaxis. *Id.* at 253. (See also Alberto Martelli, *Anaphylaxis in the Emergency Department: A Paediatric Perspective: Biphasic Anaphylaxis*, 4 Current Opinion in Allergy and Clinical Immunology 327 (2008), http://www.medscape.org/viewarticle/583328_7.)

There are varying approaches among courts to analyzing causation under the Restatement (Third) and Section 402 A. However, broadly speaking it is consistently found that in order to establish whether a product is the but-for cause of harm, a plaintiff must first demonstrate that the product was defective and that were it not for the defect, the injury would not have occurred. *E.g.*, *Joy v. Bell Helicopter Textron*, 999 F.2d 549 (D.C. Cir. 1993). Some courts have analyzed the issue of but-for cause collectively with that of proximate cause. *Payne v. Soft Sheen Prods.*, 486 A.2d 712 (D.C. 1985). In deciding a warning defect claim, the court in *Payne* found that a rebuttable presumption that a user has read a product warning exists, and that in the absence of evidence to rebut that presumption, causation cannot be established. *Id.* at 725.

In *Peck*, the Seventh Circuit Court of Appeals applied Indiana law which has adopted Section 402A; clearly the analysis which is most favorable to the Respondent's case. *Peck*, 603 F.2d at 1244. The plaintiff in this case was injured when the truck he was driving collided with another truck that was broken down and sitting still in a lane of traffic. *Id.* at 1242. The broken down truck, manufactured by the defendant Ford Motor Company, had encountered a mechanical malfunction and was unable to be pulled off to the shoulder of a multi-lane highway.

Id. The plaintiff was unable to see the Ford truck until a van he was following suddenly merged left to avoid the Ford, thus leaving the plaintiff insufficient time to react and avoid the collision. There were several other factors involved in this case that affected but-for and proximate causation. These factors included the disabled truck's driver's failure to properly place emergency warning triangles on the highway and contact police for assistance in directing traffic around his truck. Additionally, the plaintiff was following the van too closely thus restricting his visibility of the road in front of him. *Id.*

In analyzing *Peck*, the Seventh Circuit noted that it did not have definitive Indiana authority for a matter involving circumstances similar to that case, so in ruling on the matter the court gave great consideration to the fact that the legal standards of proximate cause are based on policy and on other Indiana precedent. *Id.* at 1243. The court focused on whether it was objectively foreseeable that the manufacturing defect of the Ford truck would create liability in a situation that involved such other intervening causal factors. *See Id.* at 1247. The court further noted that foreseeability does not mean that a precise hazard or the exact consequences that were encountered should have been foreseen. *Id.* at 1246 (*citing New York, New Haven & Hartford R. Co. v. Leary*, 204 F.2d 461, 467 (1st Cir. 1953). The Seventh Circuit, in quoting the Indiana Supreme court, stated that a manufacturer is not the insurer against accidents and is not obligated to produce only accident- free products. *Id.* at 1247 (*quoting J. I. Case Company v. Sandefur*, 245 Ind. 213, 222 (Ind. 1960)). In this case, the Seventh Circuit decided that it was against policy to extend liability to Ford. *Id.*

Because the services and products related to EHRs is an emerging field, there is a notable absence of case law involving this technology and product liability claims. Therefore, cases such as *Peck* are very instructive in deciding causation in this matter. As was the case in *Peck*, there

is an absence of authority on point with the particular circumstances of the Respondent's claim. As was also seen in *Peck*, there are notable intervening factors and acts of negligence by others that can be attributed to the cause of the Respondent's harm. Central to this consideration is the fact that the Respondent died as a result of biphasic anaphylaxis and not the initial allergic reaction to penicillin. UMC and Dr. Tam discharged the Respondent from the hospital with no instructions or measures to counter the well-known possibility she could suffer biphasic anaphylaxis up to 72 hours after the initial reaction. (R. at 4). Furthermore, a delay in the arrival of emergency medical help for the biphasic anaphylaxis was determined to be a contributing factor to the Respondent's death. *Id.* In light of the presence of other cause factors and lack of probative authority, this court should analyze the Respondent's claim in similar fashion as the Seventh Circuit did in *Peck*.

One of the more compelling reasons that Firefly's system is not the proximate cause of the Respondent's death is based in policy. As pointed out in *Peck*, and numerous other cases involving products liability, policy is an extremely important consideration in extending causation. *E.g., Peck*, 603 F.2d at 1242. Extending liability to Firefly for a secondary medical condition that was at least partially caused by medical provider negligence could open the door for vast numbers of plaintiffs who suffer any secondary medical condition after a hospital or physician has used a particular EHR vendor's system. Such an extension of liability would cause EHR vendors to expend vast amounts of capital to create EHR systems that are error-proof and contemplate an innumerable amount of secondary medical conditions. The long-term benefits of developing EHR systems and satisfying U.S. conversion date mandates established through the HITECH Act justify the need for EHR vendors to continue developing their systems. However, if EHR vendors are faced with need to invest significant capital to make their systems perfect

before introducing them to the medical community would drastically increase the costs of EHRs to patients and healthcare organizations. These negative effects would create a chilling effect for the development of EHR systems, and would thus be detrimental to American healthcare. Therefore, the overwhelming policy considerations justify finding that Firefly's system is not the proximate cause of the Respondent's death.

The Respondent has failed to plead any facts that show Firefly's system was the but-for cause of her death. The are several facts that show that Respondent's death could have been avoided even though there was an error in Firefly's system. First, the Respondent died from a secondary medical condition, not the initial allergic reaction that an EHR should protect against. Second, she failed to heed warning instructions to verify the accuracy of her electronic medical record. Third, the hospital and doctors discharged her without any instructions or mitigating measures to protect against biphasic anaphylaxis. And finally, the delay in emergency medical help has been established as a contributory factor in her death. Additionally, the overwhelming policy considerations that point to the need to foster development of EHR systems show that Firefly's system should not be deemed a proximate cause.

In conclusion, the Respondent has failed plead facts showing that Firefly's system contained a manufacturing, design or warning defect in accordance with Haven law. Alternatively, the Respondent has failed to show that Firefly's system was defective and unreasonably dangerous in accordance with Grace law. Finally, the Respondent has failed to show that any error in Firefly's system is a but-for and proximate cause of her death as required by both Haven and Grace law. Accordingly, this court should reverse the Thirteenth Circuit's decision and uphold the trial court's dismissal of the Respondent's claim pursuant to R. 12(b)(6).

Conclusion

The Thirteenth Circuit incorrectly held that Grace law applies in this matter. Its decision did not weigh Haven's state interests in the outcome of this dispute nor did it acknowledge any facts that indicate Haven's significant relationship to the matter. Because the appellate court failed to properly weigh all of the factors listed under § 6(2) and § 145(2) of the Restatement (Second) Conflict of Laws, this Court should reverse the Thirteenth Circuit's decision with regards to the conflict of laws issue.

The Thirteenth Circuit incorrectly held that the Respondent has stated a strict products liability claim upon which relief can be granted. The Respondent failed to plead facts sufficient to overcome a Fed. R. Civ. P. 12(b)(6) motion to dismiss under either Grace or Haven law. No alternative designs or warnings were alleged by the Respondent, and she has failed to present any facts which show that Firefly's system is unreasonably dangerous or that its risks outweigh its utility. Finally, the Respondent failed to point out any error in Firefly's system that would be considered a plausible but-for or proximate cause of her harm. Accordingly, this Court should reverse the Thirteenth Circuit's decision with regards to the strict product liability claims.

Respectfully Submitted,

_____
Team 5 P
Counsel for the Petitioner

Appendix A

Decision of United States District Court for the District of Haven

In Re Estate of Zoe Washburne v. Firefly Systems, Inc., No. XX-XX-XXXXX,
(U.S. Dist. Haven Mar. 20, 2009)

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAVEN

In re Estate of Zoe Washburne,

Plaintiff

-V-

Firefly Systems, Inc.,

Defendant

No. XX-XX-XXXXX

March 20, 2009, Decided

OPINION

PARKER, *District Judge*

Presently before the Court is Defendant's motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. For the reasons that follow, the Court holds that Plaintiff has failed to show a reasonable alternative design for her strict product liability claim. Accordingly, Defendant's Motion will be **GRANTED.**

I. Background

A. Factual Background

Zoe Washburne was born August 21, 1982. Prior to the events that gave rise to this suit, she was a middle school teacher at River Middle School, located in Whitefall, a small town in the state of Grace. Around age five, it was discovered by her parents that she suffered from an allergy to the common antibiotic penicillin. Since that discovery, Washburne and her parents have taken active steps to avoid exposure to penicillin, including notifying new doctors and educating themselves about the allergy.

At some point during late 2008, Washburne received a letter in the mail from her local primary care physician, Dr. Kaylee Frye, stating that Dr. Frye's practice would be converting to an electronic medical recordkeeping system; one that digitizes a patient's medical record to allow for easy and instant transmission between local physicians as well as out of town physicians in the event of an emergency while traveling. The letter stated that Washburne could receive a USB flash-drive containing a copy of her electronic medical record for a twenty-five dollar fee. Dr. Frye's letter further stated that several companies offered such services, but that her practice would be using a system designed by Firefly Systems, Inc., a Delaware corporation with its principle place of business in Haven. Firefly offered a lower cost for the product and had been advertising aggressively in recent months with hospitals nationwide. Firefly's software is mass-produced and they do not customize the program or individually tailor it to different hospitals. According to Washburne's complaint, Washburne wrote a personal check payable for twenty-five dollars to Firefly. Dr. Frye then provided the paper copy of Washburne's medical record to Firefly in order to digitize her health records. After the records were transferred by Firefly, Firefly securely shipped the software directly to Dr.

Frye with delivery confirmation. Washburne subsequently received her USB flash-drive copy of her records, but she never had the opportunity to review them and has since misplaced the USB drive.

The premise of Firefly's business was simple: employees of Firefly would work with hospitals to record and digitize a patient's medical record, including personal and family past medical histories, as well as notes, charts, and records of procedures both past and present. This record would then be securely stored on Firefly's servers, which were integrated both directly with participating hospital systems as well as through a secure web portal to provide access to physicians and healthcare providers that did not have a direct relationship with Firefly. When entering a patient's data, Firefly employees are instructed to make sure that the electronic data they input matches the exact paper record. In addition, Firefly customers are instructed to verify the electronic records, once returned, before disposing of the original paper copies.

Electronic medical records storage is a booming industry. Firefly's largest competitor, IBM, had developed a similar system. IBM was the first-to-market with their system. The IBM system is ten percent more costly; however, the IBM system has several technical advantages. Most noticeably, the IBM system has what it calls, "final check flag system." The flag system reviews the operator's inputs and warns of any potential errors or omissions in converting the patient's record from paper to electronic format. For example, the flag system uses a yellow flag warning for minor omissions such as a patient's hair color or eye color. On the other hand, a red flag appears for more serious omissions such as family history or known allergies. The user cannot continue with a red flag warning until he or she confirms that the red flag data field was entered correctly. The IBM system is somewhat more difficult to operate than Firefly's and requires additional training.

On Wednesday, September 10, 2008, Washburne, while acting as a chaperone on a school-sponsored field trip to Capitol City, Haven, began experiencing acute abdominal pain. At first, Washburne dismissed the pain as mere indigestion, but shortly after she began feeling feverish and sick to her stomach. Washburne notified the fellow teachers on the trip and was shortly thereafter taken to University Medical Center, a hospital serving the greater Capitol City Metropolitan area.

Upon arriving at the hospital, Washburne was rushed to the emergency room, during which time the pain she was experiencing had grown so severe that she was non-responsive and unconscious. Washburne's fellow teacher and longtime friend, Vince Gordon, was present on the field trip and he accompanied Washburne to the hospital. Gordon provided the hospital's staff with Washburne's identification, but he had no knowledge of any of Washburne's allergies or family medical history. Using Washburne's driver's license information, the hospital staff was able to access and retrieve Washburne's electronic medical file via the web portal access from Firefly. With the medical record in hand, the staff on call made a preliminary diagnosis of appendicitis.

At some point after the emergency room staff had retrieved the medical record, Dr. Simon Tam, the surgeon on call, arrived and proceeded to verify the emergency room staff's diagnosis of appendicitis. Dr. Tam concluded that immediate surgery was required to remove Washburne's appendix.

Dr. Tam, possessing only the electronic version of Washburne's chart provided by Firefly, proceeded with the operation. Unfortunately, the electronic medical chart, while accurate in all other respects, was missing any reference to Washburne's penicillin allergy. As shown in the record, the static copy of Washburne's file that was relied upon by Dr. Tam and the hospital staff contained nothing in the "Known Allergies" field. As a default, Firefly's software is designed to insert the word "NONE" in the "Known Allergies" field if no allergies are input for a patient. While it is unclear why the known allergies field of Washburne's record as obtained by University Medical Center is blank, it is undisputed that the information

on the paper record that Dr. Frye submitted to Firefly *did* contain the proper penicillin allergy warning, as does the copy of the record stored locally on Firefly's servers.

Following the surgery, Dr. Tam and his surgical assistants administered penicillin as common practice to avoid the risk of post-surgical infection. Approximately five minutes after the penicillin was administered, Washburne began to experience respiratory problems that were common for those with a penicillin allergy. The hospital's on-call staff responded to the situation and quickly administered epinephrine, which alleviated Washburne's symptoms. At this point, the hospital became aware of Washburne's penicillin allergy for the first time due to her reaction, but no other issues arose during her stay at the hospital.

Washburne recovered quickly and was discharged from the hospital on Friday, September 12. By this time Washburne's school was fully informed of her experience. While Washburne had undergone surgery and recovery in the hospital, the school had sent a substitute chaperone to meet the field trip class and bring them back home. With her responsibilities to her students no longer present, Washburne decided to meet with her parents upon her discharge from the hospital and travel back with them to their home in Grace.

The majority of the Washburne family's drive home passed without incident. However, at some point after the family had crossed into Grace, Washburne collapsed and was unable to be revived by her parents. Emergency medical technicians, responding to the 9-1-1 call placed by her parents, arrived on the scene but were unable to revive Washburne. The damage caused by the reaction, coupled with the delay before help could arrive was too great to overcome; Washburne was pronounced dead at the scene.

It was later determined that Washburne's second reaction was the result of biphasic anaphylaxis, a relatively rare form of reaction linked directly to the initial anaphylaxis reaction, in which symptoms can reoccur up to 72 hours following the initial reaction, despite the lack of further exposure to the allergen.

B. Procedural Background

Plaintiff's estate subsequently brought the instant suit against Firefly seeking recovery for the wrongful death of Zoe Washburne and damages for the pain and suffering as a result. Washburne's complaint set forth three claims against Firefly Systems: (1) breach of express warranty by Firefly; (2) breach of implied warranty of merchantability; and (3) strict product liability based upon a manufacturing, design, and warning defect.

Plaintiffs initially filed their Complaint in the Peterson County Court of Common Pleas located in Haven. Defendant removed the case to this Court based on diversity of citizenship, pursuant to 28 U.S.C. § 1332.

On March 18, 2009, the Defendant, Firefly Systems, Inc. filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. The Plaintiff filed a response the following day.

II. Parties Contentions

A. Defendant

Defendant filed a Motion to Dismiss Plaintiff's claims on the alternative grounds that (1) Haven law should apply to this case under *lex loci delicti*, and (2) even if *lex loci delicti* does not apply, Haven substantive law applies under the most significant relationship test of § 145(2) of the Restatement (Second) Conflict of Laws. Defendant asserts that under Haven law, The Restatement (Third) of Torts: Products Liability applies, and Plaintiff must show a reasonable alternative design as a prerequisite of a products liability claim. Further, the Defendant argues that under the Restatement (Third) of Products Liability, an

implied warranty of merchantability claim is duplicative of a products liability claim. Additionally, Defendant draws the Courts attention to the public policy benefits of having electronic medical records storage systems. Lastly, as Defendant states, a claim of a breach of express warranty is meritless because Plaintiff had no expectation or promise from the Defendant.

Central to the Defendant's argument is the premise that Haven Law applies. Defendant argues that because Plaintiff was administered penicillin in Haven, under *lex loci delicti* this is where the injury occurred; therefore, Haven law should apply. Alternatively, Defendant contends that even if *lex loci delicti* does not apply, Haven law should still apply under the modern "most significant relationship" test. RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 145(2) (1971). Under this test, according to the Defendant, the state with the "most significant relationship" to the litigation is the state of Haven. Thus, according to Plaintiff, under either *lex loci delicti* or the most significant relationship test, Haven law should apply to this case.

B. Plaintiff

Plaintiff opposes Defendant's Motion to Dismiss on the grounds that (1) *lex loci delicti* is no longer good law in the state of Haven, and (2) Grace substantive law applies under the most significant relationship test of § 145(2) of the Restatement (Second) Conflict of Laws (1971). Plaintiff asserts that under the most significant relationship test, Grace law and the Restatement (Second) of Torts § 402A (1977) governs the resolution of this case. Plaintiff argues that the Restatement (Second) does not require proof of a reasonable alternative design, nor does it prohibit an implied warranty of merchantability claim from being brought separately. As the Plaintiff puts it, the Uniform Commercial Code (UCC) has been adopted by forty-nine states (excluding Louisiana), while the Restatement (Third) has only been adopted by only a limited number of jurisdictions. Plaintiff argues that there has been no affirmative act by the Grace legislature to restrict an independent claim from being brought under the UCC; moreover, the Restatement (Second) does not prohibit independent claims. Further, personal injury damages are recoverable as consequential damages in a breach of implied warranty case. Therefore, the Plaintiff argues that because Grace has not adopted the Restatement (Third) of Products Liability, there is no limitation on bringing an implied warranty claim under the UCC. Moreover, Plaintiff asserts that even if the Restatement (Third) applies, it does not prohibit bringing separate claims of strict product liability and a breach of the implied warranty of merchantability.

The crux of Plaintiff's argument is that Grace law should govern this case. Plaintiff contends that the injury suffered was the death that eventually occurred in Grace. According to Plaintiff, Grace is the state with the most significant relationship to this litigation. Plaintiff is domiciled in Grace, Plaintiff is employed in Grace, the Plaintiff's primary care physician is located in Grace, the Plaintiff's records were provided to the Defendant from Dr. Frye in the state of Grace, and the Plaintiff perished in Grace. Therefore, according the Plaintiff, Grace law and the Restatement (Second) should govern this case.

III. Standard for Rule 12(b)(6) Motion to Dismiss

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). When ruling on a defendant's 12(b)(6) motion to dismiss, a Judge must accept all the factual allegations in a complaint as true. Erickson v. Pardus, 551 U.S. 89, 94 (2007). A Court will view the facts alleged in the light most favorable to the plaintiff. Christopher v. Harbury, 536 U.S. 403, 406 (2002). A complaint in the pleading stage does not need to allege detailed factual allegations; however, the Court is not required to accept legal conclusions that are couched as factual allegations. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). A well-pleaded complaint may proceed even if it appears that recovery is remote and unlikely. Id.

A Rule 12(b)(6) motion to dismiss tests the legal sufficiency of a complaint. Randall v. United States, 30 F.3d 518, 522 (4th Cir. 1994). In deciding such a motion, a court must first be mindful of the liberal pleading standards under Rule 8, which require only "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8. A court must take "the material allegations of the complaint" as admitted and liberally construe the complaint in favor of a plaintiff. Jenkins v. McKeithen, 395 U.S. 411, 421 (1969).

IV. Discussion

A. Conflict of Laws

In an action based upon diversity of citizenship, as is this case, a district court must apply the substantive law, including choice of law rules, of the state in which it sits. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 495-96, (1941); *Day & Zimmerman*, *Inc. v. Challoner*, 423 U.S. 3, 4 (1975). In this case, those are the laws of the state of Haven. Before a conflict of laws issues arises, there must actually be a conflict between the laws of the interested states. Oil Shipping (Bunkering) B.V. v. Sonmez Denizcilik Ve Ticaret A.S., 10 F.3d 1015, 1018 (3d Cir. 1993). If the laws of the forum state and those of the other interested state do not differ, there is a "false conflict" and the court need not decide the choice-of-law issue. In re Complaint of Bankers Trust Co., 752 F.2d 874, 882 (3d Cir. 1984).

Here, there is a true conflict. The conflict exists between the substantive law of the states of Haven and Grace; Haven uses the Restatement (Third) of Torts: Product Liability, while Grace adheres to the Restatement (Second). Under these differing approaches, the result of the case is likely to be inconsistent.

Haven law is the applicable law of the forum state. Although once a strong proponent of *lex loci delicti*, Haven state courts have in recent years shifted to an interest-weighing approach. *See inter alia*, *Booker v. InGen*, *Inc.*, 241 Haven 17, 24 (2007). The Supreme Court of Haven, in *Booker*, joined many other states in applying the principles of the Restatement (Second) of Conflict of Laws, which calls on courts to apply the law of the state which, with respect to the issue, has the "most significant relationship" to the occurrence and the parties. *Id.* at 26. Under well-settled Haven law, when confronted with a conflict of laws issue in a tort action, analysis must begin with Section 146 of the Restatement (Second) Conflict of Laws (1971). Pursuant to this section, a presumption is created that the law of the place of the injury controls unless another jurisdiction has a more significant relationship to the lawsuit. To determine the state with the most significant relationship, a court must then proceed to consider the general principles set forth in Section 145. The factors within this section are: (1) the place of the injury; (2) the place where the conduct causing the injury occurred; (3) the domicile, residence, nationality, place of incorporation, and place of business of the parties; (4) the place where the relationship between the parties, if any, is located; and (5) any factors under Section 6 which the court may deem relevant to the litigation. All of these factors are to be evaluated according to their relative importance to the case. RESTATEMENT (SECOND) CONFLICT OF LAWS § 145(2) (1971).

In the instant case, the Court holds that Haven has the most significant relationship to the litigation. The injury occurred in Haven, the conduct that caused the injury occurred in Haven, the place where the relationship between the parties is centered, *for this particular issue*, was Haven, and the Defendant's principal place of business is Haven. The Court acknowledges that, although the domicile of the Plaintiff is Grace and the initial relationship between the parties was created in Grace, these two factors are insufficient to outweigh the remaining factors that call for application of Haven law. Accordingly, we hold that under the choice-of-law rules of Haven, Haven substantive law applies to the adjudication of the issues.

B. Strict Product Liability

Haven law, which therefore controls the resolution of this case, has expressly adopted the Restatement (Third) of Torts: Products Liability (1998). Accordingly, a plaintiff may bring suit against a manufacturer or seller of a defective product under the theories of (1) manufacturing defect, (2) defective design, or (3) inadequate warning or failure to warn. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIAB. § 2. Further, under either a design or warning defect claim, a Plaintiff must show that a reasonable alternative design was available. *Id.* In addition, under Haven products liability law, a Plaintiff must show that the Defendant's product was the "but for" cause and the proximate cause of the Plaintiff's harm. *Id.* § 2 cmt. q (1998); *see also* HAVEN REV. CODE § 1018.11.

To prevail under a manufacturing defect theory, a plaintiff must show that the product departs from its intended design even though all possible care was exercised in preparing and marketing the product. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIAB. § 2(A) (1998). The plaintiff bears the burden of proving the defect's existence; that the product was not manufactured according to its design specifications. *Toms v. J.C. Penney Co.*, 304 Fed. Appx. 121 (3d Cir. 2008). The Haven Supreme Court has set forth guiding criteria by which a plaintiff could demonstrate the existence of a manufacturing defect: (1) direct evidence that the defect arose in the hands of the manufacturer; (2) circumstantial evidence which would create an inference that a defect existed prior to sale; or (3) by negating other causes of the failure of the product for which the defendant would not be responsible, in order to further an inference that the defect was attributable to the manufacturer. *Marcus v. Valley Hill, Inc.*, 301 Haven 197 (2006).

In the present case we find no manufacturing defect. Firefly's product was intended to passively accept inserted information, including the term "NONE", and it did no more or no less than its designers intended. Under a "but for" causation test, this injury likely would have still occurred even with a warning system that could have alerted the Firefly company's anonymous transcriber of the Plaintiff's paper medical record about this omitted fact when the electronic version was being produced. Furthermore, it cannot be said that the Defendant's product was the proximate cause of Plaintiff's harm. Reliance on the electronic record was a choice made by the treating hospital, in lieu of searching for Plaintiff's physician to check that doctor's records or memory concerning the Plaintiff. It is foreseeable that there will be some limited level of error. That is the case even with a paper record being utilized in a hospital emergency room under urgent care conditions. We find Defendant's public policy arguments in favor of its electronic medical records product particularly persuasive. This Court observes that both the Haven legislature and Congress have appropriated funds to encourage medical records cost savings through conversion to health information technology. The legislators having decided upon the need for a health care system that operates with lower costs, so it is a matter of public policy in this state and nation that reasonable measures to reduce health care costs should be fostered.

To prevail on a theory of defective design, a plaintiff must demonstrate that the foreseeable risks of harm by the product could have been reduced by implementing a reasonable alternative design. In addition, the omission of a reasonable alternative design renders the product unsafe. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIAB. § 2(B) (1998). In the case of a design defect, the consumer is not usually knowledgeable enough to form an opinion on a reasonable expectation as to how safe the design of a product should be. Consequently, a risk-utility balancing is necessary; society benefits not when products are excessively safe at a higher cost to the manufacturer, but when the optimal amount of product safety is achieved. *Id*. cmt a.

Here, Plaintiff has not alleged or shown a reasonable alternative design in their complaint. Accordingly, the Plaintiffs have failed to state a claim under Rule 12(b)(6).

To establish a claim for a warning defect, a plaintiff must show that the foreseeable risks of harm could have been avoided or reduced by reasonable instructions or warnings, and that the omission of the warning renders the product not reasonably safe. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIAB. § 2(C) (1998). Subsection (c) adopts a reasonableness test for warning defects. *Id*. cmt. i. Generally, a seller is not liable for failing to warn of risks and risk-avoidance measures that should be obvious to the foreseeable product user. *Id*. cmt. j.

In the instant case, Plaintiff has not alleged a reasonable warning alternative in their complaint. Moreover, "but for" causation considers what the proper action during records conversion should have achieved. 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 would decrease the likelihood that the allergy column was left in its default "NONE," we cannot say that under a risk-utility balancing that the additional software design, installation, and validation costs that would have been imposed upon the Defendant-manufacturer outweighs the risk.

A. Implied Warranty of Merchantability

We now address whether Plaintiff can bring an independent claim based upon a breach of the implied warranty of merchantability. We hold that Plaintiff may not. Under the 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 LIAB. § 2 CMT. N (1998). These claims are based on the same risk-utility analysis and would result in confusion or inconsistent verdicts. *Id.* Furthermore, this analysis applies to manufacturing defects. A Restatement (Third) § 2(a) manufacturing defect claim and an implied warranty of merchantability claim rest on the same factual predicate; therefore, the claims are duplicative and may not be brought together. *Id*. cmt. n.

B. Express Warranty

Plaintiff's express warranty claim fails. As a result, the express warranty claim is dismissed. Express warranty is defined in the UCC § 2-213 as a promise from the seller to the buyer that the goods shall conform to that promise or description of the goods. Plaintiff's claim fails due to the fact that she was not promised anything, nor did the Defendant represent anything to her. It was Dr. Frye, and not the Defendant, who informed the Plaintiff about converting her medical records to an electronic system.

V. Conclusion

For the reasons discussed above, the Defendant's motion to dismiss is granted.

ORDER

AND NOW, this 20th day of March, 2009, upon consideration of all motions filed, and all responses thereto, it is hereby **ORDERED:**

Defendant Firefly Systems' motion to dismiss is **GRANTED**.

Appendix B

Opinion of the United States Court of Appeals for the Thirteenth Circuit

In Re Estate of Zoe Washburne v. Firefly Systems, Inc.,

No. XX-XX-XXXXX, (U.S. 13th. Cir. 2010) (unpublished)

And

Writ of Certiorari

UNITED STATES COURT OF APPEALS

FOR THE THIRTEENTH CIRCUIT

In re Estate of Zoe Washburne,

Appellant

-V-
Firefly Systems, Inc.,

Appellee

No. XX-XX-XXXXX

August 26, 2010, Decided

Before SAFF, NIA, and EARLY, Circuit Judges

EARLY, *Circuit Judge*

Plaintiff-Appellant appeals from the district court's decision granting Defendant-Appellee's motion to dismiss. For the following reasons, we **AFFIRM IN PART, REVERSE IN PART**.

I. Introduction

The Appellant, the estate of Zoe Washburne, brought suit against the Appellee, Firefly Systems, Inc., alleging three claims: (1) breach of express warranty; (2) breach of implied warranty of merchantability; and (3) strict product liability alleging a manufacturing, design, and warning defect. It is undisputed that Zoe Washburne died following an allergic reaction to penicillin. Appellant argues that Firefly's electronic medical records system incorrectly displayed Washburne's allergy to penicillin resulting in Washburne's allergic reaction and subsequent death.

The district court granted the Defendant's motion to dismiss, ruling that Haven substantive law applied under Haven's conflict of laws rules and that Plaintiff had failed to state a claim upon which relief can be granted pursuant to Rule 12(b)(6). FED. R. CIV. P. 12(B)(6). Appellants filed a timely notice of appeal.

II. Jurisdiction

This Court has jurisdiction of Appellant's appeal pursuant to 28 U.S.C. § 1291. The district court's order granting Defendant's motion to dismiss is an appealable final order.

II. Standard of Review

A dismissal for failure to state a claim pursuant to Fed.R.Civ.P. 12, is reviewed de novo. It is a ruling on a question of law. *Pencil St. Soap Co. v. United States*, 787 F.3d 547, 549 (13th Cir. 1990). "Review is limited to the contents of the complaint." *Id.*

III. Discussion

A. Conflict-of-Laws

In an action based upon diversity of citizenship, as is this case, a district court must apply the substantive law, including choice of law rules, of the state in which it sits. *Klaxon Co. v. Stentor Elec.*

Mfg. Co., 313 U.S. 487, 495-96 (1941); *Day & Zimmermann*, *Inc. v. Challoner*, 423 U.S. 3, 4 (1975). In this case, those are the laws of the state of Haven. The state of Haven applies the most significant relationship test of the Restatement (Second) Conflict of Laws (1971). *Booker v. InGen*, *Inc.*, 241 Haven 17, 24 (2007).

The Second Restatement of Conflict of Laws, published in 1971, forcefully rejected the rigid rule of *lex loci delicti* as tending to produce arbitrary and unjust results in certain cases. Under *lex loci delicti*, the outcome in cases could be harsh and oftentimes depended on entirely random and fortuitous events. The doctrine of *lex loci delicti* has often been criticized for being a harsh and mechanical territorial rule. Ena, Michael, Note, *Choice of Law and Predictability of Decisions in Products Liability Cases*, 34 Fordham Urb. L.J. 1417, 1424 n.50 (2007).

In its brief, Appellant argues that *lex loci delicti*, the traditional rule governing conflict of laws issues in Haven, is no longer good law. We agree. According to the Haven Supreme Court in *Booker*, the "most significant relationship" test is the appropriate standard to be applied in conflict of laws issues. *Booker*, 241 Haven at 24. We hold that the balancing of state interests and contacts with the competing states weighs in favor of applying Grace law in this case. As such, we reverse the District Court's decision that Haven law is the applicable substantive law in this case.

The state of Grace has the most significant relationship to the parties and the events of this litigation. The Appellant is domiciled in Grace, works in Grace, her primary care physician is located in Grace, and the relationship between the parties was formed in Grace. As a result of these factors, Grace law applies to the resolution of this case.

C. Section 402A of the Restatement (Second) of Torts

Having determined that Grace law is the applicable law, we hold that Appellant's strict product liability claims are sufficient to present claims for manufacturing, design, and warning defect under Grace state law. Grace courts have adopted Section 402A of the Restatement (Second) of Torts in its entirety. *Turner v. Smith Bros.*, *Inc.*, 30 Grace 144 (2006). The rule creates strict liability for sellers of a defective product even though they exercised all possible care in the preparation and sale of the product. RESTATEMENT (SECOND) TORTS § 402A CMT. A (1965). In other words, under a strict product liability theory, it is the product at issue and not the conduct of the manufacturer. *Barker v. Lull Eng'g*, 20 Cal.3d 413 (Cal. 1978). Section 402A in its entirety provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> > (a) the seller is engaged in the business of selling such a product, and
> > (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in Subsection (1) applies although
>
> > (a) the seller has exercised all possible care in the preparation and sale of his product, and
> > (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

This section applies to sellers of products. RESTATEMENT (SECOND) TORTS § 402A CMT. A (1965). In the present case, there are no concerns about the software as a service. The software is mass-produced with no product differentiation. It is the medical records, a product, at issue and not the incidental service of transferring the records.

Section 402A applies to a seller of a product *in a defective condition unreasonably dangerous* to the user or consumer. (*emphasis added*); RESTATEMENT (SECOND) TORTS § 402A(1) (1965). Comment G of Section 402A defines defective condition as "a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him." *Id*. cmt. g (1965). The burden that the product was in a defective condition at the time it left the seller's hands is on the Plaintiff. *Id*. If the seller has reason to anticipate danger from the product, then the seller may be required to give warning. *Id*. cmt. h (1965). In addition to being defective, a product must be unreasonably dangerous, or "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it." *Id*. cmt. i (1965).

While the Restatement (Second) does not differentiate between manufacturing, design, and warning defect, the state of Haven analyzes the claims differently. *Turner*, 30 Grace at 153. In a case of a manufacturing defect, the Court applies a consumer expectations test. The consumer expectations test is similar to Section 402A's definition of unreasonably dangerous. Consumer expectations consist of what an ordinary consumer would expect when using the product in an intended or reasonably foreseeable manner. Liability is phrased in terms of whether the product in question deviated from other identical units in the same product line. *See e.g. Barker*, 20 Cal3d at 429; *Escola v. Coca Cola Bottling Co.*, 24 Cal.2d 453, 458-60 (Cal. 1944). On the other hand, in analyzing design defect and warning defect claims, Haven Courts use a combination of the consumer expectations test and a risk-benefit analysis. *See Barker*, 20 Cal.3d at 413. When analyzing a design or warning defect, the product may conform perfectly to all others in the product line, however, the product may be inherently unsafe due to an absence of a safety device or warning in its design. *Id.* at 428.

In applying these rules, the Court holds that Washburne's strict product liability claims of a manufacturing, design, and warning defect may state a claim upon which relief can be granted. First, a manufacturing defect likely occurred. 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. Moreover, using the consumer expectations test, consumers have an expectation that the electronic medical record will be an exact copy of the patient's paper record; here it was not. The paper record contained Washburne's allergy to penicillin; on the other hand, the allergy was absent from the electronic copy displayed to Dr. Tam.

Similarly, we reverse the lower courts determination that Washburne's design and warning defect claims fail. In designing the software, Firefly failed to incorporate a warning system for errors. Under a consumer expectations analysis, it is foreseeable that a user will overlook an entry field. Having a warning to alert the user to double-check the allergy omission would reduce the possibility of overlooking the default "NONE" entry. Further, using a risk-benefit analysis, the risk of not having a design incorporating a warning system regarding medical record omissions is high; in this case fatal. An incorrect input may result in future misdiagnosis or mistreatment. Accordingly, Appellants have stated a valid claim for a design and warning defect.

D. Implied Warranty of Merchantability

Under the Uniform Commercial Code (UCC) § 2-314, the merchant seller of goods warrants that its goods will be merchantable, or fit for the ordinary purposes for which such goods are intended to be used. The UCC provides that personal injury damages are available for a breach of the implied warranty of merchantability. UCC § 2-715(2)(B) (2003). As is the case here, when an implied warranty claim and a tort claim clash, whether goods are merchantable is to be determined by applicable state products liability law. UCC § 2-314 cmt. 7 (2003).

Applying these rules, the Court holds that Appellants have made a valid claim of a breach of the implied warranty of merchantability. Whether the goods are merchantable is to be determined using Grace products liability law as discussed in Part B. Accordingly, as the Court held there were sufficient facts to make out a product defectiveness claim under Grace law, there are sufficient facts to allege that Firefly's product is not merchantable. It should be noted that there are no concerns of privity raised by either party; Plaintiff paid twenty-five dollars directly to the manufacturer-defendant.

E. Express Warranty

We affirm the district court's dismissal of an express warranty claim. There was no promise made to the Plaintiff from the Defendant-manufacturer; accordingly, the UCC § 2-213 is not implicated here.

IV. Conclusion

For the foregoing reasons, we AFFIRM the district court's dismissal of the express warranty claim and REVERSE and REMAND the strict product liability claims and implied warranty of merchantability claims for a determination consistent with this opinion.

THE SUPREME COURT OF

THE UNITED STATES

Firefly Systems, Inc.,

Petitioners
-V-

In re Estate of Zoe Washburne,

Respondent

No. XX-XX-XXXXX

This petition for writ of certiorari to the United States Court of Appeals for the Thirteenth Circuit is hereby granted that this Court may hear and consider the following issues:

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 answer to question one, has the Respondent stated a claim for strict products liability upon which relief can be granted, or does the claim require an additional showing?

Appendix C

Relevant Provisions of the HITECH Act of 2009

42 U.S.C.A. §300jj-11 (West 2011)

§ 300jj-11. Office of the National Coordinator for Health Information Technology

Currentness

Office of the National Coordinator for Health Information Technology

(a) Establishment

There is established within the Department of Health and Human Services an Office of the National Coordinator for Health Information Technology (referred to in this section as the "Office"). The Office shall be headed by a National Coordinator who shall be appointed by the Secretary and shall report directly to the Secretary.

(b) Purpose

The National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that--

(1) ensures that each patient's health information is secure and protected, in accordance with applicable law;

(2) improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;

(3) reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;

(4) provides appropriate information to help guide medical decisions at the time and place of care;

(5) ensures the inclusion of meaningful public input in such development of such infrastructure;

(6) improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;

(7) improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;

(8) facilitates health and clinical research and health care quality;

(9) promotes early detection, prevention, and management of chronic diseases;

(10) promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and

(11) improves efforts to reduce health disparities.

(c) Duties of the National Coordinator

(1) Standards

The National Coordinator shall--

(A) review and determine whether to endorse each standard, implementation specification, and certification criterion for the electronic exchange and use of health information that is recommended by the HIT Standards Committee under section 300jj-13 of this title for purposes of adoption under section 300jj-14 of this title;

(B) make such determinations under subparagraph (A), and report to the Secretary such determinations, not later than 45 days after the date the recommendation is received by the Coordinator; and

(C) review Federal health information technology investments to ensure that Federal health information technology programs are meeting the objectives of the strategic plan published under paragraph (3).

(2) HIT policy coordination

(A) In general

The National Coordinator shall coordinate health information technology policy and programs of the Department with those of other relevant executive branch agencies with a goal of avoiding duplication of efforts and of helping to ensure that each agency undertakes health information technology activities primarily within the areas of its greatest expertise and technical capability and in a manner towards a coordinated national goal.

(B) HIT Policy and Standards Committees

The National Coordinator shall be a leading member in the establishment and operations of the HIT Policy Committee and the HIT Standards Committee and shall serve as a liaison among those two Committees and the Federal Government.

(3) Strategic plan

(A) In general

The National Coordinator shall, in consultation with other appropriate Federal agencies (including the National Institute of Standards and Technology), update the Federal Health IT Strategic Plan (developed as of June 3, 2008) to include specific objectives, milestones, and metrics with respect to the following:

(i) The electronic exchange and use of health information and the enterprise integration of such information.

(ii) The utilization of an electronic health record for each person in the United States by 2014.

(iii) The incorporation of privacy and security protections for the electronic exchange of an individual's individually identifiable health information.

(iv) Ensuring security methods to ensure appropriate authorization and electronic authentication of health information and specifying technologies or methodologies for rendering health information unusable, unreadable, or indecipherable.

(v) Specifying a framework for coordination and flow of recommendations and policies under this part among the Secretary, the National Coordinator, the HIT Policy Committee, the HIT Standards Committee, and other health information exchanges and other relevant entities.

(vi) Methods to foster the public understanding of health information technology.

(vii) Strategies to enhance the use of health information technology in improving the quality of health care, reducing medical errors, reducing health disparities, improving public health, increasing prevention and coordination with community resources, and improving the continuity of care among health care settings.

(viii) Specific plans for ensuring that populations with unique needs, such as children, are appropriately addressed in the technology design, as appropriate, which may include technology that automates enrollment and retention for eligible individuals.

(B) Collaboration

The strategic plan shall be updated through collaboration of public and private entities.

(C) Measurable outcome goals

The strategic plan update shall include measurable outcome goals.

(D) Publication

The National Coordinator shall republish the strategic plan, including all updates.

(4) Website

The National Coordinator shall maintain and frequently update an Internet website on which there is posted information on the work, schedules, reports, recommendations, and other

information to ensure transparency in promotion of a nationwide health information technology infrastructure.

(5) Certification

(A) In general

The National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this part. Such program shall include, as appropriate, testing of the technology in accordance with section 17911(b) of this title.

(B) Certification criteria described

In this subchapter, the term "certification criteria" means, with respect to standards and implementation specifications for health information technology, criteria to establish that the technology meets such standards and implementation specifications.

(6) Reports and publications

(A) Report on additional funding or authority needed

Not later than 12 months after February 17, 2009, the National Coordinator shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report on any additional funding or authority the Coordinator or the HIT Policy Committee or HIT Standards Committee requires to evaluate and develop standards, implementation specifications, and certification criteria, or to achieve full participation of stakeholders in the adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information.

(B) Implementation report

The National Coordinator shall prepare a report that identifies lessons learned from major public and private health care systems in their implementation of health information technology, including information on whether the technologies and practices developed by such systems may be applicable to and usable in whole or in part by other health care providers.

(C) Assessment of impact of HIT on communities with health disparities and uninsured, underinsured, and medically underserved areas

The National Coordinator shall assess and publish the impact of health information technology in communities with health disparities and in areas with a high proportion of individuals who are uninsured, underinsured, and medically underserved individuals (including urban and rural areas) and identify practices to increase the adoption of such technology by health care providers in such communities, and the use of health information technology to reduce and better manage chronic diseases.

(D) Evaluation of benefits and costs of the electronic use and exchange of health information

The National Coordinator shall evaluate and publish evidence on the benefits and costs of the electronic use and exchange of health information and assess to whom these benefits and costs accrue.

(E) Resource requirements

The National Coordinator shall estimate and publish resources required annually to reach the goal of utilization of an electronic health record for each person in the United States by 2014, including--

(i) the required level of Federal funding;

(ii) expectations for regional, State, and private investment;

(iii) the expected contributions by volunteers to activities for the utilization of such records; and
(iv) the resources needed to establish a health information technology workforce sufficient to support this effort (including education programs in medical informatics and health information management).

(7) Assistance

The National Coordinator may provide financial assistance to consumer advocacy groups and not-for-profit entities that work in the public interest for purposes of defraying the cost to such groups and entities to participate under, whether in whole or in part, the National Technology Transfer Act of 1995 (15 U.S.C. 272 note).

(8) Governance for nationwide health information network

The National Coordinator shall establish a governance mechanism for the nationwide health information network.

(d) Detail of Federal employees

(1) In general

Upon the request of the National Coordinator, the head of any Federal agency is authorized to detail, with or without reimbursement from the Office, any of the personnel of such agency to the Office to assist it in carrying out its duties under this section.

(2) Effect of detail

Any detail of personnel under paragraph (1) shall--
(A) not interrupt or otherwise affect the civil service status or privileges of the Federal employee; and
(B) be in addition to any other staff of the Department employed by the National Coordinator.

(3) Acceptance of detailees

Notwithstanding any other provision of law, the Office may accept detailed personnel from other Federal agencies without regard to whether the agency described under paragraph (1) is reimbursed.

(e) Chief Privacy Officer of the Office of the National Coordinator

Not later than 12 months after February 17, 2009, the Secretary shall appoint a Chief Privacy Officer of the Office of the National Coordinator, whose duty it shall be to advise the National Coordinator on privacy, security, and data stewardship of electronic health information and to coordinate with other Federal agencies (and similar privacy officers in such agencies), with State and regional efforts, and with foreign countries with regard to the privacy, security, and data stewardship of electronic individually identifiable health information.

Appendix D

Federal Rule of Civil Procedure 12

LEXSTAT USCS FED RULES CIV PROC R 12

*** CURRENT THROUGH CHANGES RECEIVED MARCH 6, 2010 ***

FEDERAL RULES OF CIVIL PROCEDURE
TITLE III. PLEADINGS AND MOTIONS

Go to the United States Code Service Archive Directory

USCS Fed Rules Civ Proc R 12

Review Court Orders which may amend this Rule.
Review expert commentary from The National Institute for Trial Advocacy

THE CASE NOTES SEGMENT OF THIS DOCUMENT HAS BEEN SPLIT INTO 4 DOCUMENTS.
THIS IS PART 2.
USE THE BROWSE FEATURE TO REVIEW THE OTHER PART(S).

Rule 12. Defenses and Objections: When and How Presented; Motion for Judgment on the Pleadings; Consolidating Motions; Waiving Defenses; Pretrial Hearing

(a) Time to Serve a Responsive Pleading.
(1) *In General.* Unless another time is specified by this rule or a federal statute, the time for serving a responsive pleading is as follows:
(A) A defendant must serve an answer:
(i) within 21 days after being served with the summons and complaint; or
(ii) if it has timely waived service under Rule 4(d), within 60 days after the request for a waiver was sent, or within 90 days after it was sent to the defendant outside any judicial district of the United States.
(B) A party must serve an answer to a counterclaim or crossclaim within 21 days after being served with the pleading that states the counterclaim or crossclaim.
(C) A party must serve a reply to an answer within 21 days after being served with an order to reply, unless the order specifies a different time.
(2) *United States and Its Agencies, Officers, or Employees Sued in an Official Capacity.* The United States, a United States agency, or a United States officer or employee sued only in an official capacity must serve an answer to a complaint, counterclaim, or crossclaim within 60 days after service on the United States attorney.
(3) *United States Officers or Employees Sued in an Individual Capacity.* A United States officer or employee sued in an individual capacity for an act or omission occurring in connection with duties performed on the United States' behalf must serve an answer to a complaint,

counterclaim, or crossclaim within 60 days after service on the officer or employee or service on the United States attorney, whichever is later.

(4) *Effect of a Motion.* Unless the court sets a different time, serving a motion under this rule alters these periods as follows:

(A) if the court denies the motion or postpones its disposition until trial, the responsive pleading must be served within 14 days after notice of the court's action; or

(B) if the court grants a motion for a more definite statement, the responsive pleading must be served within 14 days after the more definite statement is served.

(b) How to Present Defenses. Every defense to a claim for relief in any pleading must be asserted in the responsive pleading if one is required. But a party may assert the following defenses by motion:

(1) lack of subject-matter jurisdiction;
(2) lack of personal jurisdiction;
(3) improper venue;
(4) insufficient process;
(5) insufficient service of process;
(6) failure to state a claim upon which relief can be granted; and
(7) failure to join a party under Rule 19.

A motion asserting any of these defenses must be made before pleading if a responsive pleading is allowed. If a pleading sets out a claim for relief that does not require a responsive pleading, an opposing party may assert at trial any defense to that claim. No defense or objection is waived by joining it with one or more other defenses or objections in a responsive pleading or in a motion.

(c) Motion for Judgment on the Pleadings. After the pleadings are closed--but early enough not to delay trial--a party may move for judgment on the pleadings.

(d) Result of Presenting Matters Outside the Pleadings. If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion.

(e) Motion for a More Definite Statement. A party may move for a more definite statement of a pleading to which a responsive pleading is allowed but which is so vague or ambiguous that the party cannot reasonably prepare a response. The motion must be made before filing a responsive pleading and must point out the defects complained of and the details desired. If the court orders a more definite statement and the order is not obeyed within 14 days after notice of the order or within the time the court sets, the court may strike the pleading or issue any other appropriate order.

(f) Motion to Strike. The court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter. The court may act:

(1) on its own; or
(2) on motion made by a party either before responding to the pleading or, if a response is not allowed, within 21 days after being served with the pleading.

(g) Joining Motions.

(1) *Right to Join.* A motion under this rule may be joined with any other motion allowed by this rule.

(2) *Limitation on Further Motions.* Except as provided in Rule 12(h)(2) or (3), a party that makes a motion under this rule must not make another motion under this rule raising a defense or objection that was available to the party but omitted from its earlier motion.

(h) Waiving and Preserving Certain Defenses.

(1) *When Some Are Waived.* A party waives any defense listed in Rule 12(b)(2)-(5) by:

(A) omitting it from a motion in the circumstances described in Rule 12(g)(2); or

(B) failing to either:

(i) make it by motion under this rule; or

(ii) include it in a responsive pleading or in an amendment allowed by Rule 15(a)(1) as a matter of course.

(2) *When to Raise Others.* Failure to state a claim upon which relief can be granted, to join a person required by Rule 19(b), or to state a legal defense to a claim may be raised:

(A) in any pleading allowed or ordered under Rule 7(a);

(B) by a motion under Rule 12(c); or

(C) at trial.

(3) *Lack of Subject-Matter Jurisdiction.* If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action.

(i) Hearing Before Trial. If a party so moves, any defense listed in Rule 12(b)(1)-(7)--whether made in a pleading or by motion--and a motion under Rule 12(c) must be heard and decided before trial unless the court orders a deferral until trial.

Appendix E

Relevant Provisions of the Restatements

Restatement (Second) of Conflict of Laws § 6 - Choice-Of-Law Principles

(1) A court, subject to constitutional restrictions, will follow a statutory directive of its own state on choice of law.

(2) When there is no such directive, the factors relevant to the choice of the applicable rule of law 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 § 145 - The General Principle

(1) The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6.

(2) Contacts to be taken into account in applying the principles of § 6 to determine the law applicable to an issue include:

(a) the place where the injury occurred,
(b) the place where the conduct causing the injury occurred,
(c) the domicil, 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.

These contacts are to be evaluated according to their relative importance with respect to the particular issue.

Restatement (Second) of Torts § 402A -
Special Liability of Seller of Product for Physical Harm to User or Consumer

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

(a) the seller is engaged in the business of selling such a product, and
(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

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

(a) the seller has exercised all possible care in the preparation and sale of his product, and
(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Third) of Torts: Products Liability § 2 (1998) - Categories of Product Defect

A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:

(a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;

(b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;

(c) is defective because of inadequate instructions or 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 or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.