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## Putting the “Product” in Reproduction: The Viability of a Products Liability Action for Genetically Defective Sperm

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# Putting the “Product” in Reproduction: The Viability of a Products Liability Action for Genetically Defective Sperm

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## I. INTRODUCTION

In 2006, five children in Michigan were diagnosed with severe congenital neutropenia (SCN), a rare blood disease, which puts them at risk for leukemia and requires daily injections of a costly medication to prevent infection.<sup>1</sup> Although SCN only affects one in five million children, there is a fifty percent chance that an affected child will pass the gene defect to future offspring.<sup>2</sup> The specialist who diagnosed the Michigan children, Dr. Laurence A. Boxer, discovered that the children had more than just SCN in common—they also had the same father, Donor F827.<sup>3</sup>

All five children were conceived through artificial insemination<sup>4</sup> using sperm provided by an anonymous donor and purchased from a sperm bank, International Cryogenics.<sup>5</sup> Because none of the children's mothers carried the defective gene, Dr. Boxer theorized that Donor F827 carried the gene only in his sperm cells; otherwise he would have exhibited symptoms and the condition would have been detectable.<sup>6</sup> Dr. Boxer could not, however, test his hypothesis because Donor F827 had moved, International Cryogenics could not locate him, and the donor's remaining samples could not be tested without his consent.<sup>7</sup>

Upon learning of the children's condition, International Cryogenics disposed of Donor F827's remaining samples to ensure that they were not provided for future use.<sup>8</sup> Yet despite the fact that Donor F827 fathered at least eleven known children through his deposits with the sperm bank, International Cryogenics failed to notify other recipients of Donor F827's sperm that their children may also have SCN, reasoning that "even if other children had developed the disease their families would already know it."<sup>9</sup> The Michigan case illustrates the risks associated with the current artificial insemination practice—a system where sperm is sold by a self-regulated industry, without laws limiting the number of pregnancies per donor or requiring donor-tracking, and where donor anonymity is protected to the

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1. Denise Grady, *As the Use of Donor Sperm Increases, Secrecy Can Be a Health Hazard*, N.Y. TIMES, June 6, 2006, at F5, available at 2006 WLNR 9651819.

2. *Id.*

3. *Id.*

4. Artificial insemination is a reproductive procedure in which sperm is manually implanted into the recipient's cervix or uterine lining. Dawn R. Swink & J. Brad Reich, *Caveat Vendor: Potential Progeny, Paternity, and Product Liability Online*, 2007 BYU L. REV. 857, 860 n.14 (2007).

5. Grady, *supra* note 1, at F5.

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.*

detriment of the resulting offspring.<sup>10</sup>

During the twentieth century, artificial insemination by donor (AID) steadily gained popularity as an alternative method of reproduction.<sup>11</sup> Today, sperm banking is a multi-million dollar industry, and AID produces approximately 30,000 births annually.<sup>12</sup> As the sperm banking industry grew progressively more corporate and concentrated, AID became increasingly consumer-dominated.<sup>13</sup> Yet as the nature of the practice evolved from a physician-dominated infertility treatment to a modern market-driven commercial transaction, AID has remained enveloped in secrecy and lacking comprehensive regulation.<sup>14</sup> While many states have statutorily determined the legal parentage of offspring produced through AID,<sup>15</sup> other issues remain unresolved concerning the relative rights and obligations of the many potentially involved parties—including the recipient woman, her spouse, the resulting child, the treating physician, the sperm bank, and the sperm donor.

Many questions surround the issue of legal liability when a child produced through AID inherits a genetic disease or defect from the sperm donor.<sup>16</sup> One such question is whether the sale of human sperm constitutes the sale of a product, potentially subjecting sperm to products liability law.<sup>17</sup> This question, in turn, begets many more questions—both legal and normative—that must be considered before determining whether products liability law is an appropriate mechanism for regulating artificial insemination: Can an AID recipient and her spouse bring a products liability action against the physician administering AID, the sperm bank, or the

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10. *Id.*

11. See *infra* note 214 and accompanying text.

12. See *infra* notes 234–40 and accompanying text.

13. See *infra* notes 228–37 and accompanying text.

14. See *infra* notes 246–57, 259 and accompanying text.

15. See *infra* note 244 and accompanying text.

16. Although one might also consider legal liability in the seemingly analogous situation of a child inheriting a genetic disease from an egg donor, such questions are beyond the scope of this Comment. Due to the significant differences in the retrieval and implantation processes of donated sperm and eggs, the analysis within this Comment applies only to the former. See Amy Shelf, *A Need to Know Basis: Record Keeping, Information Access, and the Uniform Status of Children of Assisted Conception Act*, 51 HASTINGS L.J. 1047, 1056, 1063 (2000) (comparing the different technology required for retrieving and implanting sperm with that for harvesting ova and implanting embryos). For further discussion of the potential liability of egg donors, see Suriya E.P. Jayanti, Comment, *Guarantors of our Genes: Are Egg Donors Liable for Latent Genetic Disease?*, 58 AM. U. L. REV. 405 (2008); J. Brad Reich & Dawn Swink, *You Can't Put the Genie Back in the Bottle: Potential Rights and Obligations of Egg Donors in the Cyberprocreation Era*, 20 ALB. L.J. SCI. & TECH. 1 (2010).

17. See *infra* notes 314–76 and accompanying text.

sperm donor?<sup>18</sup> Can the resulting child bring such a claim?<sup>19</sup> Can an anonymous sperm donor be held liable for “manufacturing” a defective product?<sup>20</sup> Should he be liable if he had no reason to know of his condition?<sup>21</sup> Is strict liability in tort an appropriate remedy where a genetic defect is extremely rare, impossible to diagnose, or undiscovered at the time of insemination?<sup>22</sup> Should an AID recipient alone bear the expense of raising a child with a severe genetic defect where other parties profited from the creation of the child?<sup>23</sup> This Comment attempts to answer these and other questions regarding the possibility of regulating AID through products liability law.

Part II of this Comment provides an overview of products liability law and the history of artificial insemination in the United States.<sup>24</sup> Part II also discusses *Donovan v. Idant Laboratories*, a case in which a mother and child brought a products liability action against a sperm bank based on a genetic defect inherited by the child from the sperm donor, introducing the possibility of treating sperm as a product.<sup>25</sup> Part III analyzes the potential success of products liability actions for genetically defective sperm.<sup>26</sup> Part IV argues that strict products liability is not an appropriate response to the risks of artificial insemination and instead suggests that courts apply a shifted burden of proof to claims brought in negligence.<sup>27</sup> Part IV further suggests the need for a national donor database.<sup>28</sup> Part V concludes.<sup>29</sup>

## II. PRODUCTS LIABILITY, ARTIFICIAL INSEMINATION, AND AN UNLIKELY UNION

### A. *Products Liability: The Love Child of Torts & Contracts*

A party who commercially transfers a harm-causing product may be liable under products liability law if the product is defective or does not conform to the quality represented.<sup>30</sup> The practice of imposing liability on product providers is nothing new: although the doctrine of *caveat emptor*—

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18. See *infra* notes 405–13 and accompanying text.

19. See *infra* notes 414–21 and accompanying text.

20. See *infra* notes 398–404 and accompanying text.

21. See *infra* note 429 and accompanying text.

22. See *infra* note 433 and accompanying text.

23. See *infra* notes 422–52 and accompanying text.

24. See *infra* notes 30–264 and accompanying text.

25. See *infra* notes 265–305 accompanying text.

26. See *infra* notes 306–421 and accompanying text.

27. See *infra* notes 422–52 and accompanying text.

28. See *infra* notes 453–64 and accompanying text.

29. See *infra* notes 465–69 and accompanying text.

30. DAVID G. OWEN, PRODUCTS LIABILITY LAW 1 (2d ed., Thompson/West 2008).

meaning "buyer beware"—guided early American law,<sup>31</sup> the foundations of the modern products liability doctrine have been present since the laws of ancient Rome.<sup>32</sup> It was not, however, until the mid-twentieth century that "products liability" was first recognized in the United States as a distinct area of law.<sup>33</sup> Since emerging as an independent doctrine, products liability has expanded rapidly,<sup>34</sup> with "roughly 20,000 products liability decisions of some significance now reported in the United States."<sup>35</sup>

The American legal system has long divided civil obligation into two distinct categories—tort and contract.<sup>36</sup> This division is apparent even at the definitional level: "tort" is defined as "[a] civil wrong, *other than breach of contract*, for which a remedy may be obtained."<sup>37</sup> The distinction between tort and contract is based on the source of the obligation: a contract obligation is "voluntarily assumed (or at least the transaction that gave rise to the obligation was voluntarily entered into),"<sup>38</sup> while a tort obligation is "blundered or stumbled into through accident, negligence or fraud."<sup>39</sup> Where, however, voluntary transactions give rise to accidental, negligent, or fraudulent injury, tort and contract "merge or blur at the edges."<sup>40</sup> It was from this edge—this mixture of tort and contract—that products liability was born.<sup>41</sup>

As American society abandoned the principle of *caveat emptor*<sup>42</sup> and

31. *Id.* at 17.

32. *See id.* at 11–14 (discussing seller liability for express misrepresentations and breach of an implied warranty of quality under early Roman law).

33. DIX W. NOEL & JERRY J. PHILLIPS, PRODUCTS LIABILITY: CASES & MATERIALS 1 (2d ed. 1982) (stating that products liability "did not appear as a heading in the *Index to Legal Periodicals* before the volume covering 1961 to 1964").

34. *See* W. KIP VISCUSI, REFORMING PRODUCTS LIABILITY 6 (1991) ("The widespread perception that there has been a major expansion of the products liability system is correct.").

35. OWEN, *supra* note 30, at 5.

36. Grant Gilmore, *Products Liability: A Commentary*, 38 U. CHI. L. REV. 103, 111 (1970).

37. BLACK'S LAW DICTIONARY 1526 (8th ed. West 2004) (emphasis added).

38. Gilmore, *supra* note 36, at 111.

39. *Id.*

40. *Id.*

41. OWEN, *supra* note 30, at 4. The moral basis for imposing liability on providers of harm-causing products depends on the voluntary nature of the transaction: "By choosing to expose product users and others to certain types and degrees of risk, product makers appropriate to themselves certain interests in safety—in bodily integrity—that may belong to those other persons." David G. Owen, *The Moral Foundations of Products Liability Law: Toward First Principles*, 68 NOTRE DAME L. REV. 427, 430 (1993) [hereinafter Owen, *Moral Foundations*].

42. *See* NOEL & PHILLIPS, *supra* note 33, at 32 ("The development of the law of products liability has been closely connected with the change in the commercial world from the principle of *caveat emptor*—let the buyer beware—to one which demands that the seller beware.").

relaxed the requirement of privity,<sup>43</sup> products liability grew out of its tort and contract roots and into a life of its own<sup>44</sup>:

Principles of responsibility for accidental harm give the doctrine its torts flavor, and a heritage of contract law conveys the requirement of a commercial setting—which is one of the very few defining criteria of a products liability case. The injurious product stands for both tortious conduct and the betrayal of a promise.<sup>45</sup>

With its mixed heritage, a products liability action may be founded on either traditional tort or contract principles—or a hybrid of the two.<sup>46</sup> As such, the plaintiff's claim may be based on any combination of negligence, breach of warranty, and strict liability in tort.<sup>47</sup>

Because products liability has blurred the distinction between tort and contract and has developed without plainly established limitations, it is not always entirely clear what falls within the scope of products liability law.<sup>48</sup> Questions concerning the outer boundaries of the products field arise when “the injury-producing ‘product’ [is] something other than a typical, mass-produced chattel—such as a house, a toxic substance, a recipe, electricity, a truckload of sand, an internet game, transfused blood, or a poisonous spider in a pair of pants.”<sup>49</sup> As a result, whether a products liability action is feasible depends upon whether the item transferred is a product, the transaction is properly categorized as a sale, and the defendant is an appropriate party.<sup>50</sup>

In any products liability claim, the threshold question is thus whether the thing that caused the plaintiff's injury is, in fact, a “product.”<sup>51</sup>

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43. *Id.* at 33. Initially, “in product cases a contractual relationship, or privity of contract, was required between the parties even when negligence was alleged.” *Id.* at 32. The decline of privity, however, has since extended liability in the products field to defendants not party to a contract, while simultaneously permitting recovery by plaintiffs not party to a contract. *Id.*

44. *See id.* at 1 (stating that “the products field includes both tort and contract theories”); *see also* ANITA BERNSTEIN, A PRODUCTS LIABILITY ANTHOLOGY 47 (1995) (“Products liability is widely understood to be the progeny of tort and contract ancestors.”).

45. BERNSTEIN, *supra* note 44, at 47.

46. DERRICK OWLES, THE DEVELOPMENT OF PRODUCT LIABILITY IN THE UNITED STATES 1 (1978).

47. Courts may “utilize the terminology of negligence, strict liability, or the implied warranty of merchantability” to define liability based on a product defect. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 cmt. a (1998).

48. *See infra* notes 314–45 and accompanying text.

49. OWEN, *supra* note 30, at 3.

50. *Id.*

51. Section 19 of the *Restatement (Third) of Torts: Products Liability* defines “product” as follows:

- (a) A product is tangible personal property distributed commercially for use or consumption. Other items, such as real property and electricity, are products when the context of their distribution and use is sufficiently analogous to the distribution and use of tangible personal property that it is appropriate to apply the rules stated

Although definitions of "product" vary widely among state statutes<sup>52</sup> and courts,<sup>53</sup> this requirement is, with some exceptions,<sup>54</sup> generally satisfied without much discussion.<sup>55</sup> While a determination of whether a product conforms to the quality represented is fairly straightforward, difficulty often arises with regard to the issue of whether a product is defective.<sup>56</sup>

### 1. Product Defectiveness

Although some products liability theories of recovery do not require a showing of defectiveness,<sup>57</sup> the concept of "product defect" remains central to products liability law.<sup>58</sup> Three categories of defects are recognized:

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- in this Restatement.
  - (b) Services, even when provided commercially, are not products.
  - (c) Human blood and human tissue, even when provided commercially, are not subject to the rules of this Restatement.

RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19 (1998). Unless defined by statute, "it is for the court to determine as a matter of law whether something is, or is not, a product." *Id.* cmt. a.

52. See, e.g., MD. CODE ANN., CTS. & JUD. PROC. § 5-115 (West, Westlaw through 2010 Reg. Sess.) ("[a] tangible article, including attachments, accessories, and component parts, and accompanying labels, warnings, instructions, and packaging"); OHIO REV. CODE ANN. § 2307.71 (West, Westlaw through 2010 File 58 of the 128th GA) ("any object, substance, mixture, or raw material that constitutes tangible personal property and that satisfies all of the following: [(1)] . . . capable of delivery itself . . . ; [(2)] . . . produced, manufactured, or supplied for introduction into trade or commerce; and [(3)] . . . intended for sale or lease to persons for commercial or personal use"); TENN. CODE ANN. § 29-28-102 (LEXIS through 2010 Reg. Sess.) ("any tangible object or goods produced").

53. See, e.g., *Pierson v. Sharp Mem'l Hosp., Inc.*, 264 Cal. Rptr. 673, 676 (Ct. App. 1989) ("A product is a physical article which results from a manufacturing process and is ultimately delivered to a consumer."); *Wyrulee Co. v. Schutt*, 866 P.2d 756, 760 (Wyo. 1993) ("[A] 'product' is anything made by human industry or art." (quoting *Otte v. Dayton Power & Light Co.*, 523 N.E.2d 835, 838 (Ohio 1988))).

54. See Malcolm Wheeler, *The Need for Narrow Tort Reform: Abolishing Strict Product Liability*, in *PRODUCT LIABILITY REFORM: DEBATING THE ISSUES* (Kenneth L. Chilton ed. 1990) (summarizing court and legislative decisions regarding whether plasma and blood products, electricity, animals, and buildings are considered "products" subject to strict liability).

55. See, e.g., *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897 (Cal. 1963) (power lathe is a product); *Dunham v. Vaughan & Bushnell Mfg. Co.*, 247 N.E.2d 401 (Ill. 1969) (hammer is a product); *Barker v. Lull Eng'g Co.*, 573 P.2d 443 (Cal. 1978) (high-lift loader is a product); *Camacho v. Honda Motor Co.*, 741 P.2d 1240 (Colo. 1987) (motorcycle is a product).

56. See *infra* notes 57–102 and accompanying text.

57. See *infra* notes 135–50 and accompanying text (discussing breach of express warranty and the implied warranty of fitness for a particular purpose).

58. "We take as a starting point the principle that a manufacturer or distributor of a product is liable to compensate a person injured by a defective product." OWLES, *supra* note 46, at 1; see also RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 (1998) ("One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.").



manufacturing defects, design defects, and warning defects.<sup>59</sup> Jurisdictions utilize different definitions of defectiveness,<sup>60</sup> and the test for defectiveness varies depending on the type of defect.<sup>61</sup> If a product is found to be defective, liability may be imposed based on several different theories of liability—negligence, strict liability, and the implied warranty of merchantability.<sup>62</sup> Regardless of which of these bases of liability is applied, “[i]n order to recover, a plaintiff . . . must prove that the [product] was defective and that the defect caused the injury.”<sup>63</sup>

### *i. Manufacturing Defects*

Early products liability cases often involved injuries caused by manufacturing defects.<sup>64</sup> A claim based on a manufacturing defect may be brought under a negligence, warranty, or strict liability theory of liability.<sup>65</sup> A product “contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the

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59. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 (1998); *see also* John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 830 (1973) (a “product must be harmful or unsafe because of something wrong with it. The ‘something wrong’ may have come about quite unintentionally because of a miscarriage in the manufacturing process, so that the product was not what it was intended to be; it may, on the other hand, have come about, even though the product was exactly as it was intended to be, because of a poor design or the failure to attach a warning or suitable instructions.”).

60. *See* William C. Powers, Jr., *The Persistence of Fault in Products Liability*, 61 TEX. L. REV. 777, 783–84 (1983). The dominant approaches for determining defectiveness are the consumer expectations and risk-utility tests:

Much of the debate concerning the definition of defectiveness has focused on two basic approaches. One approach, reflecting the warranty heritage of strict products liability, provides that a product is defective if it is “dangerous to an extent beyond that which would be contemplated by the ordinary consumer.” A second approach, reflecting the tort heritage of strict products liability, provides that a product is defective if it is “unreasonably dangerous”—that is, it possesses features whose risks outweigh their benefits. Under this “risk-utility” test, a manufacturer may attempt to justify a product’s risks by referring to the social benefits derived from imposing them.

*Id.* (quoting RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (1965)).

61. *See id.* at 782–83 (“Courts have not applied a uniform concept of defectiveness to all types of defects. Flaws have usually been considered to be per se defective, warnings defects have normally been judged explicitly by a negligence standard, and design defects have been judged by a variety of complex standards.”); *see also* 1 DAVID G. OWEN ET AL., MADDEN & OWEN ON PRODUCTS LIABILITY 439–40 (3rd ed. 2000) (“Most courts and commentators have come to understand that meaningful evaluation of the acceptability of a product’s dangers logically turns on considerations that vary contextually depending upon whether the problem was one of manufacture, design, or the absence of a sufficient warning.”).

62. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 cmt. a (1998).

63. Powers, *supra* note 60, at 781.

64. *See, e.g.*, *Escola v. Coca-Cola Bottling Co.*, 150 P.2d 436 (Cal. 1944) (injury caused by exploding Coca-Cola bottle due to over pressurization or glass flaw).

65. 1 OWEN ET AL., *supra* note 61, at 399–400. “Strict liability, however, is likely to be the most effective for a plaintiff trying to prove a manufacturing defect case given that it does not require proof of fault.” *Id.*

preparation and marketing of the product."<sup>66</sup> Thus, the standard for identifying manufacturing defects requires a determination of whether the product varies in a meaningful way from its intended condition.<sup>67</sup> Because a product may depart from its intended design due to an error in the manufacturing process, which results in a flaw in—or the mis-manufacture of—the product, a manufacturing defect "may affect only a single product, or a single lot or batch of the product."<sup>68</sup> Accordingly, manufacturing defects can be contrasted with design defects, which reflect conscious design decisions and affect an entire product line.<sup>69</sup>

## ii. Design Defects

Design defects exist when a manufacturer should have designed the product differently to make it safer.<sup>70</sup> A product is defectively designed 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.<sup>71</sup>

Unlike manufacturing defects, design defects reflect the manufacturer's conscious decision to include a particular feature in the product and, when the product is manufactured as intended, affect the entire product line.<sup>72</sup> Allegations of defective design generally include a proposed reasonable (or feasible) alternative design, which, if incorporated, would reduce the risk of injury.<sup>73</sup> Because "the degree of risk or safety in every product design is

66. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(a) (1998).

67. 1 OWEN ET AL., *supra* note 61, at 397. Further, "the manufacturing defect must be such as to pose an unreasonable risk of harm to the user or consumer." *Id.* at 400.

68. *Id.* at 397.

69. See *infra* notes 70–87 and accompanying text.

70. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) (1998).

71. *Id.*

72. 1 OWEN ET AL., *supra* note 61, at 397. "For this reason, design defect claims are of greatest concern to manufacturers, since a judicial declaration that the design of a particular product on trial is 'defective' condemns the entire product line." *Id.* at 440.

73. *Id.* at 463. A reasonable alternative design serves as proof that the plaintiff's injury could have been prevented or reduced by the alteration of the product's design:

Throughout the twentieth century, the great majority of design defect cases involved proof by the plaintiff of a feasible alternative design . . . , for example, a commercial coffee urn which exploded, where the explosion could have been prevented by a simple

necessarily counterbalanced by considerations such as cost, utility, and aesthetics,”<sup>74</sup> optimal safety is the dominant standard in design cases.<sup>75</sup>

The test for identifying design defects varies by jurisdiction.<sup>76</sup> All jurisdictions, however, apply some variation<sup>77</sup> of the two primary tests—consumer expectations or risk-utility.<sup>78</sup> A design is defective under the consumer expectations test “when it is dangerous to an extent beyond which would be contemplated by the ordinary user or consumer possessing the knowledge of the product’s characteristics which were common to the community.”<sup>79</sup> Due to its inherent limitations,<sup>80</sup> many courts have

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reducing valve; a tractor steering wheel, made of rubber and fiber, that broke in the driver’s hands causing him to fall into the path of the tractor, where a rim made of wood or metal would not have broken; [and] a vaporizer which overheated and caught fire when the water boiled away, where the fire could have been prevented by a simple cutoff device.

*Id.*

74. *Id.* at 441.

75. *Id.* In design cases, “the goal of design engineers can only be to promote in products an *ideal* balance of product usefulness, cost, and safety. A product design, in other words, can only be optimally, not perfectly, safe.” *Id.* Furthermore,

[a] risk is often justifiable because it is a concomitant [sic] of a socially desirable feature of a product. The speed of automobiles and the sharpness of knives provide concomitant [sic] risks and benefits. Sometimes, however, a risk is acceptable because a product that avoided it would be inordinately expensive. Consequently, courts have considered product cost to be an appropriate factor in a risk-utility balance. If they ignored product cost, every product that imposes risks would be defective, because nearly every product could be made safer at some cost.

Powers, *supra* note 60, at 792.

76. *Compare* Hansen v. New Holland N. Am., Inc., 574 N.W.2d 250 (Wis. Ct. App. 1997) (finding consumer expectations to be the appropriate test in deciding whether a hay baler was defectively designed), *with* McCormack v. Hanksraft Co., 154 N.W.2d 488 (Minn. 1967) (applying the risk-utility balancing test to find a vaporizer manufacturer negligent in adopting an unsafe design).

77. Some jurisdictions apply a combination of the consumer expectations and risk-utility tests. *See, e.g.*, Barker v. Lull Eng’g Co., 573 P.2d 443 (Cal. 1978) (providing plaintiffs with the option of using either basis of liability to establish a design defect); Caterpillar Tractor Co. v. Beck, 593 P.2d 871 (Alaska 1979); Dart v. Wiebe Mfg., Inc., 709 P.2d 876 (Ariz. 1985); Ontai v. Straub Clinic & Hosp. Inc., 659 P.2d 734 (Haw. 1983); Lamkin v. Towner, 563 N.E.2d 449 (Ill. 1990). Other jurisdictions apply a version of the risk-utility test with the addition of constructive knowledge, known as the Wade-Keeton hindsight test. 1 OWEN ET AL., *supra* note 61, at 494. These jurisdictions define design defectiveness for strict liability “in terms of whether a manufacturer or other seller, knowing of its product’s dangerous condition (a seller with full knowledge), would be negligent in selling it in that condition.” *Id.*

78. *See* 1 OWEN ET AL., *supra* note 61, at 443 (“All courts judge the adequacy of a product’s design upon one of two basic standards, or some variation thereof—(1) by determining whether the design meets the safety expectations of an ordinary user or consumer, and/or (2) by conducting a risk-benefit evaluation of whether the foreseeable safety benefits from eliminating a harmful design or feature exceed the foreseeable safety costs.”).

79. *Hansen*, 574 N.W.2d at 253 (quoting Ransome v. WEPCO, 275 N.W.2d 641, 649 (Wis. 1979)).

80. For example, because the risk of injury from obvious dangers shifts to the consumer under the consumer expectations test, “the test perniciously rewards manufacturers for failing to adopt cost-effective measures to remedy obviously unnecessary dangers to human life and limb.” 1 OWEN

abandoned the consumer expectations test for defective design<sup>81</sup> in favor of the predominant risk-utility test,<sup>82</sup> which considers whether "the safety benefits from eliminating the design danger that harmed the plaintiff were foreseeably greater than the precaution costs."<sup>83</sup> In other words, the risk-utility test "requires the balancing of the risks inherent in a product design against the utility of the product so designed."<sup>84</sup> Where a design is otherwise inadequate, it may nonetheless be found not defective where the danger is obvious,<sup>85</sup> the product is state of the art,<sup>86</sup> or the plaintiff fails to propose a reasonable alternative design.<sup>87</sup>

### iii. Warning Defects

Despite being properly manufactured and designed, a product may nonetheless be defective if it fails to include adequate warnings or instructions to reduce the risk of harm caused by the product's hazards.<sup>88</sup> A product contains a warning defect 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

ET AL., *supra* note 61, at 447. Furthermore, in complex cases, the consumer expectations test is difficult to apply because consumers often have only vague expectations. *Id.* at 447–48.

81. *Id.* at 445.

82. *Id.* at 449–51.

83. *Id.* at 452. "The risk-utility test for establishing design defectiveness is unaffected by whether the underlying theory of recovery is negligence or strict liability in tort, or possibly even implied warranty, because the necessary balance between a particular design feature's safety, costs, and effect on product utility remains the same." *Id.* at 453–54.

84. *Foley v. Clark Equip. Co.*, 523 A.2d 379, 388 (Pa. Super. Ct. 1987).

85. I OWEN ET AL., *supra* note 61, at 600–03. The obviousness of a danger affects not only the question of defectiveness but may also be a factor in determining proximate cause and the applicability of affirmative defenses, such as assumption of risk, contributory negligence, or comparative negligence. *Id.* at 603. Comment 1 to section 2 of the *Restatement (Third) of Torts: Products Liability* provides, however, that "obviousness of risk does not necessarily obviate a duty to provide a safer design. Just as warnings may be ignored, so may obvious or generally known risks be ignored, leaving a residuum of risk great enough to require adopting a safer design." RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. 1 (1998).

86. I OWEN ET AL., *supra* note 61, at 442. State of the art involves the question of "whether the means of avoiding the risks, by designing them away, are known or reasonably knowable and feasible under the existing state of science and technology." *Id.* at 627.

87. *See id.* at 465–67 (explaining that some jurisdictions require proof of a reasonable alternative design to establish a design defect claim).

88. *Id.* at 511. An adequate warning must "by its size, location and intensity of language or symbol, . . . be calculated to impress upon a reasonably prudent user the nature and extent of the hazard involved." *Id.* at 520.

commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.<sup>89</sup>

The duty to warn advances two policy objectives: (1) reduction of risks and accident costs, and (2) informed consent.<sup>90</sup> Like the requirement of a reasonable alternative design for design defects, warning defects require a showing that a better warning or instruction—a reasonable alternative warning—could have reasonably made the product safer.<sup>91</sup>

The *Restatement (Third) of Torts: Products Liability* addresses the relationship between design and warning defects:

In general, when a safer design can reasonably be implemented and risks can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a significant residuum of such risks. . . . However, when an alternative design to avoid risks cannot reasonably be implemented, adequate instructions and warnings will normally be sufficient to render the product reasonably safe. . . . Warnings are not, however, a substitute for the provision of a reasonably safe design.<sup>92</sup>

While the inclusion of warnings will not cure a design defect, warnings are necessary when a product's use creates a risk of likely or severe harm and that risk is not readily apparent to the user.<sup>93</sup> The *Restatement (Third) of Torts: Products Liability* explains, however, that a product may not be found defective for failure to warn where the risk of harm is obvious: "The fact that a risk is obvious or generally known often serves the same function as a warning."<sup>94</sup>

Manufacturers are presumed to possess "the knowledge and skill of an

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89. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(c) (1998).

90. 1 OWEN ET AL., *supra* note 61, at 513. The relationship between the duty to warn and the policy objectives is as follows:

As to risk and accident cost reduction, point of sale warnings as to product hazards and instructions for reasonably safe use are established mechanisms of hazard and injury reduction. The latter rationale—informed consent—reflects the societal judgment that a product user or consumer is entitled to make his own choice as to whether the product's utility or benefits justify exposing himself or others to the risk of harm.

*Id.* at 513–14.

91. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 cmt. a (1998).

92. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. 1 (1998).

93. 1 OWEN ET AL., *supra* note 61, at 511–12.

94. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. 1 (1998); *see also* Maneely v. Gen. Motors Corp., 108 F.3d 1176, 1180 (9th Cir. 1997) ("At some point, manufacturers must be relieved of the paternalistic responsibility of warning users of every possible risk that could arise from foreseeable use of their product. That point comes when ordinary users readily recognize the risk on their own."); *see supra* note 85 and accompanying text (discussing the effect of a danger's obviousness on the issue of design defectiveness).

expert."<sup>95</sup> In most jurisdictions, sellers are not liable for failing to warn of risks that are unknown or unknowable when the product is distributed.<sup>96</sup> Other jurisdictions, however, impute upon a manufacturer the knowledge of risks known at the time of trial regardless of whether such risks were known or knowable at the time of distribution.<sup>97</sup>

Warning defects may arise in claims based on negligence,<sup>98</sup> implied warranty of merchantability,<sup>99</sup> or strict liability in tort<sup>100</sup> principles. While many jurisdictions treat warnings defects the same regardless of the theory of liability applied, other jurisdictions continue to distinguish between

95. *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1089 (5th Cir. 1973). In *Borel*, the court held that "[t]he manufacturer's status as expert means that at a minimum he must keep abreast of scientific knowledge, discoveries, and advances and is presumed to know what is imparted thereby." *Id.*

96. 1 OWEN ET AL., *supra* note 61, at 517; *see, e.g.*, *Fibreboard Corp. v. Pool*, 813 S.W.2d 658, 668 (Tex. App. 1991) (in a failure to warn claim, the risk must be "reasonably foreseeable or scientifically discoverable"). The *Restatement (Third) of Torts: Products Liability* explains that, "[i]n cases involving a claim of design defect in a mechanical product, foreseeability of risk is rarely an issue as a practical matter. . . . [P]hysical risks of injury are generally known or reasonably knowable by experts in the field." RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. m (1998). However:

The issue of foreseeability of risk of harm is more complex in the case of products such as prescription drugs, medical devices, and toxic chemicals. Risks attendant to use and consumption of these products may, indeed, be unforeseeable at the time of sale. Unforeseeable risks arising from foreseeable product use or consumption by definition cannot specifically be warned against.

*Id.* Two rationales are cited for imposing liability for warning defects only when manufacturers have actual or constructive knowledge:

One practical reason for the limitation is that it will almost invariably be an exercise in speculation to warn about risks that are imperceptible. The second is that "if a manufacturer could not count on limiting its liability to risks that were known or knowable at the time of manufacture or distribution, it would be discouraged from developing new and improved products for fear that later significant advances in scientific knowledge would increase its liability.

1 OWEN ET AL., *supra* note 61, at 518–19 (quoting *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 556 (Cal. 1991)).

97. *See, e.g.*, *In re Haw. Fed. Asbestos Cases*, 699 F. Supp. 233 (D. Haw. 1988), *aff'd*, 960 F.2d 806 (9th Cir. 1992); *Dambacher v. Mallis*, 485 A.2d 408 (Pa. Super. Ct. 1984); *Ayers ex rel. Ayers v. Johnson & Johnson Baby Prods. Co.*, 818 P.2d 1337, 1346 (Wash. 1991).

98. 1 OWEN ET AL., *supra* note 61, at 516–17 ("Under negligence principles, a supplier may be liable for injury or damage for failure to warn adequately when it knows or should know that without warnings, the product is likely to pose an unreasonable risk of injury or damage, but fails to exercise reasonable care to inform users of that risk.")

99. *Id.* at 517 ("In warranty, an inadequate warning may also render a product unsuited for the ordinary purpose for which it is used, constituting a breach of the implied warranty of merchantability.")

100. *Id.* at 516 ("In most jurisdictions, under strict liability, a seller's failure to provide adequate warnings or instructions may result in liability if such deficiency renders the product 'unreasonably dangerous.'")

failure to warn claims based in negligence and those based in strict liability.<sup>101</sup> For example, in *Livingston v. Marie Callender's, Inc.*, the court held that:

the fact that a manufacturer acted as a reasonably prudent manufacturer in deciding not to warn, while perhaps absolving the manufacturer of liability under the negligence theory, will not preclude liability under strict liability principles if the trier of fact concludes that, based on the information scientifically available to the manufacturer, the manufacturer's failure to warn rendered the product unsafe to its users.<sup>102</sup>

As such, in a minority of jurisdictions, the plaintiff's theory of recovery may affect the issue of whether a product contains a warning defect.

## 2. Theories of Recovery

Where a product causes injury, an injured plaintiff may bring a products liability claim against appropriate defendants based on several different legal theories.<sup>103</sup> Products liability actions may be based on any combination of negligence, breach of warranty, and strict liability claims.<sup>104</sup>

### i. Negligence

Since *MacPherson v. Buick Motor Co.*<sup>105</sup> first "gave birth to negligence claims against manufacturers,"<sup>106</sup> negligence actions have occupied a central role in products liability law.<sup>107</sup> Described as "the classic products liability

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101. *Id.* at 514–15.

102. *Livingston v. Marie Callender's, Inc.*, 85 Cal. Rptr. 2d 528, 532 (Ct. App. 1999) (quoting *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 559 (Cal. 1991)) (internal quotation marks omitted).

103. 1 OWEN ET AL., *supra* note 61, at 16.

104. *See supra* note 47 and accompanying text.

105. 111 N.E. 1050 (N.Y. 1916). In *MacPherson*, the wooden wheel spokes broke on a Buick-manufactured automobile, causing the wheel's collapse and the plaintiff's injury. *Id.* at 1051. In holding Buick liable despite a lack of privity, New York's highest court concluded that "the manufacturer of [a] thing of danger is under a duty to make it carefully." *Id.* at 1053.

106. OWEN, *supra* note 30, at 23.

107. 1 OWEN ET AL., *supra* note 61, at 43. Negligence was the standard theory of recovery in early products liability actions. *Id.* Even after strict liability in tort emerged as a popular cause of action, negligence has retained its central position. *Id.* Negligence principles remain especially relevant to products liability actions in those states that do not recognize strict liability in tort, including Delaware, Massachusetts, Michigan, North Carolina, and Virginia. *See Joseph v. Jamesway Corp.*, 1997 WL 524126 (Del. Super. Ct. 1997); *Commonwealth v. Johnson Insulation*, 682 N.E.2d 1323 (Mass. 1997); *Ryan v. Brunswick Corp.*, 557 N.W.2d 541 (Mich. 1997), *abrogated on other grounds by Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002); *Bryant v. Adams*, 448 S.E.2d 832 (N.C. Ct. App. 1994); *Harris v. T.I., Inc.*, 413 S.E.2d 605 (Va. 1992).

claim,"<sup>108</sup> negligence actions require a plaintiff to show that (1) the seller owed the plaintiff a duty of due care, (2) the seller breached that duty by furnishing a defective<sup>109</sup> product, and (3) the seller's breach caused the plaintiff's injury.<sup>110</sup> The seller's duty to provide safe products applies to a product's manufacture,<sup>111</sup> design,<sup>112</sup> and inclusion of warnings and instructions,<sup>113</sup> and it is described as a "duty to exercise reasonable care to prevent unreasonable risks of injury from the products they sell."<sup>114</sup> Because a seller's duty under negligence is one of reasonableness,<sup>115</sup> the fact that a product is defective will not in itself establish a breach<sup>116</sup>:

108. 1 OWEN ET AL., *supra* note 61, at 43.

109. The product may contain a manufacturing defect, design defect, or warning defect. *Id.* at 44.

110. *See id.* at 43–44.

111. The exercise of due care in the manufacturing context:

requires the manufacturer to exercise reasonable care in the production of the product. This duty requires the manufacturer to exercise reasonable care at two distinct stages of the manufacturing process prior to distribution of the product: (1) during the actual process of manufacturing the product, including the selection, inspection, and assembly of raw materials and component parts; and (2) after production, in the process of quality control ("quality assurance") designed to limit the output of defective products to the smallest reasonable level.

*Id.* at 45.

112. The exercise of due care in the design context:

requires that the manufacturer exercise reasonable care in a variety of different functions: that the general product concept be conceived and formulated carefully for its reasonable uses and abuses; that proper attention be devoted to selecting appropriate materials and components to be assembled together into the finished product; that safety devices for the product's expected uses be adopted as appropriate; and that prototypes of the product be tested, as appropriate, in contexts duplicating the harshest circumstances of expected use.

*Id.* at 44–45.

113. To satisfy the requirement of due care in the warnings context, "manufacturers must exercise reasonable care to instruct consumers on how to use such products safely and to warn them of hidden dangers that the products may contain." *Id.* at 45–46.

114. *Id.* at 44.

115. *See id.* at 46 ("[T]he duty under negligence law is limited to *reasonable* care—not perfect care; to protecting only persons *foreseeably* placed at risk—not all persons; and to avoid only risks that are foreseeable—not all risks."). Reasonable care is determined by weighing the cost of preventing an injury against the risk of harm: "If the risk posed by the sale and use of a product in a certain condition is great, due care therefore requires that great precautions be taken to avert the risk; if the risk is small, reasonable care requires only small precautionary measures in response." *Id.* at 55. Judge Learned Hand explained this concept in *United States v. Carroll Towing Co.*, 159 F.2d 169 (2d Cir. 1947), with the following algebraic formula:  $B < P \times L \rightarrow N$ . *Id.* at 173. This formula stands for the proposition that a party is negligent (N) if the burden or cost of preventing harm (B) is less than the product of the probability of harm (P) and the likely magnitude of harm (L). *Id.*

116. "Even the most careful manufacturers who follow all tenets of good manufacturing practices sometimes produce products that are defective." 1 OWEN ET AL., *supra* note 61, at 46. For instance, even if a manufacturer could have identified risks through additional testing and altered the product's design to reduce those risks, the manufacturer may not be negligent for defective design if the decision to forego additional testing was reasonable:



[T]he plaintiff in a negligence case generally must prove both defect and negligence: that is, (1) that the product was *defective* (in its design, manufacture, or marketing), and (2) that the manufacturer was *negligent* in some manner in allowing the product to be manufactured and sold in a defective condition.<sup>117</sup>

Because the plaintiff must show that a defendant-seller acted unreasonably, negligence—unlike the implied warranty of merchantability<sup>118</sup> and strict liability in tort<sup>119</sup>—does not extend liability to all parties in the chain of distribution without a showing of individualized fault.<sup>120</sup>

## ii. Breach of Warranty

Breach of warranty claims are contract-based causes of action involving the sale of goods.<sup>121</sup> Without regard to fault, sellers are strictly liable for any breach of warranty due to the “presumed voluntary nature of the contract.”<sup>122</sup> Warranties may be either express<sup>123</sup> or implied.<sup>124</sup> The Uniform Commercial Code (UCC) recognizes two types of implied warranties which are, unless excluded by specific language, read into agreements for the sale of goods: the implied warranty of fitness for a particular purpose<sup>125</sup> and the implied warranty of merchantability.<sup>126</sup>

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Almost any risk is foreseeable if a product is tested sufficiently. But the issue in negligence is whether a risk is *reasonably* foreseeable, an issue that depends on the reasonableness of the decision to forego further testing. If a reasonably prudent person would believe that additional research would not be cost-effective, a decision to forego the research would be reasonable, and the risks it would have disclosed would not have been *reasonably* foreseeable. Risks that are not *reasonably* foreseeable do not count against a manufacturer in a cost-benefit analysis to determine negligence.

Powers, *supra* note 60, at 792–93.

117. 1 OWEN ET AL., *supra* note 61, at 46.

118. See *infra* notes 151–62 and accompanying text.

119. See *infra* notes 173–92 and accompanying text.

120. Negligence will only impose liability on a party that acted unreasonably—which is typically the manufacturer, because a distributor or retailer is generally not involved in the product’s manufacture, design, or inclusion of warnings and instructions. See OWEN, *supra* note 30, at 29–30.

121. Under the UCC, “goods” are defined as:

all things that are movable at the time of identification to a contract for sale. The term includes future goods, specially manufactured goods, the unborn young of animals, growing crops, and other identified things attached to realty as described in Section 2-107. The term does not include information, the money in which the price is to be paid, investment securities under Article 8, the subject matter of foreign exchange transactions, or choses in action.

U.C.C. § 2-103 (2004).

122. NOEL & PHILLIPS, *supra* note 33, at 35.

123. See *infra* notes 135–42 and accompanying text.

124. See *infra* notes 143–62 and accompanying text.

125. See U.C.C. § 2-315 (2004).

126. See U.C.C. § 2-314 (2004).

Although breach of warranty has its origin in tort rather than in contract,<sup>127</sup> it has been embraced by the UCC as an integral part of contract law.<sup>128</sup>

Products liability's relaxation of warranty's privity requirement<sup>129</sup> has led some scholars to question whether "warranty without privity is really warranty at all in its contractual sense."<sup>130</sup> Although a contractual relationship is generally recognized as an essential element of a breach of warranty claim, products liability has both eliminated barriers to suing various parties in the chain of distribution<sup>131</sup> and has expanded the ability of non-purchasers<sup>132</sup> to recover in warranty for injuries caused by a product.<sup>133</sup> Because the relaxation of the horizontal privity requirement varies broadly by jurisdiction, the UCC recognizes three alternatives for extending both express and implied warranty protection to non-purchasers.<sup>134</sup>

127. William L. Prosser, *The Implied Warranty of Merchantable Quality*, 27 MINN. L. REV. 117, 118 (1943) ("In its inception, breach of warranty was a tort."); see also NOEL & PHILLIPS, *supra* note 33, at 33.

128. See U.C.C. §§ 2-313 to 2-315 (2004); see also NOEL & PHILLIPS, *supra* note 33, at 34 ("American courts . . . attribute[d] a contractual nature to implied warranty and therefore an association with privity.").

129. See OWEN, *supra* note 30, at 23–24 ("Truly modern products liability law in America began in 1960 with *Henningsen v. Bloomfield Motors* which allowed a non-purchaser injured in an accident caused by a defective automobile to maintain a breach of warranty action against the manufacturer despite the absence of privity of contract and notwithstanding a contractual disclaimer that barred such claims."); see also *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69 (N.J. 1960).

130. NOEL & PHILLIPS, *supra* note 33, at 34 (citing W. PROSSER, *THE LAW OF TORTS* 656–58 (4th ed. 1971); Thomas A. Cowan, *Some Policy Bases of Products Liability*, 17 STAN. L. REV. 1077, 1080 (1965).

131. This is commonly known as "vertical privity." 1 OWEN ET AL., *supra* note 61, at 163.

132. This is commonly known as "horizontal privity." *Id.*

133. See generally *id.* at 162–77.

134. The provision provides:

Alternative A to subsection 2:

A seller's warranty to an immediate buyer, whether express or implied, a seller's remedial promise to an immediate buyer, or a seller's obligation to a remote purchaser under Section 2-313A or 2-313B extends to any individual who is in the family or household of the immediate buyer or the remote purchaser or who is a guest in the home of either if it is reasonable to expect that the person may use, consume, or be affected by the goods and who is injured in person by breach of the warranty, remedial promise, or obligation. A seller may not exclude or limit the operation of this section.

Alternative B to subsection 2:

A seller's warranty to an immediate buyer, whether express or implied, a seller's remedial promise to an immediate buyer, or a seller's obligation to a remote purchaser under Section 2-313A or 2-313B extends to any individual who may reasonably be expected to use, consume, or be affected by the goods and who is injured in person by breach of the warranty, remedial promise, or obligation. A seller may not exclude or limit the operation of this section.

Alternative C to subsection 2:

A seller's warranty to an immediate buyer, whether express or implied, a seller's

## a. Express Warranties

Express warranties are statements made by a seller and relied upon by a buyer as part of a sales agreement.<sup>135</sup> The creation of express warranties is governed by UCC section 2-313.<sup>136</sup> Express warranties can be created by both merchants and non-merchants<sup>137</sup> through written or oral statements, images, packaging, or samples,<sup>138</sup> and the seller need not use the word “warranty” or even intend to give a warranty.<sup>139</sup> Any attempt to exclude warranties is void to the extent that the attempted exclusion is inconsistent with an express warranty.<sup>140</sup>

To establish a breach of an express warranty, a plaintiff must show that

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remedial promise to an immediate buyer, or a seller’s obligation to a remote purchaser under Section 2-313A or 2-313B extends to any person that may reasonably be expected to use, consume, or be affected by the goods and that is injured by breach of the warranty, remedial promise, or obligation. A seller may not exclude or limit the operation of this section with respect to injury to the person of an individual to whom the warranty, remedial promise, or obligation extends.

U.C.C. § 2-318 (2004).

135. U.C.C. § 2-313(2) (2004).

136. The provision states:

- (2) Express warranties by the seller to the immediate buyer are created as follows:
  - (a) Any affirmation of fact or promise made by the seller which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
  - (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
  - (c) Any sample or model that is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.
- (3) It is not necessary to the creation of an express warranty that the seller use formal words such as “warranty” or “guarantee” or that the seller have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller’s opinion or commendation of the goods does not create a warranty.
- (4) Any remedial promise made by the seller to the immediate buyer creates an obligation that the promise will be performed upon the happening of the specified event.

U.C.C. § 2-313 (2004).

137. 1 OWEN ET AL., *supra* note 61, at 128.

138. U.C.C. § 2-313(2) (2004); *see also* PRACTISING LAW INSTITUTE, PRODUCTS LIABILITY 3:3 (Sol Schreiber & Paul D. Rheingold eds. 1967) (“Oral statements by sellers, labels, containers, photographs, and advertising copy all attest to the advantages of a particular product. They are also sources of express warranties.”).

139. U.C.C. § 2-313(3) (2004).

140. *See* U.C.C. § 2-316(1) (2004). For example, in *Realmuto v. Straub Motors, Inc.*, 322 A.2d 440 (N.J. 1974), a used car salesman wrote “30 day warranty” on the front of plaintiff’s purchase agreement, but he included a printed clause on the back of the agreement that provided, “It is expressly agreed that there are no warranties, express or implied, made by either the selling dealer or the manufacturer . . .” *Id.* at 442 & n.2. Six days after the purchase, the plaintiff was injured by the malfunction of the vehicle’s carburetor linkage. *Id.* at 442. The court held that the disclaimer was inoperative to exclude the express thirty-day warranty. *Id.* at 442 n.2.

(1) the seller made a factual assertion or promise which constitutes an express warranty, (2) the assertion was a basis of the bargain, (3) the assertion was false, and (4) the falsity of the assertion caused harm to the plaintiff.<sup>141</sup> Because liability for breach of an express warranty does not require a defect, express warranties "impose a form of 'strict' liability upon the seller which requires no showing of fault."<sup>142</sup>

b. Implied Warranty of Fitness for a Particular Purpose<sup>143</sup>

The implied warranty of fitness for a particular purpose is an implied promise by the seller that the product is suitable for the buyer's special purpose.<sup>144</sup> To establish a breach of the fitness warranty, a plaintiff must show that (1) the seller had knowledge of the buyer's particular purpose, (2) the buyer relied on the seller's skill and judgment, (3) the product was not fit for the buyer's particular purpose, and (4) the unfitness of the product for the buyer's purpose caused harm to the plaintiff.<sup>145</sup>

Although it does not require a defect,<sup>146</sup> the fitness warranty demands that the seller be aware of the buyer's special purpose.<sup>147</sup> Accordingly, it usually "arises from a one-on-one dealing between the buyer and the seller calculated to create quite explicit expectations in the buyer as to the product's ability to accomplish his or her particular task."<sup>148</sup> In contrast with the implied warranty of merchantability,<sup>149</sup> the fitness warranty arises when a buyer purchases a product for a special, rather than ordinary, purpose.<sup>150</sup>

141. 1 OWEN ET AL., *supra* note 61, at 127–28.

142. *Id.* at 127.

143. U.C.C. § 2-315 (2004).

144. The provision states:

Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purposes.

*Id.*

145. *Id.*

146. 1 OWEN ET AL., *supra* note 61, at 162 ("Provided the conditions exist which give rise to the warranty, it may be breached when a product properly made and merchantable is simply the wrong one for the buyer's particular use.").

147. U.C.C. § 2-315 (2004).

148. 1 OWEN ET AL., *supra* note 61, at 154.

149. See *infra* notes 151–62 and accompanying text.

150. 1 OWEN ET AL., *supra* note 61, at 154–55. The distinction between a particular purpose and an ordinary purpose is explained as follows:

A "particular purpose" differs from the ordinary purpose for which the goods are used in that it envisages a specific use by the buyer which is peculiar to the nature of his business

c. Implied Warranty of Merchantability<sup>151</sup>

The implied warranty of merchantability<sup>152</sup> is read into a sales agreement without regard to the parties' intentions, arising "merely because the goods have been sold at all."<sup>153</sup> The underlying policy behind the implied warranty of merchantability is the promotion of fair dealing in sales agreements.<sup>154</sup> One primary justification for imposing an implied warranty on sellers is the belief that the responsibility for defective goods "is best placed upon the seller as a cost of his business, which he may distribute to the public at large as part of the price."<sup>155</sup>

To establish a breach of the implied warranty of merchantability, the plaintiff must show that (1) the seller is a merchant,<sup>156</sup> (2) the product was

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whereas the ordinary purposes for which goods are used are those envisaged in the concept of merchantability and go to uses which are customarily made of the goods in question. For example, shoes are generally used for the purpose of walking upon ordinary ground, but a seller may know that a particular pair was selected to be used for climbing mountains.

U.C.C. § 2-315 cmt. 2 (2004).

151. U.C.C. § 2-314 (2004).

152. The provision states:

- (1) Unless excluded or modified (Section 2-316), a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. Under this section the serving for value of food or drink to be consumed either on the premises or elsewhere is a sale.
- (2) Goods to be merchantable must be at least such as
  - (a) pass without objection in the trade under the contract description; and
  - (b) in the case of fungible goods, are of fair average quality within the description; and
  - (c) are fit for the ordinary purposes for which such goods are used; and
  - (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
  - (e) are adequately contained, packaged, and labeled as the agreement may require; and
  - (f) conform to the promises or affirmations of fact made on the container or label if any.
- (3) Unless excluded or modified (Section 2-316) other implied warranties may arise from course of dealing or usage of trade.

*Id.*

153. Prosser, *The Implied Warranty of Merchantable Quality*, *supra* note 127, at 124.

154. J.W. Looney, *Warranties in Livestock, Feed, Seed, and Pesticide Transactions*, 25 U. MEM. L. REV. 1123, 1127 (1995).

155. Prosser, *The Implied Warranty of Merchantable Quality*, *supra* note 127, at 122.

156. A "merchant" is defined as:

a person that deals in goods of the kind or otherwise holds itself out by occupation as having knowledge or skill peculiar to the practices or goods involved in the transaction or to which the knowledge or skill may be attributed by the person's employment of an agent or broker or other intermediary that holds itself out by occupation as having the knowledge or skill.

U.C.C. § 2-104(1) (2004). Thus, the implied warranty of merchantability "does not apply to isolated sales made by persons not fitting that description, 'isolated sales' being such as occur only once or very infrequently in the course of the seller's ordinary business." 1 OWEN ET AL., *supra* note 61, at 144.

unmerchantable<sup>157</sup>—or defective<sup>158</sup>—at the time of sale, and (3) the unmerchantable condition of the product caused the plaintiff's injury.<sup>159</sup> The implied warranty of merchantability applies to all merchants in the chain of distribution<sup>160</sup> without regard to fault.<sup>161</sup> It does not, however, apply to "open and obvious" product defects.<sup>162</sup>

#### d. Exclusion & Modification of Warranties<sup>163</sup>

UCC section 2-316 governs the exclusion or modification of warranties.<sup>164</sup> Although attempts to exclude warranties are inoperable to the

157. A product is unmerchantable when it is not fit for its ordinary purpose. See *McCabe v. L. K. Liggett Drug Co.*, 112 N.E.2d 254, 256 (Mass. 1953) ("Merchantable quality means that goods are reasonably suitable for the ordinary uses for which goods of that description are sold.").

158. Again, the defect may arise due to deficiencies in the product's manufacture, design, or warnings. 1 OWEN ET AL., *supra* note 61, at 142–43.

159. See U.C.C. § 2-314 (2004).

160. See 1 OWEN ET AL., *supra* note 61, at 144 ("The implied warranty of merchantability runs with all such goods sold . . .").

161. *Id.* at 141.

162. See U.C.C. § 2-316(3)(b) (2004) ("[W]hen the buyer before entering into the contract has examined the goods or the sample or model as fully as he desired or has refused to examine the goods there is no implied warranty with regard to defects which an examination ought in the circumstances to have revealed to him").

163. U.C.C. § 2-316 (2004).

164. The provision states:

- (1) Words or conduct relevant to the creation of an express warranty and words or conduct tending to negate or limit warranty shall be construed wherever reasonable as consistent with each other; but subject to the provisions of this Article on parol or extrinsic evidence (Section 2-202) negation or limitation is inoperative to the extent that such construction is unreasonable.
- (2) Subject to subsection (3), to exclude or modify the implied warranty of merchantability or any part of it the language must mention merchantability and in case of a writing must be conspicuous, and to exclude or modify any implied warranty of fitness the exclusion must be by a writing and conspicuous. Language to exclude all implied warranties of fitness is sufficient if it states, for example, that "There are no warranties which extend beyond the description on the face hereof."
- (3) Notwithstanding subsection (2)
  - (a) unless the circumstances indicate otherwise, all implied warranties are excluded by expressions like "as is", "with all faults" or other language which in common understanding calls the buyer's attention to the exclusion of warranties and makes plain that there is no implied warranty; and
  - (b) when the buyer before entering into the contract has examined the goods or the sample or model as fully as he desired or has refused to examine the goods there is no implied warranty with regard to defects which an examination ought in the circumstances to have revealed to him; and
  - (c) an implied warranty can also be excluded or modified by course of dealing or course of performance or usage of trade.
- (4) Remedies for breach of warranty can be limited in accordance with the provisions of

extent that such attempts are inconsistent with express warranties,<sup>165</sup> implied warranties can generally be excluded if certain conditions are met.<sup>166</sup> The implied warranty of merchantability can be disclaimed orally or in writing, provided that the seller uses the word “merchantability,” and such a disclaimer must be conspicuous only if in writing.<sup>167</sup> The exclusion of the fitness warranty, in contrast, which was likely created as part of the sale,<sup>168</sup> must be in writing and conspicuous but need not mention “implied warranty for a particular purpose.”<sup>169</sup> Despite these requirements, implied warranties are excluded when the seller provides language conveying that the good is being sold “as is,” the buyer has had the opportunity to examine the goods for apparent defects, or the implied warranty has been altered by the parties by course of dealing, course of performance, or trade usage.<sup>170</sup> The limitation of breach of warranty remedies is permitted by UCC section 2-316(4) and is addressed in UCC sections 2-718<sup>171</sup> and 2-719.<sup>172</sup>

### iii. *Strict Liability in Tort*

Three years after New Jersey’s *Henningsen* decision,<sup>173</sup> California’s Supreme Court decided *Greenman v. Yuba Power Products, Inc.*,<sup>174</sup> in which Justice Roger Traynor established the new doctrine of strict liability in tort, stating that “[a] manufacturer is strictly liable in tort when an article

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this Article on liquidation or limitation of damages and on contractual modification of remedy (Sections 2-718 and 2-719).

*Id.*

165. *See supra* note 140 and accompanying text.

166. *See* U.C.C. § 2-316 (2004).

167. U.C.C. § 2-316(2) (2004).

168. *See supra* note 148 and accompanying text.

169. *See* U.C.C. § 2-316(2) (2004).

170. U.C.C. § 2-316(3) (2004).

171. UCC section 2-718 discusses the liquidation or limitation of damages. U.C.C. § 2-718 (2004).

172. UCC section 2-719 discusses contractual modifications or limitations of remedies. U.C.C. § 2-719 (2004). UCC section 2-719(3) addresses consequential damages and provides that such damages “may be limited or excluded unless the limitation or exclusion is unconscionable. Limitation of consequential damages for injury to the person in the case of consumer goods is prima facie unconscionable but limitation of damages where the loss is commercial is not.” U.C.C. § 2-719(3) (2004).

173. *See supra* note 129 and accompanying text.

174. 377 P.2d 897 (Cal. 1963). In *Greenman*, the plaintiff was injured by a combination power tool purchased for him by his wife. *Id.* at 898. Relying on the plaintiff’s evidence that his injuries were caused by the power tool’s defective manufacture and design, the jury returned a \$65,000 verdict for the plaintiff. *Id.* at 899. In upholding the trial court’s ruling, Justice Traynor held that:

[t]o establish the manufacturer’s liability it was sufficient that plaintiff proved that he was injured while using the Shopsmith in a way it was intended to be used as a result of a defect in design and manufacture of which plaintiff was not aware that made the Shopsmith unsafe for its intended use.

*Id.* at 901.

he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being."<sup>175</sup> Prior to *Greenman*, "actions for injuries caused by defective products had been based either on breach of warranty or on negligence; after 1963, a plaintiff had the additional choice of basing his action under the new theory of strict liability in tort."<sup>176</sup> Shortly after *Greenman* was decided, the American Law Institute adopted the rule of strict liability in tort in section 402A<sup>177</sup> of the *Restatement (Second) of Torts*, which "marked the first recognition by the [American Law Institute] of privity-free strict liability for sellers of defective products."<sup>178</sup> Many other jurisdictions soon followed California's lead in adopting the doctrine.<sup>179</sup>

Strict liability in tort is "strict" in that it does not require a showing of

175. *Id.* at 900. Justice Traynor expressly recognized the limitations of warranty, explaining that although previous cases imposing strict liability on manufacturers were generally based on contractual warranties:

the abandonment of the requirement of a contract between them, the recognition that the liability is not assumed by agreement but imposed by law, and the refusal to permit the manufacturer to define the scope of its own responsibility for defective products make clear that the liability is not one governed by the law of contract warranties but by the law of strict liability in tort. . . .

. . . The purpose of [strict liability in tort] is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves. Sales warranties serve this purpose fitfully at best.

*Id.* at 901 (citations omitted).

176. OWLES, *supra* note 46, at 37.

177. Section 402A 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.

RESTATEMENT (SECOND) OF TORTS § 402A (1965).

178. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB., Introduction (1998) ("The major thrust of § 402A was to eliminate privity so that a user or consumer, without having to establish negligence, could bring an action against a manufacturer, as well as against any other member of a distributive chain that had sold a product containing a manufacturing defect.").

179. With Wyoming's adoption of strict liability in tort in *Ogle v. Caterpillar Tractor Co.*, 716 P.2d 334 (Wyo. 1986), the doctrine has been accepted by forty-five states, as well as the District of Columbia and the Virgin Islands. See 1 OWEN ET AL., *supra* note 61, at 274-75. Five jurisdictions still do not recognize the doctrine. See *supra* note 107.



any fault on the part of the seller.<sup>180</sup> There are two primary justifications for subjecting sellers to strict liability in tort: first, to compensate consumers for injuries caused by defective products through “risk-spreading,” and second, to deter the production of unsafe products.<sup>181</sup> To bring a claim in strict liability in tort, the plaintiff must establish that (1) the seller is regularly engaged in sales of products of that kind, (2) the product was in a defective<sup>182</sup> condition and unreasonably dangerous, (3) there was no causative change in the condition in which the product was sold, and (4) the defective condition of the product caused the plaintiff’s injury.<sup>183</sup> Like the implied warranty of merchantability,<sup>184</sup> strict liability in tort applies to all sellers in a product’s chain of distribution,<sup>185</sup> although it does not apply to occasional sellers.<sup>186</sup> Further, strict liability in tort does not require privity between a seller and the product’s ultimate consumer.<sup>187</sup>

The standard for establishing product defectiveness in strict liability in tort varies depending on the jurisdiction and whether the alleged defect involves the product’s manufacture, design, or warnings.<sup>188</sup> Recognizing that section 402A, which was established to address manufacturing defects,<sup>189</sup> is inappropriate for claims involving design and warning defects,<sup>190</sup> the *Restatement (Third) of Torts: Products Liability* has adopted a

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180. See RESTATEMENT (SECOND) OF TORTS § 402A(2)(a) (1965).

181. Owen, *Moral Foundations*, *supra* note 41, at 430–31.

182. See Gilmore, *supra* note 36, at 108 (“[N]o court has (‘so far’) imposed truly strict liability—that is, allowed recovery where all that the injured plaintiff proved was that his injury resulted from his use of the goods. . . . [C]ourts have insisted that the plaintiff prove, additionally, that the goods, whose use caused the injury, were, in some sense, ‘defective.’”).

183. See RESTATEMENT (SECOND) OF TORTS § 402A(1) (1965). The plaintiff’s injury must be one that is recoverable under strict liability. For example, “intangible commercial loss or pure economic loss is ordinarily not recoverable in strict liability but is normally considered under the provisions of the UCC rules governing commercial transactions.” Looney, *supra* note 154, at 1133.

184. See *supra* notes 160–61.

185. See RESTATEMENT (SECOND) OF TORTS § 402A(2)(b) (1965).

186. 1 OWEN ET AL., *supra* note 61, at 267–68.

187. See RESTATEMENT (SECOND) OF TORTS § 402A(2)(b) (1965). Before the adoption of strict liability in tort, the requirement of privity in the products field had been criticized for failing to protect foreseeable users of a product beyond the purchaser and resulting in:

such utterly preposterous decisions as those holding that the wife who buys the sausage, handles it, cooks it, eats it, and is poisoned by it, cannot recover because she was merely buying as the agent of her husband, who was to pay the bill and so is regarded as the contracting party; whereas the husband, who never saw the food, can recover on a warranty for the loss of her services.

William L. Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1118 (1960) [hereinafter Prosser, *The Assault Upon the Citadel*].

188. 1 OWEN ET AL., *supra* note 61, at 293–94; see also *supra* notes 57–102 and accompanying text.

189. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 cmt. a (1998).

190. Because of the negligence principles inherent in a risk-utility analysis of design or warning defect, section 402A has been criticized for its blanket application of strict liability in tort to all variations of defect:

The American Law Institute gave birth to . . . analytic confusion with the highly

general rule of liability for sellers of defective products.<sup>191</sup> The *Restatement (Third) of Torts: Products Liability* ignores the traditional significance attached to the theory of liability and instead defines liability based entirely on the type of defect.<sup>192</sup>

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influential section 402A of the *Restatement (Second) of Torts*, which states that strict liability applies equally well to cases involving manufacturing defects, design defects, and failures to warn. Strict liability can be applied coherently in manufacturing defect cases because a product's defectiveness can be determined without resort to negligence-oriented cost-benefit balancing. But in both defective-design and failure-to-warn cases, cost-benefit balancing is inevitably required to determine product defectiveness. Because cost-benefit balancing is also at the heart of negligence, it is no easy matter in design and warning cases to discover a difference between strict liability and negligence.

James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 271-72 (1990). Some courts have outright recognized the doctrine's relationship to negligence where the risk-utility standard is used to determine whether there is a defect under strict liability in tort involving design or warning defects. See, e.g., *Crislip v. TCH Liquidating Co.*, 556 N.E.2d 1177, 1183 (Ohio 1990) ("[T]he standard imposed upon the defendant in a strict liability claim grounded upon an inadequate warning is the same as that imposed in a negligence claim based upon inadequate warning."); see also *Olson v. Prosoco, Inc.*, 522 N.W.2d 284, 289 (Iowa 1994) ("[A]ny posited distinction between strict liability and negligence principles is illusory.").

191. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 (1998) ("One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.").

192. See *id.* cmt. a. The *Restatement (Third)* suggests that, "[a]s long as [the] functional criteria [for defect] are met, courts may utilize the terminology of negligence, strict liability, or the implied warranty of merchantability, or simply define liability in the terms set forth in the black letter." *Id.* The functional criteria for defect, as provided in the *Restatement (Third) of Torts: Products Liability* section 2, are as follows:

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.

*Id.* § 2.

### 3. Affirmative Defenses

Various defenses, based on the plaintiff's conduct, are available to a defendant in a products liability action.<sup>193</sup> Comparative fault principles may justify the outright denial of a claim or the reduction of damages where a plaintiff voluntarily assumes a risk, causes or contributes to the injury, or misuses a product.<sup>194</sup>

The assumption of risk defense is based on the notion that a plaintiff has consented to encounter a risk, and it completely bars a plaintiff's claim.<sup>195</sup> Assumption of risk requires both that the plaintiff subjectively appreciate the risk and voluntarily encounter it because "a person cannot 'consent' to what he does not know nor what is forced upon him."<sup>196</sup> Whether these elements are satisfied is generally a question of fact for a jury.<sup>197</sup>

Contributory<sup>198</sup> or comparative<sup>199</sup> negligence may be available as a defense when the plaintiff's conduct "falls below the standard of reasonable behavior required for a person's own protection which proximately contributes . . . to cause the person's harm."<sup>200</sup> Although some jurisdictions do not recognize this defense in claims brought in strict liability in tort, it is widely available in negligence claims.<sup>201</sup> Like assumption of risk, whether the plaintiff contributed to the harm is often a question of fact for a jury, although the court may rule on the issue as a matter of law if the plaintiff's action is undoubtedly reasonable or unreasonable.<sup>202</sup>

The rationale behind the misuse defense is that "products are necessarily designed to do certain limited tasks, within certain limited environments of use, and that no product can be made safe for every purpose, manner, or extent of use."<sup>203</sup> As such, unforeseeable misuse of a product may completely bar a plaintiff's claim.<sup>204</sup> Sellers remain liable, however, for reasonably foreseeable misuse of a product.<sup>205</sup> The question of foreseeability of misuse is generally a question of fact for a jury.<sup>206</sup> The

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193. 2 DAVID G. OWEN ET AL., MADDEN & OWEN ON PRODUCTS LIABILITY 3 (3rd ed. 2000).

194. *Id.*

195. *See id.* at 26–27 ("By the act of incurring the risk, the user thus implicitly agrees to take responsibility for any harmful consequences that may result from the encounter and so relieves the person who created the risk from responsibility.").

196. *Id.* at 27–28.

197. *Id.* at 28.

198. Contributory negligence acts as a total bar to a plaintiff's claim. *Id.* at 3.

199. Comparative negligence reduces a plaintiff's damages in proportion to the plaintiff's fault. *Id.*

200. *Id.* at 10.

201. *Id.*

202. *Id.* at 12.

203. *Id.* at 51.

204. *Id.* at 49–50.

205. *Id.* at 51–52.

206. *Id.* at 58.

failure to heed a product's warnings or to follow its instructions is another form of product misuse which may bar a plaintiff's claim.<sup>207</sup>

*B. Who's Your Daddy? The Evolution of Artificial Insemination in the United States*

Artificial insemination<sup>208</sup> has been utilized for more than two centuries as an alternative to sexual intercourse as a means of achieving conception.<sup>209</sup> Various insemination methods are used,<sup>210</sup> and there are two broad categories of artificial insemination: (1) artificial insemination by husband (AIH), in which a recipient's husband provides the sperm; and (2) artificial insemination by donor (AID), in which the sperm is provided by a male other than a recipient's husband.<sup>211</sup> In the AID context, the donor may be either known or anonymous.<sup>212</sup>

Since its first reported use in 1884,<sup>213</sup> AID has gradually gained

207. This position is adopted by the *Restatement (Second) of Torts*: "Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous." RESTATEMENT (SECOND) OF TORTS § 402A cmt. j.

208. See *supra* note 4.

209. The first documented case of successful human artificial insemination occurred in the late eighteenth century in Britain using the recipient's husband's sperm. See Megan D. McIntyre, Comment, *The Potential for Products Liability Actions When Artificial Insemination by an Anonymous Donor Produces Children with Genetic Defects*, 98 DICK. L. REV. 519, 519 n.1 (1994) (citing DOUGLAS J. CUSINE, *NEW REPRODUCTIVE TECHNOLOGIES: A LEGAL PERSPECTIVE* 12, 13 (1988)). The first recorded case in the United States occurred nearly one century later in 1866. Karen M. Ginsberg, Comment, *FDA Approved? A Critique of the Artificial Insemination Industry in the United States*, 30 U. MICH. J.L. REFORM 823, 826 (1997).

210. Standard vaginal insemination, for example, occurs when "a woman inserts semen into her vagina where the sperm swims into her cervix, uterus, and finally to the fallopian tubes to meet an ovum for fertilization." Swink & Reich, *supra* note 4, at 860 n.14. Intrauterine insemination, a more efficient method, occurs when "fresh semen is placed in a centrifuge where the sperm are 'washed,' extracted from the semen, and inserted directly into a woman's uterus via a long, sterile catheter syringe." *Id.*

211. *Id.* at 860-61.

212. *Id.* at 861.

213. Erica Haimes & Ken Daniels, *International Social Science Perspectives on Donor Insemination: An Introduction*, in DONOR INSEMINATION: INTERNATIONAL SOCIAL SCIENCE PERSPECTIVES 1 (Ken Daniels & Erica Haimes eds. 1998). The event was first described in a 1909 *Medical World* article, which was met with reactions "rang[ing] from outrage to applause." ELAINE TYLER MAY, *BARREN IN THE PROMISED LAND: CHILDLESS AMERICANS AND THE PURSUIT OF HAPPINESS* 67 (1997). The article reported that, upon discovering that the recipient's husband had no sperm in his semen, the treating physician anesthetized the recipient and inserted a semen sample from "the 'best-looking member of [his medical] class'" into her uterus via a rubber syringe. *Id.* at 65-66. When the woman achieved pregnancy, the doctor told the recipient's husband about the procedure, although the recipient was never informed of the method of conception. *Id.* at 66.

acceptance and popularity as a reproductive method.<sup>214</sup> Due to unresolved moral and legal questions,<sup>215</sup> the early use of AID to treat male infertility was an intensely private matter, kept secret for the protection of all parties:

When doctors placed the semen in the recipient they took the risk of creating a pregnancy outside of marriage. Secrecy thus benefited the physician, the woman receiving the sperm, any child born as a result of the procedure (who were called “artificial bastards” by some critics) and the husband whose infertility needed to be masked from public view. . . . [M]ost [practitioners] preferred donors unknown to the couple in order to avoid emotional complications.<sup>216</sup>

Initially considered a response to male infertility, AID later received attention as a means of preventing the transmission of inherited conditions following “[t]he development of screening tests to identify carriers of particular traits.”<sup>217</sup> By the middle of the twentieth century, doctors continued to select donors and dictate which couples were eligible for the administration of AID.<sup>218</sup> With the development of new technologies permitting the cryopreservation of sperm, however, “[t]he power to select donors increasingly rested not with the paternalistic physician but with the consumer who handed over the credit card to pay for the product.”<sup>219</sup> The establishment of sperm banks became possible in 1953, after two reproductive physicians claimed to have facilitated the birth of four children using frozen semen.<sup>220</sup>

With the availability of cryopreservation technologies, the U.S. sperm banking industry grew rapidly: estimates indicate that there were 10 sperm banks in operation in 1969,<sup>221</sup> 16 in 1973,<sup>222</sup> and 135 by 1989.<sup>223</sup> Although many physicians continued to rely on fresh semen, the safety of their

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214. Jenna H. Bauman, Note, *Discovering Donors: Legal Rights to Access Information About Anonymous Sperm Donors Given to Children of Artificial Insemination* in *Johnson v. Superior Court of Los Angeles County*, 31 GOLDEN GATE U. L. REV. 193, 196 (2001).

215. See Cynthia R. Daniels & Janet Golden, *Procreative Compounds: Popular Eugenics, Artificial Insemination and the Rise of the American Sperm Banking Industry*, 38 J. SOC. HISTORY 5, 12 (2004) (discussing the legal and moral issues associated with the early use of artificial insemination).

216. *Id.* at 9.

217. *Id.* at 11. Screening “refers to specific historical factors that place an individual at high risk for a given disease,” while testing “refers to specific laboratory studies.” Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology, *2008 Guidelines for Gamete and Embryo Donation: A Practice Committee Report*, 90 FERTILITY & STERILITY S30, S30 (2008) [hereinafter 2008 Guidelines].

218. Daniels & Golden, *supra* note 215, at 12.

219. *Id.* at 12.

220. *Id.* at 13.

221. *Id.* at 16.

222. *Id.* at 25 n.59.

223. *Id.* at 25 n.60.

preference was questioned after its use "resulted in a reported six cases of HIV infection in the United States between 1986 and 1989."<sup>224</sup> Because it could be preserved "until donors tested clean for HIV as well as other infectious diseases,"<sup>225</sup> demand for frozen sperm continued to grow.<sup>226</sup>

By the early 1990s, the artificial insemination industry yielded \$164 million annually.<sup>227</sup> As the expense of donor recruitment and screening pushed small operations out of the market, the sperm banking industry became increasingly corporate and concentrated between 1995 and 2001.<sup>228</sup> Sperm banks began shipping specimens nationally, advertising their services to "non-traditional families and lesbian couples," and even offering "genius sperm."<sup>229</sup> But "while sperm banking services grew, the industry remained unregulated and unorganized."<sup>230</sup>

Today, AID is used by heterosexual couples,<sup>231</sup> lesbian couples,<sup>232</sup> and unmarried women,<sup>233</sup> and it results in approximately 30,000 births annually.<sup>234</sup> Through AID, any resulting offspring may be both the

224. *Id.* at 16.

225. *Id.*

226. *Id.*

227. Ginsberg, *supra* note 209, at 826.

228. Daniels & Golden, *supra* note 215, at 16. "By 2001, only 28 sperm banks (defined as facilities which collect, store and offer sperm for sale) were operating in the U.S., based on information collected from the Sperm Bank Directory, the American Association of Tissue Banks, the Association for Reproductive Medicine, and the Food and Drug Administration (FDA)." *Id.* at 17.

229. *Id.* at 17.

230. *Id.* at 16.

231. A study analyzing data from the 2002 National Survey of Family Growth reported that "[a] total of 7.5% [3.3–4.7 million] of all sexually experienced men reported a visit for help with having a child at some time during their lifetime." John E. Anderson et al., *Infertility Services Reported by Men in the United States: National Survey Data*, 91 FERTILITY & STERILITY 2466, 2467 (2009). Of these men, "18.1% [725,000 men] reported clinician-diagnosed male-related infertility problems." *Id.* Other heterosexual couples choose AID because the man "has a known genetic disease or defect that he does not wish to pass on to his child." Bauman, *supra* note 214, at 194.

232. Swink & Reich, *supra* note 4, at 867.

233. *Id.* at 865–67. Due to increased self-sufficiency and shifting societal perceptions of family: [A] growing population of single women are now having children "by choice." This group is primarily comprised of non-married, career, heterosexual women and once-married, now-divorced, heterosexual women for whom childbearing was a lesser priority in earlier years. . . . Single women are increasingly open to the idea of having children without being married, and they are purchasing sperm for that purpose.

*Id.* at 865–67 (footnotes omitted).

234. Bauman, *supra* note 214, at 196; see also Naomi Cahn, *Accidental Incest: Drawing the Line—or the Curtain?—for Reproductive Technology*, 32 HARV. J.L. & GENDER 59, 61 (2009) [hereinafter Cahn, *Accidental Incest*]. But see Andrea Mechanick Braverman, *How the Internet is Reshaping Assisted Reproduction: From Donor Offspring Registries to Direct-to-Consumer Genetic Testing*, 11 MINN. J.L. SCI. & TECH. 477, 479 (2010) (stating that "advances in male factor fertility

biological child of the woman impregnated and, if she is married, the legal child of her spouse.<sup>235</sup> Observers remain concerned, however, that the use of AID “has progressed with minimal regulation and a great emphasis upon secrecy.”<sup>236</sup>

The artificial insemination industry has undergone a rapid transformation “from doctor-dominated AID practiced from the 1920s through the 1960s through the rise of the modern cryobanking industry which supported a consumer-dominated AID in the late twentieth century.”<sup>237</sup> Currently, in the United States, “tens of thousands of children are conceived each year through artificial insemination with semen purchased from sperm banks”<sup>238</sup>—and yet the field remains largely unregulated.<sup>239</sup> Having grown into a multi-million dollar industry in the

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treatment alone have generated significant challenges to the accuracy of that number.”).

235. Bauman, *supra* note 214, at 197. Thirty-four states statutorily determine the legal parentage of offspring produced through artificial insemination. See ALA. CODE § 26-17-201 (West, Westlaw through 2010 legislation); ALASKA STAT. § 25.20.045 (West, Westlaw through 2010 legislation); ARIZ. REV. STAT. ANN. § 25-501 (West, Westlaw through 2010 legislation); ARK. CODE ANN. § 9-10-201 (West, Westlaw through 2010 Fiscal Sess.); CAL. FAM. CODE § 7613 (West, Westlaw through 2010 legislation); COLO. REV. STAT. ANN. § 19-4-106 (West, Westlaw through 2010 Reg. Sess.); CONN. GEN. STAT. ANN. § 45a-774 (West, Westlaw through 2010 Feb. Reg. Sess.); FLA. STAT. ANN. § 742.11 (West, Westlaw through 2010 Reg. Sess.); GA. CODE ANN. § 19-7-21 (West, Westlaw through 2010 Reg. Sess.); IDAHO CODE ANN. § 39-5405 (West, Westlaw through 2010 Reg. Sess.); 750 ILL. COMP. STAT. ANN. 40/1 to 40/3 (West, Westlaw through 2010 Reg. Sess.); KAN. STAT. ANN. § 23-129 (West, Westlaw through 2010 Reg. Sess.); MD. CODE ANN., EST. & TRUSTS § 1-206 (West, Westlaw through 2010 Reg. Sess.); MASS. GEN. LAWS ch. 46 § 4b (West, Westlaw through 2010 Reg. Sess.); MICH. COMP. LAWS ANN. § 333.2824 (West, Westlaw through 2010 Reg. Sess.); MINN. STAT. ANN. § 257.56 (West 2008); MO. ANN. STAT. § 210.824 (West 2008); MONT. CODE ANN. § 40-6-106 (West, Westlaw through 2010 legislation); NEV. REV. STAT. § 126.061 (West, Westlaw through 2010 Reg. Sess.); N.H. REV. STAT. ANN. § 168-B:3 (West, Westlaw through 2010 Reg. Sess.); N.J. STAT. ANN. § 9:17-44 (West, Westlaw through 2010 Reg. Sess.); N.M. STAT. ANN. § 40-11-6 (West, Westlaw through 2010 Reg. Sess.); N.Y. DOM. REL. LAW § 73 (McKinney, Westlaw through 2010 legislation); N.C. GEN. STAT. § 49A-1 (West, Westlaw through 2010 Reg. Sess.); N.D. CENT. CODE § 14-20-60 (West, Westlaw through 2010 Reg. Sess.); OHIO REV. CODE ANN. § 3111.88 (West, Westlaw through 2010 Reg. Sess.); OKLA. STAT. ANN. tit. 10, § 551 (West, Westlaw through 2010 legislation); OR. REV. STAT. § 109.239 (West, Westlaw through 2010 Reg. Sess.); TENN. CODE ANN. § 68-3-306 (West, Westlaw through 2010 Reg. Sess.); TEX. FAM. CODE ANN. § 160.703 (Vernon 2008); VA. CODE ANN. § 20-158 (West, Westlaw through 2010 Reg. Sess.); WASH. REV. CODE ANN. § 26.26.705 (West, Westlaw through 2011 laws chapters 1 & 2); WIS. STAT. ANN. § 891.40 (West, Westlaw through 2004 Act 406); WYO. STAT. ANN. §§ 14-2-901 to 14-2-907 (West, Westlaw through 2010 Budget Sess.).

236. Shelf, *supra* note 16, at 1048.

237. Daniels & Golden, *supra* note 215, at 6. This shift can be attributed to a number of factors: “The development of other, more advanced techniques for assisted reproduction, changes in popular ideas about families and family formation, the rise of feminism, and challenges to the cultural authority of medicine pushed decision-making about AID out of the hands of doctors and made it a consumer-driven process.” *Id.* at 7.

238. *Id.* at 5.

239. See Swink & Reich, *supra* note 4, at 870 (“[T]here is a shocking absence of federal laws regulating sperm banks and artificial insemination practitioners.”); see also Ginsberg, *supra* note 209, at 836 (“Largely self-regulated, doctors and sperm banks in the majority of states view additional biological or genetic screening as purely optional.”). This dearth of regulation is likely the product of the secrecy surrounded the administration of AID and the moral and legal

United States alone,<sup>240</sup> artificial insemination has raised novel legal questions that demand reflective legal answers.

As AID gained popularity, some states enacted statutes addressing various aspects of its administration.<sup>241</sup> New York's regulation of tissue banks and storage facilities, for instance, prohibits the sale of gametes for valuable consideration.<sup>242</sup> Georgia's statute relieves physicians of civil liability other than negligence for the administration of artificial insemination.<sup>243</sup> Other states statutorily resolve parentage issues arising out of the use of AID by modeling their regulations after the Uniform Parentage Act of 1973,<sup>244</sup> while some states recognize the increased use of AID by single women, statutorily preventing the donor from asserting parental rights or assuming parental obligations where there is no presumed father.<sup>245</sup> Observers argue, however, that AID remains "an industry largely unregulated, scientifically, socially, or medically, with inconsistent or nonexistent record keeping practices."<sup>246</sup>

Recipients may expect that donors have been screened and their samples have been tested to ensure that their sperm is free from disease or defect.<sup>247</sup>

uncertainties of the practice. See *supra* note 215 and accompanying text.

240. Daniels & Golden, *supra* note 215, at 6.

241. See *infra* notes 242–45 and accompanying text.

242. N.Y. PUB. HEALTH LAW § 4364(5) (McKinney, Westlaw through 2010 legislation) ("No bank or storage facility shall sell or otherwise transfer tissue for valuable consideration. Valuable consideration shall not include reasonable costs associated with the procurement, processing, storage and distribution of tissue.").

243. GA. CODE ANN. § 43-34-37(b) (West, Westlaw through 2010 Sess.) ("Any physician or surgeon who obtains written authorization signed by both the husband and the wife authorizing him or her to perform or administer artificial insemination shall be relieved of civil liability to the husband and wife or to any child conceived by artificial insemination for the result or results of said artificial insemination, provided that the written authorization provided for in this Code section shall not relieve any physician or surgeon from any civil liability arising from his or her own negligent administration or performance of artificial insemination.").

244. "If, under the supervision of a licensed physician and with the consent of her husband, a wife is inseminated artificially with semen donated by a man not her husband, the husband is treated in law as if he were the natural father of a child thereby conceived." UNIF. PARENTAGE ACT § 5(a) (1973), *repealed by* UNIF. PARENTAGE ACT § 904 (2000), 9B U.L.A. 407 (2001).

245. See, e.g., CAL. FAM. CODE § 7613(b) (West, Westlaw through c. 14 of 2011 Reg. Sess.) ("The donor of semen provided to a licensed physician and surgeon or to a licensed sperm bank for use in artificial insemination or in vitro fertilization of a woman other than the donor's wife is treated in law as if he were not the natural father of a child thereby conceived.").

246. Shelf, *supra* note 16, at 1062. One author notes that, "[c]urrently, no legal restrictions limit the number of times a sperm bank may use an individual donor's sperm in artificial insemination, or the number of children that may be conceived." Bauman, *supra* note 214, at 199; see also Grady, *supra* note 1, at F5 ("News reports and Internet tales abound of sperm donors who claim to have fathered dozens or even more than 100 babies via one or more sperm banks, but the stories are impossible to verify because there is no requirement that sperm-donor births be identified.").

247. See *supra* note 231 (observing that some couples use artificial insemination to prevent



This was, in fact, an industry practice even during the early administration of AID.<sup>248</sup> There are, however, no legal requirements mandating genetic testing of sperm donors.<sup>249</sup> While the American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART) have issued broad guidelines for evaluating potential donors,<sup>250</sup> their recommendations are just that—recommendations—and are not legally enforceable. The federal government imposes only minimal requirements for determining anonymous<sup>251</sup> gamete donor eligibility,<sup>252</sup> which is determined based on the results of donor screening and testing.<sup>253</sup> These requirements are intended to prevent the transmission of communicable diseases.<sup>254</sup> Although the FDA defines human cells, tissues or cellular or

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passing a man's known genetic disease or defect to his child).

248. Alan Guttmacher, a famed obstetrician and gynecologist, reportedly tested the sperm purchased from his medical students for syphilis and interviewed the donors regarding their heredity and history of venereal disease. Daniels & Golden, *supra* note 215, at 10. Similarly, Dr. Ivy Albert Pelzman of Georgetown University School of Medicine was described in a 1938 *Time* magazine article as “carefully assessing the heredity and background of his donors—a list of fifteen men drawn ‘mostly from medical students and interns who are glad to get the \$25 fee per insemination.’” *Id.*

249. See *infra* notes 250–57 and accompanying text.

250. See generally 2008 Guidelines, *supra* note 217.

251. The requirements for known gamete donors are even less demanding. Under the *Code of Federal Regulations*, “[r]eproductive cells or tissue donated by a sexually intimate partner of the recipient for reproductive use” are exempt from screening and testing. 21 C.F.R. § 1271.90(a)(2) (2005). Additionally, directed donors are exempt from the retesting required under section 1271.85(d). 21 C.F.R. § 1271.85(d). A directed donor is defined as:

a donor of reproductive cells or tissue (including semen, oocytes, and embryos to which the donor contributed the spermatozoa or oocyte) to a specific recipient, and who knows and is known by the recipient before donation. The term directed reproductive donor does not include a sexually intimate partner under § 1271.90.

21 C.F.R. § 1271.3(l).

252. See 21 C.F.R. § 1271.45(b) (“A donor-eligibility determination, based on donor screening and testing for relevant communicable disease agents and diseases, is required for all donors of cells or tissue used in HCT/Ps, except as provided under § 1271.90.”).

253. Section 1271.75 describes screening requirements. 21 C.F.R. § 1271.75. Section 1271.85 requires the testing of an anonymous sperm donor's specimen for the following: human immunodeficiency virus, type 1; human immunodeficiency virus, type 2; hepatitis B virus; hepatitis C virus; *treponema pallidum*; human T-lymphotropic virus, type I; human T-lymphotropic virus, type II; cytomegalovirus (CMV); *chlamydia trachomatis*; and *neisseria gonorrhoea*. 21 C.F.R. § 1271.85(a)-(c).

254. 21 C.F.R. § 1271.85(a). To prevent the spread of communicable diseases, an anonymous sperm donor's specimen must be quarantined and retested for him to be deemed eligible: Section 1271.60(a) requires that “semen from anonymous donors [be quarantined] until the retesting required under § 1271.85(d) is complete.” 21 C.F.R. § 1271.60(a). Section 1271.85(d) provides that:

Except as provided under § 1271.90 and except for directed reproductive donors as defined in § 1271.3(1), at least 6 months after the date of donation of semen from anonymous donors, you must collect a new specimen from the donor and test it for evidence of infection due to the communicable disease agents for which testing is required under paragraphs (a), (b), and (c) of this section.

21 C.F.R. § 1271.85(d).

tissue-based products (HCT/Ps) as “articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient . . . includ[ing] . . . semen or other reproductive tissue,”<sup>255</sup> it specifically exempts human reproductive tissue from its Current Good Tissue Practice rule.<sup>256</sup> As such, there are currently no enforceable guidelines for the genetic screening and testing of sperm donors.<sup>257</sup>

Because of its questionable moral and legal nature,<sup>258</sup> the development of AID in the United States has been shrouded in secrecy and has remained, despite gaining popular acceptance, largely unregulated.<sup>259</sup> Critics have made various proposals to address the dearth of regulation of the AID industry.<sup>260</sup> While some envision regulation through a national databank of gamete donors,<sup>261</sup> others call for increased access for AID offspring to donor records,<sup>262</sup> and others still call for the adoption of mandatory, uniform guidelines for donor screening, including genetic testing.<sup>263</sup> In 2009, the case of *Donovan v. Idant Laboratories* introduced the possibility of an entirely new mechanism for AID regulation—products liability litigation.<sup>264</sup>

### C. *The Seminal Case of Donovan v. Idant Laboratories*<sup>265</sup>

In 2009, in a case of first impression, a federal court judge held that a mentally disabled child—and, but for statutory limitations, her mother—

255. 21 C.F.R. § 1271.3(d) (emphasis added).

256. See 21 C.F.R. § 1271.150(c)(3) (“[T]he regulations in this subpart are not being implemented for reproductive HCT/Ps . . . or for the establishments that manufacture them.”).

257. See *supra* notes 249–56 and accompanying text.

258. See *supra* note 215.

259. See *supra* notes 246–57 and accompanying text.

260. See *infra* notes 261–63 and accompanying text.

261. See Naomi Cahn, *Necessary Subjects: The Need for a Mandatory National Donor Gamete Databank*, 12 DEPAUL J. HEALTH CARE L. 203, 205–06 (2009) [hereinafter Cahn, *Necessary Subjects*]. Cahn argues:

[B]eyond satisfying the needs of many donor offspring and their families to find connections, a national databank would prevent the same donor from providing gametes to numerous banks and numerous families. Existing limits within banks are unenforceable across banks unless donors are identified. A registry might even help with sharing critical medical information between donor-created families.

*Id.*

262. See Bauman, *supra* note 214, at 216–17; see also Shelf, *supra* note 16, at 1061–62.

263. See Ginsberg, *supra* note 209, at 843. See generally Yaniv Heled, Comment, *The Regulation of Genetic Aspects of Donated Reproductive Tissue—The Need for Federal Regulation*, 11 COLUM. SCI. & TECH. L. REV. 243 (2010).

264. 625 F. Supp. 2d 256 (E.D. Pa. 2009).

265. *Id.* at 256.

could sue a sperm bank under a products liability theory of recovery based on a genetic defect inherited from a sperm donor.<sup>266</sup> Although reconsideration was subsequently granted and the case was dismissed for failure to allege a legally cognizable injury,<sup>267</sup> the *Donovan* holding introduced the possibility that human sperm may be treated as a product under products liability law.<sup>268</sup>

In 1994, Pennsylvania resident Donna Donovan entered into a contract with Idant Laboratories, a New York Corporation, to purchase semen for the purpose of artificial insemination.<sup>269</sup> As part of the agreement, Donna signed a consent form, which included representations as to the high quality of Idant's product.<sup>270</sup> After selecting Donor G738,<sup>271</sup> Donna paid a fee, and Idant shipped the semen to her physician.<sup>272</sup> Donna was subsequently inseminated with Donor G738's semen, and on January 4, 1996, she gave birth to a daughter, Brittany Donovan.<sup>273</sup>

After her pediatrician observed developmental abnormalities, Brittany was referred to various treatment facilities, and on December 19, 1997, she was diagnosed as a Fragile X<sup>274</sup> carrier.<sup>275</sup> Two months later, genetic tests revealed that Donna did not carry the disease.<sup>276</sup> On May 6, 1998, however, Donor G738 was identified as a Fragile X carrier.<sup>277</sup>

On July 16, 2008, Donna filed a complaint against Idant on behalf of

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266. *Id.* at 262–63, 273.

267. *Id.* at 276.

268. *Id.* at 273.

269. *Id.* at 262.

270. *Id.* The consent form included representations that “(1) semen stored at Idant is exceptionally safe; (2) Idant has a screening program that far exceeds mandated standards; and (3) Idant’s donors go through a rigorous screening process to ensure that they have a good genetic background and history.” *Id.*

271. Donna alleged that Idant made additional representations following her selection, specifically that:

Donor G738 had been fully tested in accordance with New York Health Regulations and that information did not indicate that he had any genetic defects or a history of mental retardation. . . . [Idant further] represented that Donor G738 had been a donor for over two years, his sperm had been quarantined and stored for over six months before use[,] and was retested and safe.

*Id.*

272. *Id.*

273. *Id.*

274. “Fragile X Syndrome, also known as Martin-Bell Syndrome, is a genetic syndrome which results in a spectrum of physical, intellectual, emotional and behavioral characteristics which range from severe to mild in manifestation.” *Id.* at 263. Fragile X affects approximately 0.02% of white men: “According to the CDC, the prevalence of the full mutation in [Caucasian populations is approximately 1 in 4,000 to 1 in 6,000 males. Female children of female carriers have a 50% chance of inheriting the disease and female children of male carriers have a 100% chance of inheriting the disease.” *Id.*

275. *Id.* at 262–63.

276. *Id.* at 263.

277. *Id.*

herself and on behalf of Brittany, still a minor, alleging "negligence, breach of contract, third-party beneficiary breach of contract, breach of the express warranty of merchantability, breach of implied warranty of merchantability, negligent misrepresentation, strict products liability and negligent infliction of emotional distress" for providing Ms. Donovan with "defective sperm."<sup>278</sup> The plaintiffs based their claims on Idant's failure to test Donor G738's semen for Fragile X,<sup>279</sup> alleging "that Donor G738 exhibited symptoms of Fragile X which defendant failed to recognize."<sup>280</sup>

Having decided that the plaintiffs' claims were governed by Pennsylvania's statutes of limitations,<sup>281</sup> but that New York substantive law would apply,<sup>282</sup> the court held that Donna's claims were time-barred,<sup>283</sup> regardless of whether or not the court applied the "discovery rule"<sup>284</sup> to extend the statute of limitations.<sup>285</sup> Due to the application of the

278. *Id.* at 262.

279. "Though it was first described in 1943, it was not until 1991 that scientists discovered the gene (called FMR1 for 'Fragile X Mental Retardation-1') that causes Fragile X. A DNA test for Fragile X was developed in 1992"—three years before Idant supplied Donna with Donor G738's semen. *Id.* at 263.

280. *Id.* Fragile X symptoms are generally more apparent in male carriers than in female carriers:

As the disease is carried on the X chromosome and men only have one X chromosome, male carriers are likely to exhibit symptoms of Fragile X at a much more severe level than females, though some females exhibit severe symptoms. According to the Fragile X Research Foundation, though symptoms vary even among those affected in the same family, the signs and symptoms frequently include some variation of mental impairment, ranging from learning disabilities to mental retardation, attention deficit and hyperactivity anxiety, unstable moods, autistic behaviors, seizures and physical features including a long face, large ears, flat feet and hyper-extensible joints.

*Id.*

281. *Id.* at 264.

282. The court found that New York law applied to the contract claims "since the majority of the conduct relevant to the contract at issue, i.e. the testing and screening, took place in New York and New York has a strong policy incentive to regulate the sperm banks in its state." *Id.* at 270. The court likewise held that New York law applied to the tort claims; although "the injury and the harm took place in Pennsylvania, the screening and testing at issue in the tort claims took place in New York. There is no allegation that any tortious activity took place in Pennsylvania." *Id.* at 271.

283. *Id.* at 267.

284. "Under the discovery rule, the statute of limitations is tolled until a plaintiff 'knew or should have known on the exercise of reasonable diligence of [her] injury and its cause.'" *Id.* at 266 (citing *Fine v. Checcio*, 870 A.2d 850, 858 (Pa. 2005)).

285. "A cause of action accrues 'as soon as the right to institute and maintain a suit arises, which generally is when the injury was inflicted.'" *Id.* at 265 (quoting *Padalino v. Standard Fire Ins. Co.*, 616 F. Supp. 2d 538, 546 (E.D. Pa. 2008)). The date of Donna's injury could be the time of implantation (in 1995), the date that she gave birth (January 4, 1996), or when she noticed Brittany's developmental delays (in the months following her birth). *Id.* at 266. Even applying the discovery rule, Donna's cause of action accrued at the latest on May 6, 1998, when Donna learned that that Donor G738 was a Fragile X carrier; at that time, "she knew or should have known that she had been injured and who had likely caused the injury." *Id.* at 267. Thus, the two-year statute of limitations

Pennsylvania Minors' Tolling Statute,<sup>286</sup> however, Brittany's claims were not time-barred,<sup>287</sup> and the court proceeded to address Brittany's claims for "negligence, breach of contract as a third-party beneficiary, breaches of the express and implied warranties as a third-party beneficiary, negligent misrepresentation and strict products liability."<sup>288</sup>

The court found that Brittany's claims for negligence and negligent misrepresentation constituted claims for wrongful life<sup>289</sup> and dismissed both for failure to state a claim.<sup>290</sup> Due to a dispute over the identities of the contracting parties,<sup>291</sup> the court postponed ruling on Brittany's third-party beneficiary breach of contract and breach of warranty claims.<sup>292</sup> Finally, with very little discussion, the court denied Idant's motion to dismiss Brittany's claim for strict liability, holding that "under New York law, the sale of sperm is considered a product and is subject to strict liability."<sup>293</sup> Noting that "[s]everal states including Pennsylvania and New York have by statute exempted human biological products from strict liability and [hold] them to be a service,"<sup>294</sup> the court relied upon the language of New York's

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for tort claims and four-year statute of limitations for breach of contract both expired long before Donna filed suit on July 16, 2008. *Id.* at 266–67.

286. "[I]n Pennsylvania, the statute of limitations for claims brought by minors does not run until two years after reaching the age of majority which is 18." *Id.* at 265 (citing 42 PA. CONS. STAT. ANN. § 5533(b)(1)(i-ii) (Purdon, Westlaw through 2010 Reg. and 1st Special Sess.)).

287. *Id.* at 265.

288. *Id.* at 269.

289. Inheriting Fragile X caused Brittany to suffer from:

permanently impaired developmental communication and play, motor planning, sensory and cognitive skills and . . . a high risk for premature ovarian failure and early menopause. She has already been diagnosed with ovarian cysts and is having problems with her menstrual cycles. . . . [S]he has difficulties with shyness, social anxiety, and is at risk for eye problems, seizures and mitral valve prolapse. Moreover, . . . any children she has will be at a high risk for the same problems (a child of a female carrier has a 50% chance of inheriting the disease) so . . . Brittany will have to arrange for donor eggs to avoid this complication in any offspring.

*Id.* at 263–64. The court explained, however, that Brittany's claims for negligence and negligent misrepresentation were "based on the fact that, if defendant had properly tested and screened for genetic abnormalities in Donor G738's semen, that semen would not have been used and plaintiff Brittany Donovan would not have been born." *Id.* at 271. Thus, the injury alleged is not the difference between life with Fragile X and life without Fragile X; rather, it is the difference between life with Fragile X and no life at all—constituting a claim for wrongful life. *Id.*

290. *Id.* at 271. "[I]t is well settled that no cause of action may be maintained on behalf of an infant plaintiff for "wrongful life" i.e., that he or she would never have been born but for the negligence of the defendant." *Id.* at 271 (quoting *Figueroa v. Giffone*, No. 100866/2005, 2009 WL 27763, at \*3 (N.Y. Sup. Ct. Feb. 5, 2009)). "Additionally, under New York law, there is no duty of care owed 'to an individual who was not yet in utero when the alleged negligence occurred.'" *Id.* (quoting *Andrews v. Keltz*, 838 N.Y.S.2d 363, 370 (N.Y. Sup. Ct. 2007)).

291. Idant claimed that the contract was between Idant and Donna's treating physician—not between Idant and Donna. *Id.* at 272.

292. *Id.*

293. *Id.* at 273.

294. *Id.*

blood shield statute<sup>295</sup>—in particular, the absence of the word “tissue”<sup>296</sup>—in reaching its decision.<sup>297</sup>

On reconsideration in June of 2009, Idant argued that Brittany’s strict liability and third-party beneficiary breach of warranty claims “are properly termed claims of ‘wrongful life,’”<sup>298</sup> which New York does not recognize.<sup>299</sup> Siding with Idant, the court found it “impossible to distinguish [Brittany’s] economic injuries from those of a claim for wrongful life”<sup>300</sup> on the basis that “Courts have declined to determine the economic value of the life of a person with disabilities as compared to having no life at all.”<sup>301</sup> In dismissing Brittany’s strict liability and warranty claims for failure to state a claim due to her inability to allege a legally cognizable injury, the court

295. N.Y. PUB. HEALTH LAW § 580(4) (McKinney, Westlaw through 2010 legislation) (“The collection, processing, storage, distribution or use of blood, blood components or blood derivatives for the purpose of diagnosis, prevention or treatment of disease is hereby declared to be a public health service and shall not be construed to be, and is declared not to be, a sale of such blood, blood components or blood derivatives, for any purpose or purposes whatsoever.”).

296. The court noted:

While other state blood shield laws and the *Restatement (Third) of Torts—Product Liability* § 19 include human tissue and/or organs in the list of products which are exempted, the relevant New York statute does not and no case law has extended the statute to also exempt human tissues like sperm.

*Donovan*, 625 F. Supp. 2d at 273.

297. *Id.*

298. *Id.* at 275.

299. *Id.* (citing *Becker v. Schwartz*, 386 N.E.2d 807 (N.Y. 1978)). The court stated:

The New York Court of Appeals has concluded that an infant alleging a claim of wrongful life has not suffered a legally cognizable injury because “whether it is better never to have been born at all than to have been born with even gross deficiencies is a mystery more properly to be left to the philosophers and the theologians,” and because the remedy afforded an injured party in tort is designed to place that party in the position that she would have occupied but for the alleged negligence. A cause of action based on “wrongful life” seeks to put the child in the position of having not received the defective sperm, “thereby depriving the infant plaintiff of [her] very existence.”

*Id.* (citation omitted) (quoting *Becker v. Schwartz*, 386 N.E.2d 807, 812 (N.Y. 1978)).

300. *Id.* The court explained:

If the sperm at issue was defective . . . , to place plaintiff in the position which she would have occupied had the product not been distributed . . . would be to alter plaintiff’s genetic identity so that she would be someone else. These injuries are identical to the injury that New York courts consistently find not to be legally cognizable in causes of action for negligence and medical malpractice, regardless of whether the plaintiffs argue that their claims do not allege wrongful life.

*Id.* at 275–76.

301. *Id.* at 275 (citing *Becker*, 386 N.E.2d at 807); see also Thomas A. Warnock, Comment, *Scientific Advancements: Will Technology Make the Unpopular Wrongful Birth/Life Causes of Action Extinct?*, 19 TEMP. ENVTL. L. & TECH. J. 173, 175 (2001) (“Wrongful life has been characterized as one of the most controversial pregnancy related torts.”).

acknowledged the absence of precedent<sup>302</sup> but surmised that the Court of Appeals of New York “would find that the injuries alleged in [Brittany’s] strict liability and warranty claims are essentially claims for wrongful life.”<sup>303</sup> The court did not, however, disturb its finding that Idant’s sale of sperm to Donna Donovan constituted the sale of a product, leaving open the possibility of future products liability claims based on transactions involving genetically defective sperm.<sup>304</sup> The Third Circuit subsequently affirmed the district court’s decision, finding that the statute of limitations for Donna’s claims was neither tolled on the basis of the discovery rule nor the fraudulent concealment doctrine, and it further held that the district court correctly dismissed Brittany’s claims for failure to allege a legally cognizable injury.<sup>305</sup>

### III. PRODUCTS LIABILITY ACTIONS FOR GENETICALLY DEFECTIVE SPERM: FERTILE GROUNDS FOR RECOVERY?

There have been a variety of problems with artificial insemination: recipients have contracted HIV<sup>306</sup> and received the wrong sperm,<sup>307</sup> doctors have used their own sperm to fraudulently impregnate dozens of women,<sup>308</sup> and children have inherited genetic diseases and defects from anonymous sperm donors<sup>309</sup>—yet artificial insemination remains a highly popular

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302. “New York courts have not yet barred actions other than for negligence or medical malpractice as being prohibited claims of wrongful life.” *Donovan*, 625 F. Supp. 2d at 274 n.2.

303. *Id.* at 276.

304. In dicta, the court noted that its decision would not foreclose the success of a parent’s claim for wrongful birth under New York law, “whether in negligence or otherwise, for the injury of pecuniary losses of the costs incurred in raising a child with disabilities.” *Id.* at 276 n.3 (citing *Becker*, 386 N.E.2d at 807). The court distinguished the parent’s injury from that of the child:

To bring the parent of a child with disabilities to the position in which she would have been had the act causing the disability not occurred is an economic issue. However, to bring that child into the position in which she would have been had the act causing her genetic disorder not taken place, her genetic identity would be different, so the [child] would not exist. Thus, while Donna Donovan could show a financial injury, her claims have been time-barred and the minor plaintiff has not alleged her own financial injury distinguishable from a claim for wrongful life.

*Id.* (citations omitted).

305. *D.D. v. Idant Labs.*, 374 F. App’x 319 (3rd Cir. 2010).

306. See *supra* note 224 and accompanying text; see also Heather J. Blum, Comment, *Tort Liability as the Result of the Transmission of HIV Through Artificial Insemination by Donor*, 4 ALB. L.J. SCI. & TECH. 333 (1994) (considering the potential for tort liability when an AID recipient contracts HIV through artificial insemination).

307. See *Hamicher v. Univ. of Utah Med. Ctr.*, 962 P.2d 67, 71–72 (Utah 1998) (wrong sperm used in in vitro fertilization procedure); see also Ginsberg, *supra* note 209, at 829 (woman mistakenly inseminated with “the sperm of an unknown donor, rather than that of her dying husband”).

308. See Marlene Cimons, *Fertility Doctor’s Case Raises Ethical Concerns*, L.A. TIMES, Feb. 13, 1992, at 30, available at 1992 WLNR 3961144 (describing how a fertility doctor used his own sperm to father as many as seventy-five children).

309. See *supra* notes 1–9 and accompanying text (five Michigan children inherited SCN from an

practice.<sup>310</sup> Resulting in 30,000 births annually and remaining largely unregulated,<sup>311</sup> artificial insemination is likely to be the subject of future litigation.<sup>312</sup> As introduced in *Donovan*, products liability law is one possible mechanism for regulating AID.<sup>313</sup>

#### A. Putting the "Product" in Reproduction

In a successful products liability action, the thing that caused the plaintiff's injury must be a product.<sup>314</sup> Consequently, in the case of an artificially inseminated woman giving birth to a child with a genetic defect inherited from the sperm donor, the first question that must be considered is whether sperm is a product.

Sperm is not a typical product.<sup>315</sup> Although one might argue that it is mass-produced<sup>316</sup> and that it satisfies the definition of chattel,<sup>317</sup> sperm is unlikely to come to mind when thinking about products.<sup>318</sup> For one thing,

anonymous sperm donor); *see also* notes 269–77 and accompanying text (Brittany Donovan inherited Fragile X from an anonymous donor); *Johnson v. Superior Court of L.A. Cnty.*, 80 Cal. App. 4th 1050 (2000) (Brittany Johnson inherited Autosomal Dominant Polycystic Kidney Disease from an anonymous sperm donor with a family history of kidney disease); *Doolan v. IVF Am. (MA), Inc.*, No. 99-3476, 2000 Mass. Super. LEXIS 581, at \*8–12 (Mass. Super. Ct. 2000) (child born with cystic fibrosis due to fertility clinic's negligent genetic screening of in vitro fertilization embryos); Ginsberg, *supra* note 209, at 830 (child inherited cystic fibrosis from an anonymous donor despite reassurances from the sperm bank that it screened for the condition).

310. *See supra* note 214 and accompanying text.

311. *See supra* notes 234–59 and accompanying text.

312. Ginsberg, *supra* note 209, at 828 ("The rarity of litigation over unsafe artificial insemination techniques should not give potential [artificial insemination] candidates a false sense of security about the quality of the procedure nationwide; rather, the lack of precedent may stem from the fact that most of these cases are resolved in hushed, out-of-court settlements intended to conceal the risks of [artificial insemination] from the public."). Further, "many genetic disorders, such as Huntington's disease, often do not appear until late in life, and therefore some AID children may carry such traits and not yet be aware of them." McIntyre, *supra* note 209, at 521.

313. *See supra* notes 266–68 and accompanying text.

314. *See supra* note 51 and accompanying text.

315. *See supra* note 49 and accompanying text.

316. *See* Gloria J. Banks, *Traditional Concepts and Nontraditional Conceptions: Social Security Survivor's Benefits for Posthumously Conceived Children*, 32 LOY. L.A. L. REV. 251, 270 (1999) ("[A] single ejaculate could contain more than 400 million sperm." (footnote omitted)). In 2000, mean sperm density was 56 million sperm per milliliter with an average volume of 2.7 milliliters per sample. Hamida Begum et al., *Environmental and Nutritional Aspect in Male Infertility*, 10 J. MED. 16, 16 (2009).

317. Chattel is defined as "[m]ovable or transferable property; personal property, esp., a physical object capable of manual delivery and not the subject matter of real property." BLACK'S LAW DICTIONARY 251 (8th ed. West 2004).

318. In contrast to chattel, product is defined as "[s]omething that is distributed commercially for use or consumption and that is [usually] (1) tangible personal property, (2) the result of fabrication or processing, and (3) an item that has passed through a chain of commercial distribution before



each sperm is a living entity,<sup>319</sup> its purpose is to fertilize an egg and produce a resulting offspring,<sup>320</sup> and it occurs naturally in the human body without any effort or innovation on the part of man<sup>321</sup>—even though its retrieval may be another story.<sup>322</sup>

Although sperm is not produced as a “result of fabrication or processing,”<sup>323</sup> donor sperm is regularly sold for use through a chain of commercial distribution,<sup>324</sup> and it can certainly be categorized as tangible personal property.<sup>325</sup> In fact, several courts have recognized a property interest in sperm.<sup>326</sup> Consequently, while sperm’s unique qualities place it at the outer boundaries of the products field,<sup>327</sup> it can nonetheless appropriately be considered a product.<sup>328</sup>

The legal treatment of animal semen supports the classification of sperm as a product.<sup>329</sup> For instance, bull semen has been recognized as a product<sup>330</sup>

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ultimate use or consumption.” BLACK’S LAW DICTIONARY 1245 (8th ed. West 2004).

319. Ernest Waintraub, *Are Sperm Cells a Form of Property? A Biological Inquiry into the Legal Status of the Sperm Cell*, 11 QUINNIAC HEALTH L.J. 1, 10 (2007).

320. *Id.* at 10–11.

321. *See id.* at 9–11 (discussing spermatogenesis, or the maturation of sperm cells). Spermatogonia, germ cells with forty-six chromosomes, rest dormant in the testes until the male reaches puberty. *Id.* at 9. At puberty, “spermatogonia replicate DNA and divide to give rise to primary spermatocytes,” each of which genetically recombines and divides to produce two spermatocytes, such that each resulting spermatocyte has twenty-three chromosomes. *Id.* The spermatocytes then divide a second time, producing a total of four spermatids, each with twenty-three chromosomes. *Id.* at 9–10. Over time, the spermatids develop into mature sperm cells, after which they acquire forward motility. *Id.* at 10.

322. *See, e.g.,* Carson Strong, *Ethical and Legal Aspects of Sperm Retrieval After Death or Persistent Vegetative State*, 27 J.L. MED. & ETHICS 347 (1999) (discussing postmortem methods of extracting sperm).

323. *See supra* notes 318–19 and accompanying text.

324. *See infra* notes 347–63 and accompanying text.

325. Property is something that can be “used, destroyed, given away, sold, and so forth.” Bonnie Steinbock, *Sperm as Property*, 6 STAN. L. & POL’Y REV. 57, 57 (1995). Tangible personal property is “[c]orporeal personal property of any kind; personal property that can be seen, weighed, measured, felt, or touched, or is in any other way perceptible to the senses, such as furniture, cooking utensils, and books.” BLACK’S LAW DICTIONARY 1254 (8th ed. West 2004). Capable of being “seen, weighed, measured, felt, [and] touched,” and regularly “used destroyed, given away, [and] sold,” sperm can be found to satisfy the definition of tangible personal property. *See also* Kermit Roosevelt III, *The Newest Property: Reproductive Technologies and the Concept of Parenthood*, 39 SANTA CLARA L. REV. 79, 79 (1998) (finding that the law recognizes property rights in human reproductive materials); David A. Rameden, Note, *Frozen Semen as Property in Hecht v. Superior Court: One Step Forward, Two Steps Backward*, 62 UMKC L. REV. 377, 395 (1994) (“[F]rozen semen . . . exhibits all of the basic attributes of property.”).

326. *See Hecht v. Superior Court*, 20 Cal. Rptr. 2d 275, 275 (Ct. App. 1993); *Kurchner v. State Farm Fire & Cas. Co.*, 858 So. 2d 1220, 1221 (Fla. Dist. Ct. App. 2003); *Phillips v. Irons*, No. 1-03-2992, 2005 WL 4694579, at \*6 (Ill. App. Ct. 2005).

327. *See supra* note 49 and accompanying text (identifying the types of products that exist at the outer boundaries of the products field).

328. *See infra* notes 330–39 and accompanying text.

329. *See infra* notes 330–44 and accompanying text.

330. *See Two Rivers Co. v. Curtiss Breeding Serv.*, 624 F.2d 1242 (5th Cir. 1980).

and has regularly been the subject of sales contracts.<sup>331</sup> In *Two Rivers Co. v. Curtiss Breeding Service*, the Fifth Circuit considered whether a seller was liable for damages based in strict liability in tort and breach of implied warranty for providing bull semen that carried a genetic defect.<sup>332</sup> In analyzing the issue, the court, without discussion, identified the semen as a product.<sup>333</sup> It struggled, however, to classify the injury that the plaintiff suffered as a result of the genetically defective semen.<sup>334</sup> Focusing on the nature of the injury,<sup>335</sup> the court found that strict liability could not support the plaintiff's claim for economic loss<sup>336</sup> and further held that the defendant

331. See, e.g., *Genex Coop., Inc. v. Bujnevicie*, No. CIV. 00-120-M, 2000 WL 1507319 (D.N.H. Jul. 17, 2000); *Persson v. Comm'r of Internal Revenue*, Nos. 6472-86 & 41889-86, 1989 WL 123010 (T.C. Oct. 19, 1989); *Gray v. ABS Global, Inc.*, 850 So. 2d 180 (Miss. Ct. App. 2003); *J.R. Prentice v. Williams*, 324 S.W.2d 466 (Mo. Ct. App. 1959).

332. 624 F.2d 1242, 1243-44 (5th Cir. 1980). In *Two Rivers*, the plaintiff contracted with the defendant to purchase bull semen to artificially inseminate its cattle. *Id.* at 1243. The plaintiff inseminated sixty-four of its heifers, but it stopped using the purchased semen after learning that the bull had sired other offspring exhibiting signs of syndactylism, a genetic abnormality that is only apparent when both the sire and the dam carry the recessive gene. *Id.* at 1244-45. As a result of the sixty-four inseminations, twenty-two calves were born alive, and four were stillborn, exhibiting signs of syndactylism. *Id.* at 1244. The plaintiff claimed that the defendant sold it a genetically defective product and sued the defendant seeking damages for the lost value of the stillborn calves and for the injured reputation of the remaining herd. *Id.* at 1245-47.

333. *Id.* at 1248.

334. The court had difficulty defining the nature of the injury to the calves born with syndactylism or the recessive gene, stating that "[t]he damage suffered by Two Rivers does not fit neatly into any one of the four categories [of property loss recognized in Texas]." *Id.* at 1247. The four types of loss discussed were (1) "personal injury to the user (or consumer) or physical injury to the property of the user (or consumer)"; (2) direct economic loss "resulting from a product with defective workmanship or materials"; (3) "economic loss to the purchased product itself"; and (4) "a hybrid involving physical harm to a plaintiff's other property as well as to the product itself." *Id.* at 1245 (quoting *Mid Continent Aircraft Corp. v. Curry County Spraying Service*, 572 S.W.2d 308 (Tex. 1978)). The court suggested that the situation may involve the third category of loss and would therefore involve non-recoverable economic loss based on the argument that "a calf is a continuation of the product (bull semen) so any damage was to the product itself and not to any other property." *Id.* at 1247-48. The court indicated, however, that the situation may instead involve the fourth category of loss, as it could "be argued that the product (bull semen) is a constituent part of a new product (the calf) which is other property. Because there is damage to other property . . . [the plaintiff could recover] under the doctrine of strict liability." *Id.* at 1248. Considering the differences between "mechanical items involving incorporation of parts into a whole" and the natural process of fertilization "where the product (bull semen) reacts with another product to create something new," the court noted that neither type of loss squarely fit the situation. *Id.*

335. Comparing the situation to *Pioneer Hi-Bred Int'l, Inc. v. Talley*, 493 S.W.2d 602 (Tex. Civ. App. 1973), a case involving defective corn seed, the court ultimately concluded that the injury was one of economic loss only. *Two Rivers*, 624 F.2d at 1250.

336. Under Texas law, a plaintiff can receive damages for economic loss under negligence or breach of implied warranty, but not under strict liability. *Id.* at 1246. The Texas Supreme Court defined direct economic loss as:

damage based on insufficient product value; thus, direct economic loss may be "out of pocket"—the difference in value between what is given and received—or "loss of

effectively disclaimed any implied warranties.<sup>337</sup> In so holding, the Fifth Circuit reversed the district court's award of damages<sup>338</sup>—but the court did not waiver in classifying semen as a product.<sup>339</sup>

Although animal sperm has been treated as a product and human sperm exhibits the same characteristics as animal sperm,<sup>340</sup> section 19(c) of the *Restatement (Third) of Torts: Products Liability* explicitly excludes human blood and human tissue from the definition of “product.”<sup>341</sup> This exclusion is based on the rationale that “public policy concerns behind the availability of both human blood and tissue outweigh the risks inherent in their supply.”<sup>342</sup> Because there is no urgent need for a readily available supply of sperm (as there is for blood or other tissue), however, such public policy concerns are not relevant to the classification of sperm.<sup>343</sup> In fact, one might even argue that the contrary is true—that public policy favors the treatment of human sperm as a product.<sup>344</sup> Even if courts opt to treat human sperm as

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bargain”—the difference between the value of what is received and its value as represented. Direct economic loss also may be measured by costs of replacement and repair.

*Id.* at 1246 n.2 (quoting *Nobility Homes of Tex. Inc. v. Shivers*, 557 S.W.2d 77, 78 n.1 (Tex. 1977)). Consequential economic loss, in contrast, “includes all indirect loss, such as loss of profits resulting from inability to make use of the defective product.” *Id.*

337. *Id.* at 1251–53.

338. *Id.* at 1245.

339. *See supra* note 333 and accompanying text.

340. Both serve the purpose of fertilizing an egg, and both are produced naturally without any effort on the part of the male. *See supra* notes 320–21 and accompanying text.

341. Comment c of the *Restatement (Third) of Torts: Products Liability* section 19 explains:

Although human blood and human tissue meet the formal requisites of Subsection (a), they are specifically excluded from the coverage of this Restatement. Almost all the litigation regarding such products has dealt with contamination of human blood and blood-related products by the hepatitis virus or the HIV virus. Absent a special rule dealing with human blood and tissue, such contamination presumably would be subject to the rules of §§ 1 and 2(a). Those sections impose strict liability when a product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product. However, legislation in almost all jurisdictions limits the liability of sellers of human blood and human tissue to the failure to exercise reasonable care, often by providing that human blood and human tissue are not “products” or that their provision is a “service.” Where legislation has not addressed the problem, courts have concluded that strict liability is inappropriate for harm caused by such product contamination.

RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19 cmt. c (1998); *see also supra* note 51 and accompanying text.

342. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB., Reporters' Note, § 19 cmt. c (1998).

343. *See Steinbock, supra* note 325, at 65 (“Sperm, unlike blood, is not lifesaving, nor necessary for health.”).

344. This position can actually be supported by the text of the *Restatement (Third) of Torts: Products Liability*:

When the applicable definition fails to provide an unequivocal answer, decisions regarding whether a “product” is involved are reached in light of the public policies behind the imposition of strict liability in tort. Some of the policy considerations include: (1) the public interest in life and health; (2) the invitations and solicitations of the manufacturer to purchase the product; (3) the justice of imposing the loss on the

a product, commercial transfers of sperm must also be categorized as sales to bring the transaction within the scope of products liability law.<sup>345</sup>

*B. Artificial Insemination: Selling the Goods or Providing a Service?*

For a sperm transaction to fall within the scope of products liability law, the transaction must constitute a sale of goods rather than the rendering of a service.<sup>346</sup> Although some may find it distasteful to treat the commercial transfer of human reproductive tissue as the equivalent of any other transaction, this ignores reality: “In the fertility industry the commodification of gametes and embryos is entirely accepted, with the sole exception of Louisiana’s prohibition on the sale of embryos.”<sup>347</sup>

Not only is the commercial nature of sperm transfers evident from the transaction itself,<sup>348</sup> but it is also prevalent in the industry’s marketing, which targets both sperm purchasers<sup>349</sup> and sperm donors.<sup>350</sup> For example,

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manufacturer who created the risk and reaped the profit; (4) the superior ability of the commercial enterprise to distribute the risk of injury as a cost of doing business; (5) the disparity in position and bargaining power that forces the consumer to depend entirely on the manufacturer; (6) the difficulty in requiring the injured party to trace back along the channel of trade to the source of the defect in order to prove negligence; and (7) whether the product is in the stream of commerce.

RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB., Reporters’ Note, § 19 cmt. a (1998).

345. See *supra* note 50 and accompanying text.

346. *Id.* The question of whether sperm transactions constitute a sale of goods or the rendering of a service triggers other questions—for instance, whether there should be a uniform rule that characterizes these transactions (i.e., all commercial transfers of sperm constitute a service) or whether the classification as sale or service may vary depending on the type of transaction and method of insemination (for example, physician-selected and administered AID versus self-selected sperm administered through self-insemination). See *infra* note 375 and accompanying text.

347. Shelf, *supra* note 16, at 1065 n.104; see also Swink & Reich, *supra* note 4, at 878 (“No one disputes that sperm is a product that has the potential to create life; however, on the open market, sperm is a ‘good’ that is bought and sold in the course of interstate commerce.”).

348. See, e.g., Daniels & Golden, *supra* note 215, at 17 (“Sales and business practices in the sperm banking industry resemble those of other retailers. The largest banks offer fully-articulated product liability and return policies: no returns for unused product and credit issued to buyers if sperm falls below minimum sperm counts, arrangements for shipping via private carriers, credit card purchasing, and marketing via the internet.”); see also *Frozen Donor Semen Purchase/Storage Agreement*, CAL. CRYOBANK, available at [http://www.cryobank.com/\\_resources/pdf/Documents/PurchaseStorageAgreement.pdf](http://www.cryobank.com/_resources/pdf/Documents/PurchaseStorageAgreement.pdf) [hereinafter *Purchase and Storage Agreement*].

349. See *infra* notes 351–64 and accompanying text.

350. California Cryobank advertises that sperm donors can “Earn up to \$1200.00/month” and “Be your own boss—Donate at your convenience up to 3 times a week.” Cal. Cryobank, Inc., *California Cryobank Sperm Donor Compensation*, SPERMBANK.COM, <http://www.spermbank.com/newdonors/index.cfm?ID=4> (last visited Feb. 16, 2011). In promoting the benefits of sperm donation, California Cryobank even provides donor testimonials: “I really love the convenience and ease that comes with being a CCB donor. I can fit it into my schedule without worrying about deadlines.” Cal. Cryobank, Inc., *Sperm Donor Testimonials*, SPERMBANK.COM, <http://www.spermbank.com/>

California Cryobank invites prospective sperm purchasers to peruse its donor catalog, which includes a list of donors and numerous images of babies—including an infant emerging from a box labeled “FRAGILE” and five babies lounging in an ice cube tray.<sup>351</sup> California Cryobank also provides the option of selecting a donor using its “advanced search” feature on its website, which is literally a checklist of donor characteristics—including skin tone, eye color, hair color, hair texture, height, level of education, area of study, ethnicity, religion, and blood type.<sup>352</sup> In doing so, the industry effectively “markets the ‘traits’ of donors”<sup>353</sup> like any other commodity.<sup>354</sup>

Even beyond the selection of a donor, every step in a commercial sperm transaction suggests that it is a typical sale of goods.<sup>355</sup> California Cryobank charges \$335 to \$685 per vial of donor semen, with several factors affecting price.<sup>356</sup> For an additional fee, purchasers can obtain donor information packages, which may include the donor’s baby photograph, audio interview, handwriting analysis, full profile, and facial features report.<sup>357</sup> California Cryobank also offers optional related services, including donor matching consultation, genetic counseling, and private storage at an added cost—but

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newdonors/index.cfm?ID=51 (last visited Feb. 16, 2011). “It’s been a great way to supplement my income on my schedule. I love the free snacks.” *Id.* “A very warm and friendly place, very supportive and helpful staff and a really cool donor coordinator. Plus lots of perks!!!—free movie tickets, a massage chair, and free snacks.” *Id.* Although sperm banks often suggest that donors are compensated for their time and services, rather than for the sperm itself, this is inaccurate. California Cryobank, for example, does not compensate donors for the first sperm sample provided, “as it is only used for analysis.” Cal. Cryobank, Inc., *Sperm Donor Screening Process*, SPERMBANK.COM, <http://www.spermbank.com/newdonors/index.cfm?ID=9> (last visited Jan. 30, 2011). The same amount of time and services are required to provide the first sample as is required for any other sample, but the sperm donor is not compensated for the first sample—which is used for analysis, rather than for sale to a prospective purchaser. *Id.* Even after a donor’s sample is analyzed and his application is accepted, he is only compensated for “acceptable donations.” *Id.*

351. DONOR CATALOG - JAN, FEB, MAR 2011, CAL. CRYOBANK, available at [http://www.cryobank.com/\\_resources/pdf/catalogs/print-catalog.pdf](http://www.cryobank.com/_resources/pdf/catalogs/print-catalog.pdf).

352. *Advanced Search*, CAL. CRYOBANK, <http://www.cryobank.com/Donor-Search/Advanced-Search/> (last visited Feb. 16, 2011). There is even a box to check for purchasers to select those “must have” features. *Id.* One industry observer has commented that, “[i]n short, in contemporary society, sperm is a commodity, alienated from its producer and yet sold as the embodiment of that producer’s particular traits.” Daniels & Golden, *supra* note 215, at 5.

353. Daniels & Golden, *supra* note 215, at 6.

354. This point is illustrated by a comparison of California Cryobank’s website with the popular American Girl website, where one can select for skin tone, eye color, hair color, and hair texture to create a “my American Girl” doll. MY AM. GIRL, <http://store.americangirl.com/html/myagconfig2/main.html> (last visited Feb. 16, 2011).

355. See *infra* notes 356–64 and accompanying text.

356. *Services Fees*, CAL. CRYOBANK, <http://www.cryobank.com/Services/Pricing/> (last visited Feb. 16, 2011). Pricing variables include whether the donor is anonymous or open, the specimen is intended for intracervical (standard unwashed) or intrauterine (pre-washed prior to freezing) insemination, and the specimen’s density (premium or A.R.T.). *Id.*

357. *Id.*

California Cryobank does not actually administer artificial insemination.<sup>358</sup> After selecting a donor and submitting the Purchase and Storage Agreement,<sup>359</sup> a purchaser can place an order online or by telephone, and the sperm vials will be shipped in liquid nitrogen "dry" shippers, domestically or internationally, to either the purchaser's home or her physician's office.<sup>360</sup> Finally, California Cryobank pressures its consumers to stock up on donor sperm, cautioning: "Once you find your ideal donor, the only way to guarantee he will be available in the future is to purchase and store extra vials. Whether you are hoping for one, two, or ten children, planning ahead is very important."<sup>361</sup> AID is no longer just a treatment administered by physicians to treat infertility,<sup>362</sup> it is now a consumer-dominated commercial transaction in which a purchaser can select a commodity from a catalog based on size and color, buy it online with a credit card, and have it shipped to her residence<sup>363</sup>—yet commercial sperm transfers may nonetheless be treated as the rendering of a service.<sup>364</sup>

Despite the widespread commodification of sperm sales, such transfers may be statutorily defined as services—regardless of the actual nature of the transaction.<sup>365</sup> In an effort to protect the national blood supply, most states have enacted "blood shield" laws that serve to limit the liability of suppliers of blood and blood products.<sup>366</sup> Some statutes limit suppliers' liability to claims of negligence or willful misconduct,<sup>367</sup> others expressly exempt

358. *Services*, CAL. CRYOBANK, <http://www.cryobank.com/Services/> (last visited Feb. 1, 2011).

359. *See Purchase and Storage Agreement*, *supra* note 348.

360. *Ordering and Shipment*, CAL. CRYOBANK, <http://www.cryobank.com/How-It-Works/Ordering-and-Shipment/> (last visited Feb. 1, 2011).

361. *Storage Process*, CAL. CRYOBANK, <http://www.cryobank.com/How-It-Works/Storage-Process/> (last visited Feb. 1, 2011).

362. *See supra* notes 216–18 and accompanying text.

363. *See supra* notes 348–61 and accompanying text.

364. *See infra* notes 365–73 and accompanying text.

365. *See infra* note 373 and accompanying text.

366. Many courts have declined to impose no-fault liability on blood suppliers in order to ensure the continued availability of blood transfusions, an extremely beneficial medical procedure . . . . As the concern over liability for supplying contaminated blood has grown during the recent AIDS crisis, many states have statutorily adopted [this] approach. These so-called "blood shield statutes" expressly provide that the supply of blood for transfusions is a medical service and not a sale . . . .

McIntyre, *supra* note 209, at 529.

367. MONT. CODE ANN. § 50-33-104 (West, Westlaw through 2009 legislation). Montana's statute states:

No blood bank or tissue bank may be held liable in the absence of fault or negligence for injuries resulting from the injecting, transfusing, transplanting, or transferring of whole blood, plasma, blood products, blood derivatives, human tissue, organs, or bones supplied by any such blood bank or tissue bank to any hospital or physician if such blood products

suppliers of blood and blood products from strict liability and breach of implied warranty claims,<sup>368</sup> and yet others still preclude strict liability and breach of warranty claims by explicitly determining that suppliers are rendering a service rather than furnishing a product.<sup>369</sup> Although such laws

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or tissue products have been tested by the latest testing procedures in accordance with recommendations of the American association of blood banks or the American association of tissue banks and by such test are not found to be dangerous to the health of the recipient of such blood products or tissue products.

*Id.*; see also N.M. STAT. ANN. § 24-10-5 (West, Westlaw through 2010 legislation) (“human tissue”).

368. See, e.g., ARIZ. REV. STAT. ANN. § 32-1481(A)-(B) (West, Westlaw through 1st Special Sess. and legislation effective Feb. 18 2011 of the First Reg. Sess. of the 15th Leg. (2011)). Arizona law provides that:

No physician, surgeon, hospital or person who assists a physician, surgeon or hospital in obtaining, preparing, injecting or transfusing blood or its components from one or more human beings to another human being shall be liable on the basis of implied warranty or strict tort liability for any such activity but such person or entity shall be liable for his or its negligent or willful misconduct. . . . No nonprofit blood bank, tissue bank, donor or entity who donates, obtains, processes or preserves blood or its components from one or more human beings for the purpose of transfusing or transferring blood or its components to another human being shall be liable on the basis of implied warranty or strict tort liability for any such activity but such person or entity shall be liable for his or its negligent or willful misconduct.

*Id.*; see also HAW. REV. STAT. § 327-51 (West, Westlaw through 2010 Reg. and Spec. Sessions) (protects transfer of “any tissue”).

369. See, e.g., ARIZ. REV. STAT. ANN. § 36-1151 (West, Westlaw through 1st Special Sess. and legislation effective Feb. 18 2011 of the First Reg. Sess. of the 15th Leg. (2011)). Arizona law determines that blood providers render a service:

The procurement, processing, distribution, or use of whole human blood, plasma, blood products and blood derivatives for the purpose of injecting or transfusing them into the human body shall be construed as to the transmission of serum hepatitis to be the *rendition of a service by every person participating therein and shall not be construed to be a sale.*

*Id.* (emphasis added); see also ALA. CODE § 7-2-314(4) (West, Westlaw through End of 2010 First Spec. Sess.); CAL. HEALTH & SAFETY CODE § 1606 (West, Westlaw through all 2010 Reg. Sess. laws); COLO. REV. STAT. ANN. § 13-22-104(2) (West, Westlaw through the end of the Second Reg. Sess. of the 67th General Assemb. (2010)); FLA. STAT. ANN. § 672.316(5)-(6) (West, Westlaw through Chapter 274 (End) of the 2010 Second Reg. Sess. of the Twenty-First Leg. and Chapter 283 of the 2010 Spec. “A” Sess. of the Twenty-Second Leg.); GA. CODE ANN. §§ 11-2-316(5), 51-1-28(a) (West, Westlaw through the 2010 Reg. Sess.); IDAHO CODE ANN. § 39-3702 (West, Westlaw through the end of the 2010 Second Reg. Sess. of the 60th Leg.); IND. CODE ANN. § 16-41-12-11(a) (West, Westlaw through the end of the 2010 Second Reg. Sess.); IOWA CODE ANN. § 142C.12 (West, Westlaw through Acts from the 2010 Reg. Sess.); KY. REV. STAT. ANN. § 139.125 (West, Westlaw through end of 2010 Legis.); LA. REV. STAT. ANN. § 9:2797(A) (West, Westlaw through the 2010 Reg. Sess.) (includes “human tissue”); MD. CODE ANN., CTS. & JUD. PROC. § 5-630 (West, Westlaw through all chapters of the 2010 Reg. Sess. of the General Assemb., effective through Oct. 1, 2010); MINN. STAT. ANN. § 525A.25 (West, Westlaw through the 2010 Second Spec. Sess.); MISS. CODE ANN § 41-41-1 (West, Westlaw through the 2010 Reg. and 1st and 2nd Extraordinary Sessions); MO. ANN. STAT. § 431.069 (West, Westlaw through the end of the 2010 1st Extraordinary Sess. of the 95th General Assemb.); NEV. REV. STAT. ANN. § 460.010 (West, Westlaw through the 2009 75th Reg. Sess. and the 2010 26th Spec. Sess. of the Nevada Leg.); N.M. STAT. ANN. § 24-10-5 (West, Westlaw through 2010 legislation); OHIO REV. CODE ANN. § 2108.30 (West, Westlaw through 2010 File 58 of the 128th GA (2009–2010)); OKLA. STAT. ANN. tit. 63, § 2151 (West, Westlaw through Chapter 479 (End) of the Second Reg. Sess. of the 52nd Leg. (2010)); R.I. GEN.

have been widely enacted, they have been criticized as artificial and inappropriate legal maneuvers.<sup>370</sup>

Although some blood shield statutes apply only to blood and blood products,<sup>371</sup> others include human tissue within their scope.<sup>372</sup> Because sperm is considered human tissue, the possibility of bringing a products liability action for genetically defective sperm may be effectively eliminated in jurisdictions with broad blood shield laws.<sup>373</sup> This result, however, fails to advance the public policy concerns behind the enactment of the blood shield statutes.<sup>374</sup> Furthermore, blood transfusions, by their very nature, are inherently more compatible with the concept of a service than are sperm transactions.<sup>375</sup> For these reasons, courts may refrain from interpreting broad blood shield statutes as encompassing sperm transactions.<sup>376</sup> If courts

LAWS ANN. § 23-17-30 (West, Westlaw through chapter 320 of the Jan. 2010 sess.); S.C. CODE ANN. § 44-43-10 (West, Westlaw through End of the 2010 Reg. Sess.); UTAH CODE ANN. § 26-31-1 (West, Westlaw through 2010 Gen. Sess.); WASH. REV. CODE ANN. § 70.54.120 (West, Westlaw through Laws 2011, chapters 1 and 2); W. VA. CODE ANN. § 16-23-1 (West, Westlaw through Laws of the 2010 Second Extraordinary Sess.); CONN. GEN. STAT. ANN. §§ 19a-280 (repealed 2010).

370. See Philippe Ducor, *The Legal Status of Human Materials*, 44 DRAKE L. REV. 195, 247-48 (1996), arguing that the characterization of blood transfers as a service, rather than a sale:

is designed primarily to avoid the strict product liability rules applicable to the sales of goods. Accordingly, a blood provider, including a donor, hospital, or blood bank, can be held liable only for negligence in handling the blood. This solution appears artificial considering the true nature of blood transactions. If public policy considerations grant blood providers immunity from strict products liability, then a specific statutory exemption for blood products, rather than a modification of the transaction, is the best solution. Another acceptable approach treats blood as an unavoidably unsafe product; therefore, no test can safely eliminate all the dangers.

371. See, e.g., ARIZ. REV. STAT. ANN. § 36-1151 (West, Westlaw through 1st Special Sess. and legislation effective Feb. 18 2011 of the First Reg. Sess. of the 15th Leg. (2011)).

372. See, e.g., IND. CODE ANN. § 16-41-12-11(a) (West, Westlaw through end of 2010 Second Reg. Sess.).

373. See Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 Fla. L. Rev. 603, 647 (2003).

374. McIntyre, *supra* note 209, at 530 (explaining that "the underlying intent behind most blood shield statutes was to ensure that the blood supply did not suffer due to donors' fears of being held accountable if their blood proved to be contaminated. This policy decision was made in view of the essential role that donated blood plays in our health care system. Donor semen, by contrast, does not enjoy a comparable status in our society. . . . [U]navailability of donor semen would not create a national crisis as would occur with a depletion of our blood supply.")

375. Whereas blood transfusions must be administered by a medical professional, insemination can be performed without assistance: "Because vaginal insemination is simple and does not require formal training, many women are 'self-inseminating' at home." Swink & Reich, *supra* note 4, at 861 n.18 (citing Justyn Lezin, *(Mis)Conceptions: Unjust Limitations on Legally Unmarried Women's Access to Reproductive Technology and Their Use of Known Donors*, 14 HASTINGS WOMEN'S L.J. 185, 193 (2003)).

376. See Noah, *supra* note 373, at 646 ("Historically, courts have refused to impose strict liability against providers of professional medical services. In the case of elective—and perhaps aggressively promoted—health care services such as fertility treatments, however, courts may rethink this



adopt this interpretation—and in jurisdictions with narrowly tailored blood shield laws—a plaintiff may be able to bring an action in products liability against a seller of genetically defective sperm.

### C. *Taking It to the Bank: Products Liability Actions for Genetically Defective Sperm*

Even if a plaintiff can overcome the hurdles of classifying sperm as a product and its transfer as a sale, numerous other factors will affect the success of a products liability action against a seller of genetically defective sperm: the genetic defect must fit one of the traditional categories of defect;<sup>377</sup> the seller must be a proper defendant;<sup>378</sup> the party bringing the claim must be a proper plaintiff;<sup>379</sup> and the plaintiff must claim a legally cognizable injury.<sup>380</sup>

Although claims for breach of an express warranty<sup>381</sup> or the implied

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traditional reluctance.”); see also Richard L. Cupp, Jr., *Sharing Accountability for Breast Implants: Strict Products Liability and Medical Professionals Engaged in Hybrid Sales/Service Cosmetic Products Transactions*, 21 FLA. ST. U. L. REV. 873 (1994) (suggesting that the justifications for protection physicians from strict liability are not applicable to cosmetic surgeons implanting defective nontherapeutic products that cause harm).

377. See *infra* notes 384–92 and accompanying text.

378. See *infra* notes 398–402 and accompanying text.

379. See *infra* notes 405–21 and accompanying text.

380. See *infra* notes 406–21 and accompanying text.

381. A seller of sperm who makes false representations about the quality of its product may be liable for breach of express warranty. Sellers of sperm may make various representations through their advertisements and literature. For instance, California Cryobank advertises that its:

donors are hand-picked and screened intensely before being accepted into our donor program. The quality of our donors is the foundation of our service, with less than 1% of all applicants making it through the selection process. Potential donors are subjected to an exhaustive medical, genetic, and psychological screening—as well as a detailed examination of their background and family medical history. In fact, it is this superior qualification process that sets us apart from other sperm banks. Our screening is detailed and far-reaching to ensure that our clients are provided the best of the best.

CAL. CRYOBANK, <http://www.cryobank.com/> (last visited Feb. 17, 2011). Regardless of California Cryobank’s intention, such language constitutes an express warranty. California Cryobank’s Purchase and Storage Agreement provides:

EXCEPT AS SET FORTH IN SECTION 3 (SPECIMEN QUALITY), ALL CRYOBANK PRODUCTS AND SERVICES . . . ARE PROVIDED “AS IS” WITH NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING (BUT NOT LIMITED TO) THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT. IN PARTICULAR (BUT WITHOUT LIMITATION), CRYOBANK DOES NOT WARRANT THAT SPECIMENS ARE FREE OF GENETIC DEFECTS OR DISEASES, THAT A PREGNANCY WILL RESULT FROM THE USE OF A SPECIMEN, OR THAT A CHILD BORN USING A SPECIMEN WILL BE FREE OF DISEASE OR MENTAL DEFECTS. . . .

*Purchase and Storage Agreement*, *supra* note 348. Despite this exculpatory language, the Purchase and Storage Agreement may not preclude California Cryobank’s liability for failure to comply with its express warranty. For instance, if California Cryobank did not, as it advertised, perform “an exhaustive medical, genetic, and psychological screening—as well as a detailed examination of their

warranty of fitness for a particular purpose<sup>382</sup> do not involve a showing that the product is defective,<sup>383</sup> a defect is required to establish negligence, breach of the implied warranty of merchantability, and strict liability in tort.<sup>384</sup> While the court in *Donovan* accepted without question that a genetic defect constitutes a defect for purposes of products liability,<sup>385</sup> genetic defects do not fit neatly into any of the three standard defect categories in products liability—manufacturing, design, and warning.<sup>386</sup> Defect classification is crucial to the resolution of a products liability claim because the standard for evaluating defectiveness varies depending on whether the product is defective in its manufacture, design, or warnings.<sup>387</sup>

In *Two Rivers*, the court suggested that genetic defects are most akin to manufacturing defects: "This case presents a flaw in the product in that it was not improperly designed, but it arrived in a state which did not comport with its expected condition."<sup>388</sup> Similarly, others have declared that genetic "defects could be both manufacturing and warning."<sup>389</sup> One might instead

background and family medical history" of its potential donors, its attempt to exclude all warranties would be inoperable to the extent that the attempted exclusion is inconsistent with the express warranty. *See supra* note 140 and accompanying text.

382. It is unlikely that a plaintiff will be able to establish a claim against a seller of sperm for breach of implied warranty of fitness for a particular purpose. The fitness warranty requires that the buyer have—and the seller be aware of—a special purpose for the product. *See supra* notes 144–47 and accompanying text. Because sperm has one purpose—to fertilize an egg and produce a resulting offspring—it would be difficult to establish that the buyer sought to achieve another purchase. One might, however, argue that she selected a donor with specific characteristics for the special purpose of producing offspring with those features. *See supra* note 352 and accompanying text (discussing California Cryobank's checklist for selecting donor characteristics). This argument is unlikely to be persuasive, though, "because of the complexity of human genetics, it is generally unclear which traits will be inherited by the child." L. Thomas Styron, Comment, *Artificial Insemination: A New Frontier for Medical Malpractice and Medical Products Liability*, 32 *LOY. L. REV.* 411, 414 (1986). The seller, thus, is unlikely to know of the buyer's special purpose.

383. *See supra* notes 135–50 and accompanying text.

384. *See supra* note 62 and accompanying text.

385. *See supra* notes 265–305 and accompanying text.

386. *See supra* notes 64–102 and accompanying text.

387. The test for manufacturing defects is whether the product departs from its intended design, while design defects require a showing that the product should have been designed differently to make it safer. *See* A. Mitchell Polinsky & Steven Shavell, *The Uneasy Case for Product Liability*, 123 *HARV. L. REV.* 1437, 1453 nn.60–61 (2010). Warning defects exist when a product is unsafe for its ordinary use due to inadequate warnings or instructions. *See supra* notes 64–102 and accompanying text.

388. *Two Rivers Co. v. Curtiss Breeding Serv.*, 624 F.2d 1242, 1249 (5th Cir. 1980).

389. Swink & Reich, *supra* note 4, at 887. Warning defects require that a plaintiff establish that a better warning could have made the product safer. *See supra* note 89 and accompanying text. No warnings or instructions, however, could make genetically defect sperm any safer. Adequate warnings are nonetheless necessary for purposes of informed consent. *See supra* note 90 and accompanying text. A woman who does not know of the risk that a resulting child may inherit a genetic defect from donor sperm cannot fully consent to AID. But if a woman undergoes

argue that genetic defects are, in effect, design defects.

Genetically defective sperm could be categorized as defective in design regardless of whether the sperm donor is classified as a manufacturer and the sperm bank as a distributor,<sup>390</sup> or whether the sperm donor is considered a raw material supplier and the sperm bank a manufacturer.<sup>391</sup> As such, genetic defects in sperm should be considered design defects, and the standard for determining whether the sperm is defective is whether it should have been designed differently to make it safer.<sup>392</sup> The rationale for imposing liability for defectively designed products is only present, however, when the sperm bank is considered the manufacturer.<sup>393</sup>

Applying the standard for design defects, the plaintiff must show that the sperm was in fact defective. The sperm will be defective in negligence if the plaintiff can show that the seller reasonably should have discovered the genetic defect but failed to do so.<sup>394</sup> To establish a breach of the implied warranty of merchantability, the sperm must be unmerchantable at the time of sale.<sup>395</sup> Under strict liability, the test for design defects varies by

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insemination with donor sperm despite warnings regarding the possibility that the sperm carries genetic defects, then the woman effectively assumes that risk. *See supra* notes 195–97 and accompanying text.

390. If the sperm donor is considered a manufacturer, then the sperm bank would simply be a distributor of his product. If the sperm donor carries a genetic defect, however, then the design of his “product line” is compromised. The genetic defect does not simply affect one batch or lot of his product—it affects the entire line. He simply manufactures a bad product. When his sperm produces offspring with genetic defects, this is not caused by the mismanufacture of his product, but rather by the very nature of his product—sperm that carries a genetic defect. His sperm is defectively designed.

391. If the sperm donor is treated as a raw material supplier rather than a manufacturer, then the sperm bank will be considered the manufacturer. Such a classification seems appropriate in light of the conscious design decisions made by sperm banks in selecting and testing its raw materials. Although the sperm bank may intend to provide sperm that is free from genetic defects, sperm that in fact carries such defects may not actually depart from its intended design. Just like automobile manufacturers intend to make safe cars, actual safety levels depends on the features selected and tests performed. Where a sperm bank chooses to forego testing for rare genetic disorders, this represents a conscious design decision. If a child inherits that rare genetic disorder, the genetic defect is not a manufacturing defect, but rather a design defect reflecting conscious design decisions that affect the entire product line. Whether such a design is defective depends on whether the sperm bank should have tested for that rare genetic disorder, based on some combination of a risk-utility analysis or consumer expectations. *See supra* notes 76–78 and accompanying text.

392. Although a sperm donor is physically unable to alter the design of his sperm, he arguably should not put such a reasonably unsafe product in the stream of commerce.

393. Because the sperm donor’s product only reflects natural processes, that rationale for imposing liability for design defects—that the injury was caused by the manufacturer’s conscious design decisions—does not apply. In contrast, the sperm bank makes conscious decisions in selecting and testing the sperm, and so there the rationale would be relevant.

394. If, however, the sperm bank’s decision to test only for the most prevalent genetic defects were reasonable in regard to cost and likelihood of harm, the sperm bank would not be found negligent, despite selling sperm that carried a genetic defect.

395. *See supra* note 157 and accompanying text (defining unmerchantable as “not fit for its ordinary purpose”). Sperm’s purpose is to fertilize an egg and produce a resulting child. Although genetically defective sperm can achieve this purpose, it arguably cannot do so safely, and may thus

jurisdiction, involving consumer expectations<sup>396</sup> or a risk utility analysis.<sup>397</sup>

While a plaintiff "may very well sue any party who had an opportunity to discover the defect in the semen and failed to do so,"<sup>398</sup> the issue of whether a seller can be liable for providing genetically defective sperm depends on the asserted basis of liability and the seller's status. Negligence actions require a showing of individualized fault, with liability attaching only to parties that have acted unreasonably,<sup>399</sup> as such, the most likely target is the sperm bank responsible for selecting and testing the sperm.<sup>400</sup> Because of issues associated with sperm donor anonymity, the plaintiff may have difficulty proving the sperm bank's negligence.<sup>401</sup> In contrast, any

be considered unmerchantable.

396. One author suggests that recipients of AID expect "healthy sperm, a safe artificial insemination process, and ultimately, a healthy child." Ginsberg, *supra* note 209, at 823. It is debatable whether such expectations are reasonable in light of evidence that "[t]he rate of genetic defects in naturally conceived live-born children is approximately six to seven percent . . ." McIntyre, *supra* note 209, at 521. Nonetheless, the fact that some couples use AID to prevent the transmission of the husband's known genetic defect is revealing of their expectations about the procedure. See Ginsberg, *supra* note 209, at 823 ("While the majority of couples use artificial insemination to overcome fertility problems, many recipients use artificial insemination to avoid passing a genetic disease to their children."). This purpose is defeated, and a consumer's expectations may be frustrated, if donors are not adequately tested to prevent the transmission of genetic diseases and defects.

397. The risk-utility analysis will balance a variety of factors, including the likelihood that a sperm sample carries the particular genetic defect, the severity of associated disease, and the cost of testing for the defect.

398. McIntyre, *supra* note 209, at 521. "This could include the physician who performed the procedure, the sperm bank that distributed the semen, and the donor himself." *Id.*

399. See *supra* note 115 and accompanying text.

400. See Anita M. Hodgson, Note, *The Warranty of Sperm: A Modest Proposal to Increase the Accountability of Sperm Banks and Physicians in the Performance of Artificial Insemination Procedures*, 26 IND. L. REV. 357, 369 (1993) ("[I]t is generally the sperm bank, not the physician, that selects and screens donors; the physician usually has little or no contact with the donor."). If, however, a sperm donor provides incomplete or inaccurate information regarding his background and family history during the application and screening process, he might also be found to be liable under negligence, as may a physician who procures sperm on behalf of a patient from a disreputable source.

401. See Blum, *supra* note 306, at 339–40 ("In order to prove negligence in a tort action, a woman may need to question the semen donor about whether certain guidelines were followed. The discovery of information about donors has been an issue in suits against blood banks and hospitals that have distributed HIV-contaminated blood."). A plaintiff may argue that it is necessary to interview a sperm donor regarding the screening methods employed by the sperm bank. One author suggests that "[a] court in a negligence action against a semen bank may allow the discovery of a semen donor's laboratory reports or answered questionnaires to prove what screening methods were used. However, it is very unlikely that a court would allow the disclosure of the donor's identity." *Id.* at 342 (footnote omitted). There may, however, be strong reasons for disclosing a sperm donor's identity where the donor passed a genetic defect to a child produced through AID. For instance, the donor's appearance may be relevant to the question of the sperm bank's negligence. The donor's physical characteristics may exhibit indications that he carries a particular disease. See *supra* note

seller in the chain of distribution may be held liable for genetically defective sperm in implied warranty of merchantability<sup>402</sup> and strict liability actions, so a plaintiff may sue not only the sperm bank, but also the sperm donor and administering physician.<sup>403</sup> Furthermore, while any blameworthy seller of genetically defective sperm may be held liable in negligence, only a seller who regularly engages in sperm sales can be liable under the implied warranty of merchantability or strict liability in tort.<sup>404</sup>

Products liability claims for genetically defective sperm may be brought by an AID recipient, her spouse,<sup>405</sup> or the resulting child. The AID recipient's claim<sup>406</sup> can be characterized as one of wrongful birth.<sup>407</sup> In contrast with a direct injury to the AID recipient,<sup>408</sup> the injury caused by a wrongful birth is the denial of the recipient's opportunity to make an informed decision regarding whether or not to have the child.<sup>409</sup> Because wrongful birth is not legally accepted in all states,<sup>410</sup> an AID recipient may be unable to establish her prima facie case in states unwilling to recognize her injury.<sup>411</sup> An AID recipient must also be cognizant of the statutory

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280 (describing the physical characteristics of a Fragile X carrier).

402. Sellers may, however, escape liability by disclaiming the implied warranty of merchantability. See *supra* note 167 and accompanying text.

403. Thus, even if a physician has no opportunity to test the sperm and simply procures it from a sperm bank claiming to vigorously test the product, he can be held liable under implied warranty of merchantability or strict liability. Where, however, sperm is purchased directly by a consumer from a sperm bank and only shipped to a physician's office for the procedure, the administering physician may not be considered part of the chain of distribution. See *supra* notes 353–62 and accompanying text.

404. See *supra* notes 156–86 and accompanying text. If a sperm donor only sells his sperm sporadically, it is unlikely that he will satisfy the requirement of being a seller regularly engaged in sales of that kind of product. See *supra* note 156. If, however, he instead donates three times per week, as suggested by California Cryobank, he would likely be subject to liability under the implied warranty of merchantability and strict liability. See *supra* note 352 and accompanying text.

405. See McIntyre, *supra* note 209, at 521 n.14 (“[T]hese claims can theoretically be brought by both the birth mother of a child conceived through artificial insemination and her husband (since the husband is treated as the legal father of the child in most states).” (citation omitted)).

406. For purposes of simplification, this Comment does not separately address the recipient's claim and the spouse's claim because the spouse's claim is a derivative of the recipient's claim.

407. See *supra* note 304 and accompanying text (recounting the *Donovan* court's suggestion that Donna Donovan could have brought a wrongful birth claim had the statutory period not expired).

408. See, e.g., Blum, *supra* note 306 (considering the potential for tort liability when an AID recipient contracts HIV through artificial insemination).

409. Wrongful birth claims are “brought by the parents of a child born with severe defects against a physician who negligently fails to inform them . . . of an increased possibility that the mother will give birth to such a child, thereby precluding an informed decision as to whether to have the child.”

*Smith v. Cote*, 513 A.2d 341, 344 (N.H. 1986). “The most common measure of damages in wrongful birth cases is the extraordinary medical and educational expenses which the parents will incur due to the child's mental or physical handicaps.” McIntyre, *supra* note 209, at 540.

410. Wrongful birth was recognized by twenty-two states as of 2002. See Kelly E. Rhinehart, *The Debate Over Wrongful Birth and Wrongful Life*, 26 LAW & PSYCHOL. REV. 141, 142 (2002). Three states—Georgia, Michigan, and North Carolina—have explicitly rejected wrongful birth claims. *Id.*

411. See *supra* note 302–03 and accompanying text (describing the *Donovan* court's dismissal of Brittan's action for failure to state a claim because she could not allege a legally cognizable injury,

period in which she can bring a claim, which is likely to begin as soon as she knows or has reason to know of the defect and its source.<sup>412</sup> Although the state recognizes wrongful birth claims and the statutory period has not expired, the AID recipient's claim may be denied if the defendant successfully argues that she assumed the risk.<sup>413</sup>

Even if the AID recipient assumed the risk of being inseminated with genetically defective sperm, this may not adversely affect the resulting child's claim.<sup>414</sup> Likewise, if the recipient's statutory period to bring an action has expired, the child may still have time to initiate a claim if the jurisdiction has a minor's tolling statute.<sup>415</sup> Nonetheless, the child may face other obstacles to recovery, most of which, however, can be overcome.

In negligence actions, defendants may argue that they owe no duty of care to the potential offspring created through AID; however, "it is hard to accept that an artificial insemination practitioner, sperm bank, and sperm donor owe no duty of care whatsoever to the child whose conception they are actively seeking."<sup>416</sup> While defendants may argue that the child was not a party to the contract between the AID recipient and the sperm bank, the child will likely be granted third-party beneficiary status as to the

where New York does not recognize wrongful life claims).

412. See *supra* note 284 and accompanying text (discussing the discovery rule for tolling the statutory period).

413. Whether the recipient assumed the risk would be a question of fact for the jury. See *supra* notes 196–97 and accompanying text. The defendant would have to prove that the recipient was both subjectively aware of the risk and encountered it voluntarily. See *supra* notes 196–97 and accompanying text. The defendant might argue that "[d]espite significant advances in medical technology over the past quarter-century, the detection and prevention of genetic defects and diseases is not one hundred percent." Hodgson, *supra* note 400, at 383. Nonetheless, the determination of whether the recipient actually assumed the risk would likely depend on how broadly or narrowly the risk is framed (for example, the possibility that the resulting child would inherit a genetic defect, as opposed to the possibility that the resulting child would inherit that specific genetic defect) and the recipient's expectations regarding the testing. See *supra* note 309 and accompanying text (describing a case in which the resulting child inherited cystic fibrosis despite assurances by the sperm bank that they tested for the condition).

414. See Noah, *supra* note 373, at 642 ("[E]xpress assumption of risk by a patient probably would not bar a claim brought on behalf of a child."). "Any assumption of risk or comparative negligence by [the mother], even if valid defenses . . . , typically would not be imputed to her [child]." *Id.* at 642–43; see also *id.* at 645 (discussing the effect of intrafamily immunities in relation to third-party claims for contribution).

415. See, e.g., 42 PA. CONS. STAT. ANN. § 5533(b)(1)(i–ii) (Purdon, Westlaw through 2010 Reg. and 1st Special Sess.); N.Y. C.P.L.R. 202 (McKinney, Westlaw through 2010 legislation).

416. McIntyre, *supra* note 209, at 538. Support for the position that the defendants do in fact owe a duty of due care to the potential offspring produced through AID can be found in existing case law. See, e.g., Huddleston v. Infertility Ctr. Of Am., Inc., 700 A.2d 453, 460 (Pa. Super. Ct. 1997) (holding that a surrogacy business "must be held accountable for the foreseeable risks of the surrogacy undertaking because a 'special relationship' exists between the surrogacy business, its client-participants, and, most especially, the child which the surrogacy undertaking creates.").

contract.<sup>417</sup> Although a sperm donor named as a defendant may try to claim parental immunity, this defense is unlikely to succeed since many states have adopted statutes that determine legal parentage.<sup>418</sup> The most significant obstacle to the resulting child's claim will be the characterization of the child's injury as one of wrongful life.<sup>419</sup> Because wrongful life claims are only recognized in three states—California, New Jersey, and Washington<sup>420</sup>—the resulting child's claim will often be barred for failure to assert a legally cognizable injury.<sup>421</sup>

Despite numerous obstacles and jurisdictional variables, an AID recipient, her spouse, or the resulting child may be able to bring a products liability action against a seller of genetically defective sperm. Products liability may not, however, be the most appropriate or effective mechanism for regulating AID. Because AID is likely to be the subject of future litigation, further consideration should be given to alternative methods of regulation.

#### IV. *DONOVAN* REVISITED: SOWING THE SEEDS OF DISSENT

Regardless of whether current law permits products liability actions for

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417. See *supra* note 278 and accompanying text.

418. See *supra* note 244 and accompanying text.

419. See McIntyre, *supra* note 209, at 539. Some authors have suggested that:

[A] child who is born with [a genetic] disease has experienced, and will experience, several legally recognized and compensable injuries: she has been damaged in her enjoyment of life, has suffered and will suffer physical and mental pain, has endured past medical expenses, and is likely to incur future medical expenses.

Swink & Reich, *supra* note 4, at 887. This, however, misframes the injury. In wrongful life actions, the injury claimed is not the genetic defect that the child suffers, but rather "it is the birth of plaintiff with such defect." *Curlender v. Bio-Science Labs.*, 106 Cal. App. 3d 811, 829 (Cal. App. 1980); see also China R. Rosas, *A Necessary Compromise: Recognizing the Rights of a Donated Generation to Tame the Wild Wild West of California's Sperm Banking Industry*, 37 SW. U. L. REV. 393, 413 (2008) (quoting Susan L. Crockin, *Reproductive Genetics: Conceiving New Wrongs?*, 3 SEXUALITY, REPROD. & MENOPAUSE 37, 37 (2005)) ("Donor offspring asserting wrongful life claims are claiming that 'but for professionals' actions or inactions [they] would not have been born.' Generally speaking, both claims lead to a conclusion that if certain genetic tests had been conducted, the decision to bring a child into this world would have been different. . . . [M]ost states 'refuse to recognize wrongful life claims on the theory that any life is better than none, and because public policy frowns on assigning damages for a life.'").

420. Rhinehart, *supra* note 410, at 152; see also *Turpin v. Sortini*, 643 P.2d 954 (Cal. 1982); *Moscattello v. Univ. of Med. & Dentistry of N.J.*, 776 A.2d 874 (N.J. Super. Ct. App. 2001); *Harbeson v. Parke-Davis, Inc.*, 656 P.2d 483 (Wash. 1983).

Many courts have rejected wrongful life based on the difficulty in determining damages. The goal of damages in tort law is compensatory, putting the plaintiff in the position that he was in before the negligent conduct. Consequently, in a wrongful life suit, the position the plaintiff would have been in if the tort had not occurred would be nonexistence.

Rhinehart, *supra* note 410, at 155.

421. See *supra* notes 298–303 and accompanying text (describing the *Donovan* court's decision that Brittany's claim was one of wrongful life).

genetically defective sperm, it is necessary to consider whether such claims are appropriate and effective in achieving the primary goals of products liability law. While negligence actions require a showing of individualized fault, both the implied warranty of merchantability and strict liability in tort hold all sellers in the chain of distribution liable irrespective of fault.<sup>422</sup> Because sperm banks are in the best position to screen donors and test the sperm,<sup>423</sup> it is not only unfair to hold physicians and sperm donors liable without fault, but it also defeats a primary rationale for products liability—the reduction of risks and accident costs.<sup>424</sup> Similarly, imposing strict legal liability for genetic defects that are impossible to diagnose or are yet undiscovered at the time of insemination does not effectively advance these policy objectives.<sup>425</sup>

Because the injury caused by genetically defective sperm is not strictly classified as "personal injury," sperm banks may effectively exclude damages caused by genetically defective sperm through exculpatory clauses in their contracts.<sup>426</sup> Regardless of the enforceability of such provisions, plaintiffs may believe that the broad disclaiming language included in sperm bank waivers<sup>427</sup> bars their claims against the sperm bank. As a result, they may be inclined to pursue other parties in the chain of distribution<sup>428</sup>—

422. See *supra* notes 151–92 and accompanying text.

423. See *supra* note 400 and accompanying text.

424. See *supra* note 90 and accompanying text; see also Stephen P. Teret & Michael Jacobs, *Prevention and Torts: The Role of Litigation in Injury Control*, 17 *LAW, MED. & HEALTH CARE* 17, 17 (1989) ("Prevention of injuries, then, deals with man's control over his own creations. It deals with providing incentives or requirements for product makers and others to anticipate hazards and to reduce them to the extent feasible. These incentives and requirements are usually created through the legal system. They can come in the form of legislation, regulation, or litigation.").

425. See Henderson & Twerski, *supra* note 190, at 273 ("However tempting it may be for courts to hold distributors 'strictly' liable for unknowable risks, doing so prevents the achievement of either of two contrasting objectives underlying tort law, as identified by the majority of commentators.").

426. See *supra* note 172 and accompanying text (explaining that damages may be excluded or limited, except where they involve injury to the person).

427. See *supra* note 381 and accompanying text.

428. William Prosser described plaintiffs' inclination to sue various parties in the chain of distribution when the primarily responsible party is out of reach:

There are other sellers than the manufacturer of the product. It will pass through the hands of a whole line of other dealers, and the plaintiff may have good reason to sue any or all of them. The manufacturer is often beyond the jurisdiction. He may even, in some cases, be unknown. If he is identified and can be sued, it is very often impossible to pin the liability upon him. Even where there is a proved defect which speaks of obvious negligence on the part of some one, it may still not be possible to prove that it was on the part of the maker. The cracked Coca Cola bottle may have been cracked long after it left his plant. And even when the cause can be fixed upon the manufacturer, he may turn out, in these days of chain stores and large supply houses, to be a small concern, operating on a shoestring, and financially the least responsible person in the whole chain of



namely the sperm donor or the physician—whose conduct is not as blameworthy as that of the sperm bank.<sup>429</sup>

It is similarly unfair to hold a diligent sperm bank liable for failing to detect a condition that is extremely rare, impossible to detect, or not yet discovered at the time of insemination. “In light of the fact that more than 2,000 genetic diseases exist,”<sup>430</sup> even with strong screening and testing standards, there is a chance that a child produced through AID will inherit a genetic defect<sup>431</sup>:

Although there are a variety of tests capable of detecting many diseases and genetic defects in sperm donors, a child could still be born with a defect or disease despite every possible precaution on the part of the sperm bank and physician. Thus, if strict liability in its traditional form were applied to commercial sperm transactions, the result would be a virtual “warranty on human life.”<sup>432</sup>

Because testing for all rare conditions may be prohibitively expensive, liability should be limited to a sperm seller’s failure to identify defects that are reasonably capable of detection.<sup>433</sup> Rather than imposing strict liability on sellers of genetically defective sperm, courts should instead apply a shifted burden of proof to claims brought in negligence.<sup>434</sup>

#### A. *The Sterile Doctrine of Strict Liability*

The doctrine of strict liability was adopted to relieve plaintiffs of the

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distribution. If the plaintiff is to recover at all, he must often look to the wholesaler, the jobber, and the retailer.

Prosser, *The Assault Upon the Citadel*, *supra* note 187, at 1116–17.

429. Although the sperm donor’s misrepresentation of his family medical history would of course constitute blameworthy conduct, it would be unfair to hold him liable for transmitting a genetic disease that he has no reason to know that he carries; if a lifetime of health examinations has not revealed his condition, he cannot reasonably be expected to know of it. Similarly, the physician will likely never even meet the sperm donor and will thus have limited opportunities to discover a defect. *See supra* note 400 and accompanying text. Some commentators suggest that strict liability encourages sellers to “take appropriate care” and sell their products at “a price reflecting accident losses.” Steven Shavell, *Strict Liability Versus Negligence*, 9 J. LEGAL STUD. 1, 4 (1980). However, knowing that other parties in the chain of distribution may absorb the costs of injuries caused by defective sperm, sperm banks may be more inclined to forego certain screening and testing measures.

430. Ginsberg, *supra* note 209, at 845.

431. *See* Ginsberg, *supra* note 209, at 845 (“Each person carries between three and five lethal recessive genes, and, therefore, may carry some deleterious genetic disease gene.”).

432. Hodgson, *supra* note 400, at 383.

433. One possibility for precluding recovery where detection of a genetic defect is not feasible involves the classification of sperm as an “unavoidably unsafe product.” *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) (denying recovery under strict liability for unavoidably unsafe products).

434. *See infra* notes 442–51 and accompanying text.

considerable difficulties that they face in proving negligence in products liability claims.<sup>435</sup> In effect, strict liability shifts the plaintiff's burden of proof to the seller of a defective product based on the notion that the seller is in a better position to describe its actions:

Strict liability shifts the burden of proof from the plaintiff to the manufacturer. A plaintiff lacks the information necessary to say exactly how a product was defective: a user does not know how the product was made or whether the manufacturer acted unreasonably. Manufacturers have such knowledge. As applied, products liability serves as a rebuttable presumption of fault on the part of the manufacturer, which tends to bring out the truth.<sup>436</sup>

Strict liability, unfortunately, goes considerably further than simply shifting the burden of proof and is thus an inappropriate cause of action for sales of genetically defective sperm.<sup>437</sup>

Negligence, however, resolves the problems of applying strict liability to claims involving the sale of genetically defective sperm.<sup>438</sup> In negligence, a seller of sperm will only be liable if shown to have individually engaged in blameworthy conduct.<sup>439</sup> Furthermore, a seller will not be held liable for providing genetically defective sperm if the defect could not have reasonably been detected.<sup>440</sup> A fault-based standard imposes incentives for

435. See 1 OWEN ET AL., *supra* note 61, at 400 ("[S]trict liability was proposed as a mechanism for alleviating the difficulties of proof in a negligence case and thus is typically preferable to a negligence action.").

436. Anita Bernstein, *Product Dynamism and the Law*, in MEANING, MEASURE, AND MORALITY OF MATERIALISM 115 (Floyd Rudmin & Marsha Richins eds., 1992); see also *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 455 (Cal. 1978) ("[Courts] have repeatedly emphasized that one of the principal purposes behind the strict product liability doctrine is to relieve an injured plaintiff of many of the onerous evidentiary burdens inherent in a negligence cause of action.").

437. Strict liability holds all sellers in the chain of distribution liable regardless of individualized fault. See *supra* notes 173–92 and accompanying text.

438. See *infra* notes 439–41 and accompanying text.

439. See *supra* note 115 and accompanying text.

440. See 1 OWEN ET AL., *supra* note 61, at 633, discussing the relationship between actions in negligence and a seller's ability to reduce risks and accident costs:

State of the art evidence is highly relevant to the negligence issue, because such evidence and negligence claims are predicated on a manufacturer's ability to prevent product accidents. . . . [T]he state of the art issue usually concerns either: (1) the foreseeability of a particular risk of which the plaintiff claims the defendant failed to warn, or (2) the feasibility of modifying a design in a particular manner to eliminate a risk of which the manufacturer was aware. In a negligent warnings case, if a risk is 'unknowable,' it is 'unforeseeable' and so lies outside the manufacturer's duty to avoid. In a negligent design case, if the manufacturer had no practical ability to eliminate a danger, then the burden on the manufacturer to avoid the injury outweighs virtually any risk of harm.

sellers of sperm to act reasonably, and these features of negligence function to advance the primary policy objectives of reducing risks and accident costs.<sup>441</sup>

Unfortunately, traditional negligence actions preserve the considerable evidentiary burdens that inspired the creation of the doctrine of strict liability.<sup>442</sup> The rationale for shifting the burden of proof from a plaintiff to a seller in a strict liability action is especially apparent in the context of AID, where the donor is often anonymous and the plaintiff has little information available regarding the precise screening and testing methods employed by the sperm bank.<sup>443</sup> Although it is very possible that a genetic defect may be transmitted through donor sperm without any negligence at all on the part of the sperm bank, sperm donor, or recipient's physician, the sperm seller is in a uniquely superior position to rebut a presumption of negligence.<sup>444</sup>

To reduce risks and create incentives for preventing the transmission of genetic defects, liability for providing genetically defective sperm should be based on the seller's fault.<sup>445</sup> Because of the plaintiff's severe evidentiary burdens arising out of donor anonymity, the seller should, however, have the burden of proving that the screening and testing methods employed were reasonable.<sup>446</sup> Therefore, in AID litigation, courts should adopt a negligence standard with a shifted burden of proof.<sup>447</sup> The presence of a genetic defect

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441. See Sheila L. Birnbaum, *Unmasking the Test for Design Defect: From Negligence [to Warranty] to Strict Liability to Negligence*, 33 VAND. L. REV. 593, 645 (1980) ("The primary goal underlying any standard of liability for product-related injuries resulting from defective design should be, not compensation, but the reduction of the incidence of injuries. As a matter of rational social policy, it is of foremost importance to build into the rule of law an approach aimed at deterring conduct that exposes consumers and users to unreasonable risks of harm. . . . Broadly spreading the risk of product-related injuries, without more, meets only a secondary goal of compensating injured plaintiffs. Only by fusing the rule of law governing design cases to a notion of faulty conduct will the rationale of providing manufacturers with a true incentive to design safer products have any meaning.").

442. See *supra* notes 435–36 and accompanying text.

443. See *infra* note 444 and accompanying text.

444. See *supra* notes 5–7 and accompanying text (describing the Michigan case in which the treating specialist for five children diagnosed with SCN could not test his theory that the anonymous sperm donor carried the defective gene only in his sperm cells because the sperm donor could not be located and his additional samples could not be tested without his consent). In the Michigan case, if the sperm donor did not carry the gene only in his sperm cells, he would have exhibited symptoms of his condition, and it would have been detectable. In that case, the sperm bank might have been negligent for failing to detect the defect. The children would be unable, however, to prove the sperm bank's negligence because they could not identify and examine the anonymous sperm donor. Similarly, in the *Donovan* case, although the sperm bank may have acted reasonably in foregoing tests for a rare condition, it may have been negligent in failing to identify symptoms of Fragile X exhibited by the sperm donor. See *supra* note 280 and accompanying text (explaining that male Fragile X carriers generally exhibit severe symptoms). The *Donovans*, however, would be unable to prove the sperm bank's negligence without access to the anonymous sperm donor.

445. See *supra* note 441 and accompanying text.

446. See *supra* notes 442–44 and accompanying text.

447. Support for a shifted burden of proof can be found in the rationale for imposing strict liability, as discussed above, and in other case law. See, e.g., *Brousseau v. Rosenthal*, 443 N.Y.S.2d

in offspring produced through AID should raise a rebuttable presumption of a seller's negligence.<sup>448</sup> The seller may then offer evidence that its conduct was reasonable.<sup>449</sup>

Applying a negligence standard with a shifted burden of proof may require sperm banks to adjust their conduct such that their transactions are less like a consumer-driven sale of goods and more like the rendering of a professional service. Due to the complexities of reproduction, the implementation of a uniform system for the screening and testing of donors for genetic defects may, by itself, be insufficient. Instead, sperm banks may be expected to screen both donors *and* recipients.<sup>450</sup> Based on a recipient's unique genetic makeup and medical history, a sperm bank may, in some cases, be negligent for screening, but failing to test, the selected sperm for any diseases for which the recipient is predisposed to a higher carrier rate.<sup>451</sup>

Finally, although plaintiffs may be expected to prefer bringing claims in strict liability, Paul Rheingold suggests that they may actually have more success with the fault-based language of negligence:

In McLuenesque terms negligence is "hot" and strict liability is "cold." It is easier to prevail by showing that the defendant did something wrong than that there is something technically defective about the product. It is easier to win (and collect substantial damages) by showing that a drug company concealed information about side effects than to show that in fact there was no warning on the labeling about the risks.<sup>452</sup>

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285, 285 (N.Y. Civ. Ct. 1980) (holding that "defendant's failure to return the bailed dog presumptively establishes his negligence, shifting the burden of proving due care to the defendant-bailee").

448. See *supra* note 444 and accompanying text.

449. Such evidence may include statistics demonstrating that a condition is extremely rare, evidence that the cost of testing for rare defects is prohibitively expensive, or information obtained through donor screening indicating that the donor likely did not carry the defective gene.

450. Some genetic disorders are inherited in an autosomal recessive pattern, meaning that the condition is caused by the "inheritance of a defective gene from two carrier parents. The chance of an affected child is 1 in 4 or 25% for each pregnancy." DIV. OF MED. GENETICS EMORY UNIV. SCH. OF MED., BASIC ASHKENAZI GENETIC DISEASE SCREEN (TAY SACHS, CANAVAN DISEASE, FAMILIAL DYSAUTONOMIA, CYSTIC FIBROSIS) (2005), available at [http://genetics.emory.edu/pdf/Emory\\_Human\\_Genetics\\_Basic\\_AJ\\_Panel.PDF](http://genetics.emory.edu/pdf/Emory_Human_Genetics_Basic_AJ_Panel.PDF).

451. Some ethnic groups have higher carrier rates than the general population for certain genetic diseases. For example, persons with Ashkenazi Jewish ancestry have a carrier rate of one in thirty for Tay Sachs, one in thirty-six for Canavan Disease, one in thirty for Familial Dysautonomia, and one in twenty-nine for Cystic Fibrosis. *Id.* Sperm banks may likewise be negligent for screening, but failing to test, donors from these ethnic groups for related genetic diseases. See *id.*

452. Paul D. Rheingold, *The Expanding Liability of the Product Supplier: A Primer*, 2 HOFSTRA

Thus, a plaintiff may actually have a better chance of recovery using the “hot” language of negligence instead of the sterile language of strict liability.

*B. Ties that Bind: The Necessity of a National Donor Database*

Litigation alone is insufficient to effectively resolve the problems caused by the inadequate regulation of the sperm banking industry. While the FDA regulations geared towards the prevention of transmitting communicable diseases through donor sperm are a step in the right direction, they are not enough.<sup>453</sup> The establishment of a national donor database is necessary to reduce the risk of transmitting genetic defects to children produced through AID.<sup>454</sup>

While some sperm banks self-regulate by limiting the number of pregnancies per donor, there is nothing to stop a sperm donor from donating to multiple sperm banks and potentially fathering hundreds of children.<sup>455</sup> A national donor database could set important limits on sperm donations and pregnancies per donor by utilizing nationwide tracking.<sup>456</sup>

Additionally, regulations could impose a continuing duty to warn on sperm donors and sperm banks, requiring the disclosure of genetic conditions discovered later in life.<sup>457</sup> In light of the possibility that an AID recipient may purchase and store numerous vials of donor sperm for future use,<sup>458</sup> a continuing duty to warn may prevent recipients from using stored sperm after the donor’s sperm has been found to carry a genetic defect.<sup>459</sup>

The establishment of a donor database and nationwide limitations on sperm donations could even serve to reduce the likelihood of genetic

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L. REV. 521, 531 (1974); see also Owen, *Moral Foundations*, *supra* note 41, at 429 (“[The] focus of modern products liability law expressly upon the products—both the one which caused the injury, and some hypothetical one of proper safety—thus tends to direct the liability issue into a barren, technologically based determination.”).

453. See *supra* notes 253–54 and accompanying text.

454. See *infra* notes 455–62 and accompanying text; see also Cahn, *Necessary Subjects*, *supra* note 261 (advocating the establishment of a mandatory national donor databank).

455. See *supra* note 10 and accompanying text; see also Cahn, *Accidental Incest*, *supra* note 234, at 60–61.

456. As evidenced by the case in Michigan in which five children with SCN were all treated by the same specialist, it is possible that AID offspring will meet their half-siblings. See *supra* notes 1–5 and accompanying text. In the event that even healthy half-siblings unknowingly procreate, their children could suffer significant health consequences as a result of inbreeding. Limitations on pregnancies per donor will reduce the possibility of this result.

457. A continuing duty to warn may assist in the prompt diagnosis of a condition in AID offspring and may even enable the offspring to make informed lifestyle decisions that can affect the progression of a condition, such as diabetes. See also *supra* note 312 and accompanying text (discussing late-onset genetic conditions, such as Huntington’s disease).

458. See *supra* note 361 and accompanying text.

459. See *supra* note 9 and accompanying text (recounting International Cryogenics’s reasoning for failing to notify other recipients of Donor F827’s sperm after it was discovered to carry the gene for SCN).

abnormalities in future generations. If a sperm donor's offspring discovers that he is a carrier of a genetic disease inherited from his father, other offspring who learn of the condition through the database may get tested or take other precautions to reduce the likelihood of passing that condition to their own children. Furthermore, nationwide donation limitations may also reduce the risk of "inadvertent inbreeding."<sup>460</sup>

Because current FDA regulations requiring that sperm be tested for communicable diseases have already imposed registration requirements, additional oversight for a donor database would not be impracticable:

The promulgation of FDA regulations has added considerable oversight to gamete and embryo donation, including mandatory registration of all assisted reproductive technology (ART) programs with the federal government, federal inspections of programs that are performing donation, required documentation, and written protocols attendant to donor screening, testing, selection, rejection, and follow-up. Complete records of all donor cycles, including documentation of adherence to FDA regulations, must be made available to FDA inspectors at their request.<sup>461</sup>

Sperm banks must already compile and maintain donor information to ensure that AID recipients are not harmed by the procedure.<sup>462</sup> A national databank that tracks donor pregnancies and donors' genetic conditions would further protect public health and safety by providing for the offspring produced through AID.<sup>463</sup>

Although some donor offspring registries already exist, they are insufficient because they do not uniformly track and maintain information related to donors' genetic conditions.<sup>464</sup> A mandatory national donor database is a necessary step in reducing the risk of transmitting genetic defects to children produced through AID.

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460. Cahn, *Accidental Incest*, *supra* note 234, at 59–60. Half-siblings who share a donor father could potentially meet and reproduce without knowledge of their relation—causing severe genetic abnormalities in their children. The likelihood of this possibility is higher in the absence of laws limiting the number of pregnancies per donor or requiring donor-tracking. See Vanessa L. Pi, Comment, *Regulating Sperm Donation: Why Requiring Exposed Donation is Not the Answer*, 16 DUKE J. GENDER L. & POL'Y 379, 381 (2009).

461. 2008 Guidelines, *supra* note 217, at S30.

462. See *supra* note 461 and accompanying text.

463. See *supra* notes 455–60 and accompanying text.

464. See, e.g., Braverman, *supra* note 234, at 486.

## V. CONCLUSION

AID offers infertile heterosexual couples, lesbian couples, and unmarried women the opportunity to realize the dream of a family.<sup>465</sup> While AID has gained acceptance and popularity as an alternative means of achieving conception, it has simultaneously raised novel legal issues that must be resolved to protect the health and safety of the resulting offspring.<sup>466</sup> Because, however, the sperm banking industry has remained enveloped in secrecy and anonymity, the field remains largely unregulated.<sup>467</sup> Although strict liability is neither appropriate nor effective as a mechanism for regulating AID, a shifted burden of proof in negligence actions can address proof problems without treating sellers of sperm as virtual insurers of human life.<sup>468</sup> Finally, the adoption of a national donor database can serve to address additional challenges associated with the practice of AID.<sup>469</sup>

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465. *See supra* notes 231–33 and accompanying text.

466. *See supra* notes 214–15 and accompanying text.

467. *See supra* note 236 and accompanying text.

468. *See supra* notes 422–52 and accompanying text.

469. *See supra* notes 454–64 and accompanying text.

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