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## Note

### **A Broken Theory: The Malfunction Theory of Strict Products Liability and the Need for a New Doctrine in the Field of Surgical Robotics**

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#### INTRODUCTION

In early October, Roland Mracek underwent a routine prostate biopsy,<sup>1</sup> which revealed that three out of six regions of his prostate were positive for adenocarcinoma.<sup>2</sup> Following his diagnosis, Roland consulted Dr. David McGinnis regarding his treatment options but expressed concerns about the possibility of developing erectile dysfunction<sup>3</sup> as a result of any treatment.<sup>4</sup> De-

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1. *Prostate Biopsy*, MAYO CLINIC (Nov. 10, 2018), <https://www.mayoclinic.org/tests-procedures/prostate-biopsy/about/pac-20384734> [<https://perma.cc/ZK3H-YASZ>] (defining a prostate biopsy as “a procedure to remove samples of suspicious tissue from the prostate”).

2. Brief for Appellant at 2, *Mracek v. Bryn Mawr Hosp.*, 363 F. App’x 925 (3d Cir. 2010) (No. 09-2042). See generally *Adenocarcinoma*, CANCER TREATMENT CTRS. AM., (Nov. 10, 2018), <https://www.cancercenter.com/terms/adenocarcinoma/> [<https://perma.cc/ZY4Z-HBTR>] (defining adenocarcinoma as a type of cancer that “forms in mucus-secreting glands throughout the body,” including prostate glands).

3. *Erectile Dysfunction*, MAYO CLINIC (Nov. 10, 2018), <https://www.mayoclinic.org/diseases-conditions/erectile-dysfunction/symptoms-causes/syc-20355776> [<https://perma.cc/MCN3-LC95>] (defining erectile dysfunction, or impotence, as the “inability to get and keep an erection firm enough for sex”).

4. Brief for Appellant, *supra* note 2, at 2.

spite Roland's concerns, Dr. McGinnis recommended that a radical prostatectomy<sup>5</sup> be performed using the daVinci surgical system,<sup>6</sup> a robotic technology that translates surgeons' hand movements into smaller, more precise movements.<sup>7</sup> After extensive independent research, Roland consented to the surgery believing that the robotic system would minimize post-operative risks, especially compared to traditional laparoscopic surgery.<sup>8</sup>

In June, Roland's prostatectomy was commenced using the daVinci system.<sup>9</sup> Part way through the surgery<sup>10</sup> the robot suddenly began displaying error messages.<sup>11</sup> The surgical team immediately restarted the system, but Dr. McGinnis was only able to operate briefly before the system again displayed error messages.<sup>12</sup> The surgical team called the daVinci manufacturer's support line and local daVinci representatives to assist in troubleshooting the system,<sup>13</sup> but despite several attempts to make

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5. *Radical Prostatectomy*, JOHNS HOPKINS MED. (Nov. 10, 2018), <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/radical-prostatectomy> [<https://perma.cc/MK8Z-UNDM>] (defining radical prostatectomy as "a surgical procedure for the partial or complete removal of the prostate").

6. See Brief for Appellant, *supra* note 2, at 3 (noting that the physician recommended the daVinci system in order to minimize the risk of developing post-operative erectile dysfunction).

7. See *Prostate Surgery*, INTUITIVE, (June 19, 2019) <https://www.davincisurgery.com/procedures/urology-surgery/prostatectomy> [<https://perma.cc/YDQ5-ZKMC>] (stating that the daVinci system allows surgeons to perform operations through small incisions and includes a magnified vision system that gives surgeons a three-dimensional view inside the patient's body).

8. Brief for Appellant, *supra* note 2, at 3; see *Prostate Surgery*, *supra* note 7 (noting that the daVinci Prostatectomy offers several benefits compared to traditional laparoscopy, including patients returning to pre-surgery erectile function more quickly, lower risk of complications, and shorter hospital stays). See generally *Prostatectomy*, MAYO CLINIC (2019), <https://www.mayoclinic.org/tests-procedures/prostatectomy/about/pac-20385198> [<https://perma.cc/V94H-YEE6>] (describing a laparoscopic prostatectomy as a surgical procedure where the surgeon makes several small incisions in the patient's abdomen and inserts special tools to remove the prostate).

9. Brief for Appellant, *supra* note 2, at 3.

10. *Id.* (noting that the surgeon was part way through taking the bladder down and dividing the urachus). See generally *Urachal Abnormalities*, UCSF DEPT UROLOGY (2019), <https://urology.ucsf.edu/patient-care/children/urachal-abnormalities> [<https://perma.cc/86YT-AKZ2>] (defining the urachus as "the remnant of a channel between the bladder and the . . . belly button").

11. Brief for Appellant, *supra* note 2, at 3.

12. *Id.*

13. *Id.* at 4.

the robot operational,<sup>14</sup> the robot ultimately completely failed to function.<sup>15</sup> The surgical team was forced to abandon the robotic surgery and completed the surgery using traditional laparoscopic equipment.<sup>16</sup> A week after the surgery was completed, Roland suffered a gross hematuria<sup>17</sup> in a public restroom.<sup>18</sup> He was helped to the hospital by his daughter and was readmitted for further hospitalization.<sup>19</sup> Roland now suffers from daily abdominal pain, which prevents him from sleeping through the night and sitting comfortably for extended periods of time.<sup>20</sup> Additionally, Roland now also suffers from total erectile dysfunction,<sup>21</sup> turning his pre-operative concerns into his post-operative reality.

Roland sued the daVinci manufacturer, Intuitive Surgical, Inc. (Intuitive), under, inter alia, the malfunction theory of strict products liability.<sup>22</sup> Under the malfunction theory, a plaintiff may present circumstantial evidence to raise a supportable inference of a product defect.<sup>23</sup> Such an inference is afforded upon satisfying the malfunction theory's three-pronged test, which requires providing evidence of a malfunction, evidence eliminating

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14. The surgical team attempted multiple times to reposition the robotic arms, undock the robot from its trocars, and undock and restart the system and the surgeon attempted to manually position the robot's camera to use it while he performed the remainder of the surgery laparoscopically; however, the system remained nonoperational. *See id.*

15. *Id.*

16. *See id.* (noting that by the time the robotic surgery was abandoned and the laparoscopic equipment was brought in and utilized, nearly forty-five minutes had elapsed).

17. *See Blood in Urine (Hematuria)*, MAYO CLINIC (2019), <https://www.mayoclinic.org/diseases-conditions/blood-in-urine/symptoms-causes/syc-20353432> [<https://perma.cc/4ZVP-W49X>] (defining a gross hematuria as blood that is visible in a person's urine).

18. Brief for Appellant, *supra* note 2, at 4.

19. *See id.* at 5 (noting that the man's gross hematuria also required irrigation of his bladder). *See generally Management of Clot Retention Following Urological Surgery*, NURSINGTIMES, <https://www.nursingtimes.net/archive/management-of-clot-retention-following-urological-surgery-09-07-2002> [<https://perma.cc/MA82-TZH6>] (defining bladder irrigation as "a procedure in which sterile fluid is used to prevent clot retention by continuously irrigating the bladder," and noting that it is generally necessary when glands and organs bleed during postoperative periods).

20. Brief for Appellant, *supra* note 2, at 5.

21. *Id.*

22. *Mracek*, 610 F. Supp. 2d at 403.

23. *Id.*

abnormal use, and reasonable secondary causes of the malfunction.<sup>24</sup> The court relied on Intuitive's assertion that "[t]he use and timing of various ancillary medical equipment in connection with th[e] innovative and complex procedure reinforces that any number of reasonable secondary causes could or were responsible for the alleged damages," and stated that Roland failed to offer evidence to eliminate reasonable secondary causes of the malfunction.<sup>25</sup> As a result, the court concluded that Roland failed to meet the burden necessary to survive a motion for summary judgment and granted summary judgment for Intuitive.<sup>26</sup>

This Note explores the boundaries of products liability law in the field of robotics, specifically the application of the malfunction theory of products liability to surgical robots. Looking at the technological complexities of robotics in the modern digital age, the frequency of human-robot interactions, and the underlying policy concerns surrounding products liability law, this Note argues that a new approach to the malfunction theory should be adopted to better address the advent of robotics in modern society. Part I explores the history of products liability and the development of strict products liability, discusses the advent of the malfunction theory of products liability in response to technological advances, and highlights the significant advances in the field of robotics over the past several decades. Part II explores the current legal landscape surrounding the malfunction theory and frames its application to the medical device field. Part III revisits the three-pronged malfunction theory test, and purports that although the court in *Mracek v. Bryn Mawr Hospital*<sup>27</sup> applied a legal standard that aligns with existing malfunction theory jurisprudence, a new standard is needed in the field of surgical robotics. Ultimately, this Note proposes that, in applying the malfunction theory of products liability to surgical robotics, state courts should infer a product defect from the occurrence of a malfunction in the absence of abnormal use, and raise a rebuttable presumption that there were no reasonable secondary causes of the malfunction.

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24. *Id.*

25. *Id.*

26. *Id.*

27. 363 F. App'x 925 (3d Cir. 2010) (No. 09-2042).

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I. TRACING THE DEVELOPMENT OF THE  
MALFUNCTION THEORY OF PRODUCTS LIABILITY AND  
ITS RELEVANCE IN THE MODERN DIGITAL AGE

Products liability law has developed over several centuries.<sup>28</sup> Initially, courts and legislators spurned claims against manufacturers out of an underlying desire to encourage economic growth.<sup>29</sup> However, with the coming of age of the U.S. industrial system, courts began to take notice of consumers' naiveté concerning the safety of the products they purchased.<sup>30</sup> As a result, over the past century courts and legislators have developed a body of law surrounding products liability that centers around balancing consumer safety and economic growth. This Part begins with Section A, which explores the history of products liability and the development of the strict products liability doctrine. Then, Section B discusses the emergence of demonstrating product defects through circumstantial evidence and the advent of the malfunction theory in response to technological advances. Finally, Section C outlines the history of robotics, its evolution into modern society, and the extent to which robotics are used in surgical applications.

A. THE HISTORY OF PRODUCTS LIABILITY AND THE  
DEVELOPMENT OF THE MODERN STRICT PRODUCTS LIABILITY  
DOCTRINE

The foundational principles surrounding products liability law consist of a mixture of contract law and tort law, which have developed over several centuries.<sup>31</sup> Because products liability is hybrid in nature, it is important to appreciate how technological advances over the past century have influenced this area of law,

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28. *Product Liability Law: Some Legal Background*, FINDLAW (2019), <https://injury.findlaw.com/product-liability/product-liability-background.html> [<https://perma.cc/BT2T-S4KC>].

29. Solly Robins, *Products Liability Cases*, 12 AM. JUR. TRIALS 1, 6 (2019) (noting that historically, "claims against manufacturers were denied on the basis of a wide range of theories, including caveat emptor, lack of privity, contributory negligence," and other defenses that "fitted the peculiar facts and circumstances").

30. See *infra* Parts I.A.2–3.

31. *Product Liability Law: Some Legal Background*, *supra* note 28 (noting that aspects of product liability law relating to tort law include strict liability, negligence, and deceit, and aspects relating to contract law include privity of contract and implied warranties).

and how the growth of robotics in today's digital age has inevitably impacted the current legal landscape.

1. Caveat Emptor, Implied Warranties, and the General Rule of Privity

The origins of products liability law trace back to English courts in the early 1600s.<sup>32</sup> Rooted in contract law, English courts established the doctrine of caveat emptor, Latin for “let the buyer beware.”<sup>33</sup> Under this doctrine, a vendor had no duty to communicate latent defects “in his wares,” unless the vendor represented that no defect existed.<sup>34</sup> As a result, English courts consistently held that buyers were expected to protect themselves from both obvious and hidden defects in the products they purchased,<sup>35</sup> which led to centuries of decisions that strongly favored product manufacturers.<sup>36</sup>

Over time, English courts exhibited a modest shift toward consumer safety and gradually reduced the burden placed on consumers by recognizing what are now known as implied warranties.<sup>37</sup> In products liability cases, English courts recognized

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32. See generally DENIS W. STEARNS, *PRODUCT LIABILITY: A BRIEF HISTORY OF ITS EARLY ORIGINS* (2005), <https://marlerclark.com/pdfs/product-liability-history.pdf> [<https://perma.cc/WS5F-7GCL>] (noting that products liability law traces back to ancient Rome and that the modern framework evolved from contract law).

33. See *Caveat emptor*, BLACK'S LAW DICTIONARY (11th ed. 2019) (noting that under the doctrine, a purchaser buys at his or her own risk).

34. WILLIAM R. ANSON, *PRINCIPLES OF THE LAW OF CONTRACT* 245 (Arthur L. Corbin ed., 3d Am. Ed. 1919).

35. *Product Liability Law: Some Legal Background*, *supra* note 28; see *Caveat Emptor*, WEXOLOGY/CORNELL L. SCH., [https://www.law.cornell.edu/wex/caveat\\_emptor](https://www.law.cornell.edu/wex/caveat_emptor) [<https://perma.cc/6QVY-DEX4>] (noting caveat emptor places the burden on buyers to “examine property” before purchasing, and to “take responsibility for its condition”).

36. Stearns, *supra* note 32; see *Chandelor v. Lopus* [1603] 79 Eng. Rep. 3 (holding that a goldsmith, with special knowledge of stones, was not liable for selling a “bezoar” stone that in fact possessed no healing powers because the quality of the stone was a risk the buyer assumed).

37. See *Implied Warranty*, BLACK'S LAW DICTIONARY (11th ed. 2019) (defining implied warranty as “[a]n obligation imposed by law when there has been no representation or promise,” which arises “because of the circumstances of a sale, rather than by the seller’s express promise”); see also *Crosse v. Gardner* [1688] 90 Eng. Rep. 656 (holding that although the defendant was not the true owner of an oxen, and the plaintiff had failed to allege a warranty, a warranty of title could be inferred from the defendant’s affirmation that he was entitled to sell the chattel).

implied warranties of merchantability<sup>38</sup> and held that sellers were presumed to implicitly warrant that the products they sold did not contain any hidden defects.<sup>39</sup> Despite this shift in English courts, U.S. courts continued to employ the doctrine of *caveat emptor* for most of the nineteenth century.<sup>40</sup>

By the late 1800s, U.S. courts had gradually begun to recognize implied warranties in products liability cases,<sup>41</sup> but compared to English courts, this shift was considerably limited.<sup>42</sup> Most notably, courts in the United States required end users<sup>43</sup> to have privity of contract<sup>44</sup> with the seller in order to bring suit.<sup>45</sup> Rooted in the English case *Winterbottom v. Wright*,<sup>46</sup> the

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38. *Implied Warranty of Merchantability*, BLACK'S LAW DICTIONARY (11th ed. 2019) (defining an implied warranty of merchantability as a "merchant seller's warranty—implied by law—that the thing sold is fit for its ordinary purposes").

39. *Product Liability Law: Some Legal Background*, *supra* note 28; see *Gardiner v. Gray* (1815) 171 Eng. Rep. 46 (stating a purchaser had a right to inspect silk "answering the description in the contract" because even without a warranty "there is an implied term in every such contract," and that when "there is no opportunity to inspect the commodity . . . *caveat emptor* does not apply").

40. *Product Liability Law: Some Legal Background*, *supra* note 28; see *Seixas v. Wood*, 2 Cai. 48 (N.Y. Sup. Ct. 1804) (holding that a merchant that inadvertently sold peachum wood, which was advertised as braziletto wood, was not liable because the purchaser had a duty to inspect the goods); see also *Laidlaw v. Organ*, 15 U.S. (2 Wheat.) 178, 194 (1817) (holding a tobacco purchaser was not required to communicate information regarding a peace treaty that would increase the price of tobacco because "[i]t would be difficult to circumscribe the contrary doctrine within proper limits").

41. See *Hawkins v. Pemberton*, 51 N.Y. 198, 202 (1872) (holding a merchant that resold bottles labeled "blue vitriol," which were in fact of inferior quality, liable despite the lack of an express warranty because if "the representation as to the character and quality of the article sold be positive . . . and the vendee understand[s] it as a warranty . . . the vendor is bound").

42. *Product Liability Law: Some Legal Background*, *supra* note 28.

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

44. *Privity*, BLACK'S LAW DICTIONARY (11th ed. 2019) (defining privity as "the relationship between two parties, each having a legally recognized interest in the same subject matter").

45. *Product Liability Law: Some Legal Background*, *supra* note 28; see also *infra* note 48 and accompanying text.

46. See *Winterbottom v. Wright* (1842) 152 Eng. Rep. 402 (holding that since a mail delivery driver lacked privity of contract with a coach manufacturer, the driver could not sue based on a contract made between the manufacturer and Postmaster-General). The court reasoned that "there [was] no privity of contract between [the] parties; and if the [delivery driver could] sue, every passenger, or even any person passing along the road, who was injured . . . might bring a similar action." *Id.* at 405.

privity requirement mandated that consumers and sellers have a legally cognizable interest in the same transaction.<sup>47</sup> As a result, U.S. courts consistently required that consumers purchased a product directly from a vender to recover for a product's defect.<sup>48</sup> Accordingly, as industries developed and manufacturers relied more heavily on intermediary retailers, U.S. courtrooms remained closed and consumers were unable to recover due to lack of privity.<sup>49</sup>

## 2. Opening the Courtroom Through Exceptions and *MacPherson*

In the decades that followed *Winterbottom*, U.S. courts slowly began to recognize exceptions to the general rule of privity.<sup>50</sup> Initially, courts granted exceptions in cases involving products that were imminently or inherently dangerous.<sup>51</sup> Then, courts recognized exceptions in cases where sellers knew that a

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47. *Privity*, *supra* note 44.

48. *Product Liability Law: Some Legal Background*, *supra* note 28; *see* *Sav. Bank v. Ward*, 100 U.S. 195 (1879) (holding that an attorney who reported on a land title was not liable to a third party that relied on such report because the parties lacked privity of contract); *see also* *Houseman v. Girard Mut. Bldg. & Loan Ass'n*, 81 Pa. 256 (1876) (holding the recorder of deeds is liable only to the party that asks and pays for certificates, not subsequent alienees).

49. *Product Liability Law: Some Legal Background*, *supra* note 28; *see* *Galbraith v. Ill. Steel Co.*, 133 F. 485, 486 (7th Cir. 1904) (holding that a building owner that contracted with a sprinkler company could not recover from a sub-contracted engineering company for damages arising out of the collapse of a water tank because, *inter alia*, the owner and engineering company lacked privity of contract).

50. Kyle Graham, *Strict Products Liability at 50: Four Histories*, 98 MARQ. L. REV. 555, 564 (2014).

51. *See* *Huset v. J.I. Case Threshing Mach. Co.*, 120 F. 865, 866 (8th Cir. 1903) (holding that the manufacturer of a grain threshing rig, which contained a pliable sheet over a self-feeding band cutter, liable to a user that lost his leg after stepping on the pliable sheet). The court reasoned that the manufacturer of a machine known "to be imminently dangerous . . . to any one [sic] who shall use it for the purpose for which it was made and intended, [is] liable." *Id.* at 866; *see also* *Thomas v. Winchester*, 6 N.Y. 397, 397 (1852) (holding a drug and medicine manufacturer liable for allowing a deadly poison, which was erroneously labeled as a harmless medicine, to reach the market). *Thomas* indicated that deadly poisons are inherently dangerous, and noted that the rule in *Winterbottom* is inappropriate where the inherently dangerous nature of the product involved makes "death or great bodily harm of some person . . . the natural and almost inevitable consequence of the sale." *Thomas*, 6 N.Y. at 409.



product was inherently dangerous, but failed to disclose the danger to the unknowing buyer.<sup>52</sup> Ultimately, these exceptional cases set the stage for the decision in *MacPherson v. Buick Motor Co.*,<sup>53</sup> which drastically changed the scope of products liability law.

*MacPherson* involved an automobile that suddenly “collapsed”<sup>54</sup> and injured the automobile owner.<sup>55</sup> The owner attributed the accident to a defective wheel supplied by a components manufacturer, which was integrated into the finished vehicle by Buick.<sup>56</sup> Since the automobile was purchased from an intermediary, Buick disclaimed liability due to lack of privity of contract with the owner.<sup>57</sup> In a divergence from its jurisprudential framework, the court held that the lack of privity did not protect Buick from liability.<sup>58</sup> The court drew on the “inherent danger” exception, and expanded it so as to essentially swallow the general rule of privity.<sup>59</sup> The court stated that the inherent danger exception “is not limited to poisons, explosives, and things of like nature . . . [If] the thing is such that it is reasonably certain to place life and limb in peril when negligently made, it is then a thing of danger.”<sup>60</sup> Ultimately, this watershed decision effectively swept the doctrine of privity aside,<sup>61</sup> and

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52. See *Lewis v. Terry*, 43 P. 398 (Cal. 1896) (holding a vendor with knowledge of defects in a folding bed liable to a purchaser that suffered injuries resulting from the bed collapsing); see also *Kuelling v. Roderick Lean Mfg. Co.*, 75 N.E. 1098 (N.Y. 1905) (holding the manufacturer of a road roller that concealed defects in the tongue attachment liable to a purchaser that was run over by the roller after the tongue attachment broke away from his team of horses).

53. 111 N.E. 1050 (N.Y. 1916).

54. *Id.* at 1052 (noting that one of the wheels was made of defective wood, and its spokes crumbled causing the owner to be thrown from the vehicle).

55. *Id.*

56. *Id.* at 1051.

57. *Id.*

58. See *id.* at 1054 (noting that “there is nothing anomalous in a rule which imposes upon A, who has contracted with B, a duty to C and D and others according as he knows or does not know that the subject-matter of the contract is intended for their use”).

59. See *id.* at 1053 (stating that “[b]eyond all question, the nature of an automobile gives warning of probable danger if its construction is defective . . . unless wheels are sound and strong, injury was almost certain. It was as much a thing of danger as a defective engine for a railroad”).

60. *Id.*

61. See *Carter v. Yardley & Co.*, 64 N.E.2d 693, 700 (Mass. 1946) (stating that the doctrine of the *MacPherson* case was then generally accepted); see also

opened the courtroom to anyone that was foreseeably expected to suffer an injury as a result of a defective product.

### 3. Modern Products Liability and the Development of Strict Products Liability in Tort

Throughout the 1900s, the rise of mass production, the introduction of wholesale intermediaries into supply chains, and the expansion of product advertising placed a physical distance between the makers and users of many products.<sup>62</sup> Recognizing this, courts gradually adopted more plaintiff-friendly attitudes toward products liability cases,<sup>63</sup> though, much of courts' doctrinal analysis remained rooted in contract law and theories of implied warranties.<sup>64</sup>

After *MacPherson*, the legal community largely believed that negligence law could not adequately address all of the problems posed by defective products in the evolving industrial age.<sup>65</sup> Most notably, William Prosser, a leading twentieth century tort law scholar, believed that there was "an increased feeling that social policy demands that . . . [a] consumer [be] entitled to maximum protection at the hands of some one . . . and that the producer, practically and morally, [was] the one to provide it."<sup>66</sup> As a result, Prosser proposed the idea of imposing strict liability in tort law on manufacturers.<sup>67</sup> Judges first supported Prosser's idea of imposing strict products liability in tort law in 1944;<sup>68</sup>

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*id.* (supporting such assertion by citing to the American Law Institute's RESTATEMENT (FIRST) OF TORTS §§ 394–402 (AM. LAW INST. 1934); and several other treatises on tort law, including FOWLER HARPER, TREATISE ON THE LAW OF TORT (1933); WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORT (1941); P.H. WINFIELD, A TEXT-BOOK ON THE LAW OF TORTS (1937)).

62. See Graham, *supra* note 50, at 565 (describing the shifts in the market for consumer goods over the course of the late 1800s and early 1900s).

63. See *id.* at 567 (noting an upswell of products liability cases in the 1960s).

64. *Id.*

65. *Id.* at 568.

66. PROSSER, *supra* note 61, at 689; see also Graham, *supra* note 50, at 569 (stating that there is "an increased feeling that social policy demands that the burden of accidental injuries caused by defective chattels be placed upon the producer").

67. PROSSER, *supra* note 61, at 689.

68. Graham, *supra* note 50, at 568; see *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 440 (Cal. 1944) (Traynor, J., concurring) (stating it should be "recognized that a manufacturer incurs an absolute liability when the article that he has placed on the market, knowing that it is to be used without inspection,

however, it was not until 1963 that courts' views on products liability reform shifted from warranty protections to "pure" tort law.<sup>69</sup> Then in 1964, Prosser tendered to the American Law Institute (ALI)<sup>70</sup> a provision that allowed the ultimate user or consumer to proceed in tort, on a strict liability basis, against the seller of any product in a defective condition.<sup>71</sup> The ALI approved of Prosser's work, and in 1965 published § 402A of *Restatement (Second) of Torts*.<sup>72</sup> In the years that followed, courts and legislators rushed to adopt a tort-based theory of products liability,<sup>73</sup> and by 1976 forty-two states had adopted strict liability in tort.<sup>74</sup>

Since the mid-1970s, § 402A of *Restatement (Second) of Torts* has defined American products liability law.<sup>75</sup> Under

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proves to have a defect that causes injury to human beings").

69. Graham, *supra* note 50, at 576. See generally *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 900 (Cal. 1963) (supporting the idea that a manufacturer can be strictly liable in tort). The court stated that "[a] manufacturer is strictly liable in tort when an article 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." *Id.* at 900. The court reasoned that tort, rather than warranty, was the optimal doctrinal solution to the problems presented by defective products. *Id.* at 901.

70. See *About ALI*, AM. LAW INST. (2019), <https://www.ali.org/about-ali/> [<https://perma.cc/D86L-H296>] (noting that the American Law Institute is the leading independent organization in the United States that produces scholarly work to clarify, modernize, and improve the law, including Restatements of the Law, Model Codes, and Principles of Law).

71. Graham, *supra* note 50, at 577.

72. See RESTATEMENT (SECOND) OF TORTS § 402A (AM. LAW INST. 1965) ("(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. 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.").

73. See Graham, *supra* note 50, at 578 n.161 (outlining the jurisdictions that adopted strict liability in tort through either judicial decision or legislative acts).

74. See generally *id.* at 579 (noting that today only Delaware, Massachusetts, Michigan, North Carolina, and Virginia have not adopted strict liability in tort, and continue to couch their consumer protection laws in warranty doctrines).

75. Michael J. Töke, *Restatement (Third) of Torts and Design Defectiveness in American Products Liability Law*, 5 CORNELL J.L. & PUB. POL'Y 239, 239 (1996).

§ 402A, a manufacturer that “sells any product in a defective condition unreasonably dangerous to the user or consumer” is liable for the physical harm caused if “the seller is engaged in the business of selling such a product” and the product is “expected to and does reach the user or consumer.”<sup>76</sup> The comments to § 402A clarify that “user” is meant to include those that are “passively enjoying the benefit of the product.”<sup>77</sup> Courts have also construed the term “consumer or user” broadly to provide protection to purchasers as well as non-purchasing users or consumers.<sup>78</sup> Moreover, in furtherance of predominant equitable considerations,<sup>79</sup> courts have historically held that third-party bystanders that are foreseeably expected to “come within the range of danger” of a defective product are entitled to greater protection under § 402A.<sup>80</sup> Although the comments to and courts’ interpretations of § 402A suggest a theoretically broad class of plaintiffs, additional comments to § 402A have drastically circumscribed the utility of the modern strict products liability doctrine. Most notably, comments advise that § 402A should only apply “where the product is, at the time it leaves the sellers hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous,” and that “[t]he burden of proof that the product was in a defective condition at the time that it left the hands of the particular seller is upon the

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

77. *See id.* § 402A cmt.1 (illustrating that “those who are passively enjoying the benefit of the product” includes passengers in automobiles or airplanes).

78. STUART M. SPEISER ET AL., AMERICAN LAW OF TORTS § 18:136 (2019).

79. *Id.* (noting previous sources that held that bystanders are entitled to greater protection than consumers or users because the consumers and users have at least the opportunity to inspect for defects and to limit their purchases to articles that are manufactured by reputable manufactures and sold by reputable dealers, whereas a bystander ordinarily has no such opportunities); *see also* *Elmore v. Am. Motors Corp.*, 451 P.2d 84, 89 (Cal. 1969) (stating that “if any distinction should be made between bystanders and users, it should be made . . . to extend greater liability in favor of the bystanders”); *Darryl v. Ford Motor Co.*, 440 S.W.2d 630, 633 (Tex. 1969) (stating that “[t]here is no adequate rationale or theoretical explanation why non-users and non-consumers should be denied recovery against the manufacturer of a defective product,” and that “[t]he reason for extending the strict liability doctrine to innocent bystanders is the desire to minimize risks of personal injury and/or property damage”).

80. SPEISER, *supra* note 78. *See generally* *Horst v. Deere & Co.*, 769 N.W.2d 536 (Wis. 2009) (allowing an infant’s guardian ad litem to bring a strict products liability action against the manufacturer of a riding lawn mower after the infant’s feet were cut off by the lawn mower being operated in reverse by the infant’s father).

injured plaintiff.”<sup>81</sup> As a result, over the past fifty years the plaintiff’s burden of demonstrating that a “product was in a defective condition at the time it left the hands of the particular seller”<sup>82</sup> has significantly limited the utility of strict products liability, specifically in cases involving remote or third-party bystander plaintiffs, and cases containing evidentiary questions surrounding whether a product defect was attributable to the manufacturer, improper maintenance by the user, a party’s negligence, and/or simply the result of an accident.

B. THE USE OF CIRCUMSTANTIAL EVIDENCE IN STRICT PRODUCTS LIABILITY CASES AND THE ADVENT OF THE MALFUNCTION THEORY OF PRODUCTS LIABILITY

Courts have consistently held that in order for users to prevail on a strict products liability claim the user must prove “that a product was defective, that the product contained the defect when it left the defendant’s control, and that the defect proximately caused the plaintiff harm.”<sup>83</sup> Sometimes, consumers can offer direct evidence that identifies a specific product defect;<sup>84</sup> however, other times users are unable to point to a specific defect, either because the product no longer exists, the defect cannot be precisely identified,<sup>85</sup> or the injured plaintiff is far too removed from the product so as to opine to the specific defect.<sup>86</sup> As a result, courts have developed alternative ways for consumers and remote users to bring products liability claims, despite lacking direct evidence of a defect.<sup>87</sup>

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81. RESTATEMENT (SECOND) OF TORTS § 402A cmt.g.

82. *Id.*

83. Ashley Menage, *When Products Self-Destruct: Making the Case for the Product-Less Plaintiff Using Res Ipsa Loquitur, the Malfunction Doctrine, and § 3*, 56 S. TEX. L. REV. 349, 357 (2014) (quoting *Fallon v. Matworks*, 918 A.2d 1067, 1075 (Conn. Super. Ct. 2007)).

84. *See id.* at 357 (stating that consumers can identify a specific defect either by providing the product itself for examination or through expert testimony).

85. Bruce H. Raymond & Lanell H. Allen, *Malfunction Theory as a Triple Threat for the Defense*, 80 DEF. COUNS. J. 297, 298 (2013).

86. *Cf. Wentworth v. Kawasaki, Inc.*, 508 F. Supp. 1114 (D.N.H. 1981) (holding that although the driver did not own nor know about the safety and maintenance of his friend’s snowmobile, the injured driver could proceed on a strict products liability claim).

87. *See, e.g., Welge v. Planters Lifesavers Co.*, 17 F.3d 209, 211 (7th Cir. 1994) (reversing grant of summary judgment for defendant despite the plaintiff

### 1. Proving Product Defects Through Circumstantial Evidence

Over the past century, U.S. courts have allowed plaintiffs to use circumstantial evidence surrounding an injury to support their products liability claims.<sup>88</sup> This approach stems from the negligence doctrine of *res ipsa loquitur*, Latin for “the thing speaks for itself,”<sup>89</sup> under which a plaintiff is afforded a strong inference of a manufacturer’s negligence without the need to identify any particular misconduct.<sup>90</sup> Today, *res ipsa loquitur* is recognized in *Restatement (Second) of Torts* § 328D<sup>91</sup> and has been adopted in one form or another in a majority of states; however, many states expressly reject its application to strict products liability cases.<sup>92</sup>

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being unable to prove a specific defect that caused a jar of peanut butter to shatter when replacing the cap); Raymond & Allen, *supra* note 85, at 298. *See generally* Liberty Mut. Co. v. Sears, Roebuck & Co., 406 A.2d 1254 (Conn. Super. Ct. 1979) (permitting the jury to rely on circumstantial evidence surrounding a fire that was caused by a television that erupted into flames during normal use).

88. Menage, *supra* note 83, at 362.

89. *Res Ipsa Loquitur*, BLACK’S LAW DICTIONARY (11th ed. 2019).

90. Menage, *supra* note 83, at 352; *see also* Escola v. Coca Cola Bottling Co., 150 P.2d 436, 439 (Cal. 1944) (allowing *res ipsa loquitur* to supply an inference that Coca Cola’s negligence was responsible for a bottle exploding in the waitress’s hand). *See generally* Byrne v. Boadle (1863) 159 Eng. Rep. 299 (holding a building owner liable for a barrel that fell from a window and injured a pedestrian, despite no evidence of the building owner’s negligence). The court stated, “[t]here are certain cases of which it may be said *res ipsa loquitur* . . . A barrel could not roll out of a warehouse without some negligence, and to say that a plaintiff who is injured by it must call witnesses from the warehouse to prove negligence seems . . . preposterous.” *Id.* at 300–01.

91. *See* RESTATEMENT (SECOND) OF TORTS § 328D (AM. LAW INST. 1965) (“It may be inferred that harm suffered by the plaintiff is caused by negligence of the defendant when (a) the event is of a kind which ordinarily does not occur in the absence of negligence; (b) other responsible causes, including the conduct of the plaintiff and third persons are sufficiently eliminated by the evidence; and (c) the indicated negligence is within the scope of the defendant’s duty to the plaintiff.”).

92. Menage, *supra* note 83, at 366–67. Although the justifications for rejecting *res ipsa* vary, the common theme appears to be that courts are unwilling to apply a negligence doctrine to a concept that, by definition, does not require a plaintiff to prove negligence. *Id.* *See also generally* Barrett v. Atlas Powder Co., 150 Cal. Rptr. 339 (Cal. Ct. App. 1978) (stating that the doctrine of *res ipsa loquitur* is not applicable in any action predicated upon the theory of strict liability); Eisenmenger v. Ethicon, Inc., 871 P.2d 1313, 1317 (Mont. 1994) (stating that the theory of *res ipsa loquitur* is not applicable in products liability cases under a strict liability theory).

The ALI appeared to recognize the issues surrounding the application of *res ipsa loquitur* to strict products liability cases, stating that although indeterminate product defect cases represent “a small number of cases, they are an important number of cases, and as a matter of fairness they must be able to be preserved because of the inherent destructibility of some products.”<sup>93</sup> As a result, the ALI published § 3: Circumstantial Evidence Supporting Inference of Product Defect in *Restatement (Third) of Torts: Products Liability*.<sup>94</sup>

Despite the apparent similarities between § 328D of *Restatement (Second) of Torts* and § 3 of *Restatement (Third) of Torts*, the distinctions between the two have had significant impact on the use of circumstantial evidence in complex products liability cases. For example, although § 3 defines the “incident that harmed the plaintiff” more broadly than § 328D, including all incidents that “ordinarily occur as a result of [a] product defect,”<sup>95</sup> § 3 imposes a more demanding standard on the elimination of alternative causes, requiring proof that the incident was not “solely the result of causes other than [a] product defect existing at the time of sale.”<sup>96</sup> And although § 3’s commentary suggests that courts should apply their traditional frameworks in evaluating the elimination of reasonable secondary causes,<sup>97</sup>

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93. *Thursday Morning Session – May 18, 1995*, 72 A.L.I. PROC. 239, 240 (1995).

94. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 3 (“It may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the incident that harmed the plaintiff: (a) was of a kind that ordinarily occurs as a result of product defect; and (b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution.”).

95. Compare *id.* (defining “incident that harmed the plaintiff” to include incidents that “ordinarily occur as a result of [a] product defect”), with RESTATEMENT (SECOND) OF TORTS § 328D (AM. LAW INST. 1965) (requiring that the incident be of the kind that “would not have occurred in the absence of a [product] defect”).

96. Compare RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 3 (requiring that the incident was not “solely the result of causes other than product defect existing at the time of sale or distribution”), with RESTATEMENT (SECOND) OF TORTS § 328D (requiring only that other reasonable causes “are sufficiently eliminated by the evidence”).

97. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 3, reporters’ note to cmt.d. *But see infra* Part II.A (describing the modern trend toward a more nuanced approach to the malfunction theory of products liability).

some courts have interpreted § 3's commentary more strictly, requiring evidence that eliminates improper maintenance or repair, or negligence by the user or third-parties, as a potential cause of the product defect.<sup>98</sup> As a result, the utility of circumstantial evidence has proven to be vastly different, depending on the jurisdiction, industry, and factual scenario of each case.<sup>99</sup>

## 2. The Advent of the Malfunction Theory of Products Liability

Despite courts' historic rejection of *res ipsa loquitur* to products liability cases, over the past fifty years a vast body of case law has developed that affords consumers an inference of a product defect through circumstantial evidence. One theory that courts have accepted is the malfunction theory of products liability.<sup>100</sup> Under the malfunction theory, a plaintiff may establish a *prima facie* case by providing evidence of the nature of a product's malfunction, under circumstances that give rise to an inference that the malfunction would not have occurred absent a defect existing at the time of sale.<sup>101</sup> Courts have articulated the malfunction theory's three-pronged test as permitting a plaintiff to prove a product defect with "evidence of the occurrence of a malfunction and with evidence eliminating abnormal use [and] reasonable, secondary causes for the malfunction."<sup>102</sup> As a result, a plaintiff is relieved of "demonstrating precisely the defect yet it permits the trier-of-fact to infer one existed from the evidence

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98. See *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 602 (Tex. 2004) (stating that "a product defect cannot be inferred without proof of a specific defect because of a product's age or the presence of modifications or repairs").

99. See *infra* Part II.A.

100. See Phillip Earl Wilson Jr., *Doctrinal Malfunction: Spoliation and Products Liability Law in Pennsylvania*, 69 TEMP. L. REV. 899, 904 (1996) (noting that the malfunction theory has its origins in Pennsylvania case law and encompasses nothing more than circumstantial evidence of product malfunction); see also *Rogers v. Johnson & Johnson Prods., Inc.*, 565 A.2d 751, 753-54 (Pa. 1989) (accepting the malfunction theory of products liability). See generally *Gordner v. Dynetics Corp.*, 862 F. Supp. 1303, 1305 (M.D. Pa. 1994) (citing *Rogers* and permitting a worker to use circumstantial evidence to maintain an action against an industrial machine manufacturer under the malfunction theory); *Schlier v. Milwaukee Elec. Tool Corp.*, 835 F. Supp. 839, 841 (E.D. Pa. 1993) (citing *Rogers* and permitting a plaintiff to maintain an action under the malfunction theory of strict products liability, so long as the plaintiff shows a malfunction free of secondary causes).

101. *Raymond & Allen*, *supra* note 85, at 298.

102. *Rogers*, 565 A.2d at 754; *Schlier*, 835 F. Supp. at 841 (quoting *Rogers*); *Gordner*, 862 F. Supp. at 1305 (quoting *Rogers*).



of the malfunction, of the absence of abnormal use and of the absence of reasonable, secondary causes.”<sup>103</sup>

It is important to recognize that although the prevailing articulation of the malfunction theory, in large part, tracks the language of § 3 of *Restatement (Third) of Torts: Products Liability*, much of the doctrine’s developments occurred prior to § 3’s publication.<sup>104</sup> Accordingly, a substantial portion of the malfunction theory’s framework was influenced by *Restatement (Second) of Torts*, and the *res ipsa loquitur* approach of § 328D.<sup>105</sup> And in response to enormous technological advances over the past several decades, courts have attempted to balance changes in doctrinal frameworks, the applicability of existing products liability concepts, and underlying policy concerns. Advances in robotic technologies continue to be implemented into practice, and the following Section foreshadows that the legal field will inescapably be challenged to balance the efficacy of existing products liability doctrines in complex robotics cases involving remote plaintiffs, with the underlying social concerns arising from the dangers posed by robotics in today’s digital age.<sup>106</sup>

### C. THE ADVENT OF ROBOTICS IN THE MODERN DIGITAL AGE

The Industrial Revolution presented a conundrum: machines provided sprawling social and industrial benefits, but radically changed the United States’ socioeconomic makeup and drastically altered the way people lived and worked.<sup>107</sup> Analogously, the development of the microprocessor<sup>108</sup> has thrust society into a “second Industrial Revolution,” presenting a similar

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103. *Rogers*, 565 A.2d at 754.

104. For examples of the limited cases that cite the malfunction theory of strict products liability prior to § 3’s publication in 1996, see *Wasson v. HRI Liquidating Corp.*, No. CIV. A. 92-3053, 1995 WL 130652 (E.D. Pa. Mar. 17, 1995); *Gordner*, 862 F. Supp. at 1303; *Schwartz v. Subaru of Am., Inc.*, 851 F. Supp. 191 (E.D. Pa. 1994); *Schlier*, 835 F. Supp. at 839; *Rogers*, 565 A.2d at 754.

105. See, e.g., *Rogers*, 565 A.2d at 755 (Flaherty, J., dissenting) (arguing that the majority’s approach to the malfunction theory “could be said to be a *res ipsa loquitur* approach”).

106. See *infra* Part II.A.

107. See Debra J. Zidich, *Robotics in the Workplace: The Employer’s Duty To Bargain over Its Implementation and Effect on the Worker*, 24 SANTA CLARA L. REV. 917, 919 (1984) (stating the industrial revolution marked humans’ first love/hate relationship with machines).

108. See generally *Microprocessor*, TECHOPEDIA, (Jan. 5, 2019), <https://www.techopedia.com/definition/2874/microprocessor> [perma.cc/26QT-P2V2] (describing a microprocessor as the central unit of a computer that executes logical

conundrum: computers have positively impacted societal standards but pose significant risks to consumer safety and security.<sup>109</sup> As the following discussion reveals, the technological developments of the “second Industrial Revolution” have on the one hand significantly transformed today’s society, but on the other give rise to a multitude of complex legal issues in products liability law.

### 1. The History of Robotics and Its Evolution in Modern Society

Although the concept of robotics can be traced back to Greek philosophers,<sup>110</sup> robots initially entered the popular consciousness in the early 1900s through literary works.<sup>111</sup> However, technological inadequacies of the twentieth century prevented robots from being anything more than science fiction until the mid-1900s.<sup>112</sup> It was not until 1954 that George Devol designed “Unimate,” the first truly programmable robotic arm.<sup>113</sup> Then in 1961 General Motors introduced Unimate into its assembly lines;<sup>114</sup> this paved the way for robots to complete repetitive, difficult, or dangerous tasks in industrial applications.<sup>115</sup>

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instructions and performs tasks in processing).

109. Zidich, *supra* note 107, at 917.

110. Scott Carey & Laurie Clarke, *A Brief History of Robotics – A Timeline of Key Achievements in the Fields of Robotics and AI, from Azimov to AlphaGo*, TECHWORLD (May 1, 2018), <https://www.techworld.com/picture-gallery/apps-wearables/brief-history-of-robotics-timeline-of-key-achievements-in-field-since-1941-3645131/> [<https://perma.cc/92KA-Z6NF>].

111. See Neil G. Hockstein et al., *A History of Robots: From Science Fiction to Surgical Robots*, 1 J. ROBOTIC SURGERY 113, 113 (2007) (noting that in 1920, Karl Capek first introduced society to the word “robot” in his play Rossum’s Universal Robots); see also Carey & Clarke, *supra* note 110 (noting that in 1943, American author Isaac Asimov established today’s conception of robots as humanoids through his Three Laws of Robotics).

112. See Carey & Clarke, *supra* note 110 (noting that in 1948 William Grey Walter developed what are considered to be the first electronically autonomous robots); see also *History of Robotics: Timeline*, ROBOTSHOP DISTRIBUTION, INC. (2008), <https://www.robotshop.com/media/files/PDF/timeline.pdf> [<https://perma.cc/GN52-T3RC>] (noting that Walter’s “turtle robots” were the first robots capable of locating and returning to a charging station when their battery power ran low).

113. Carey & Clarke, *supra* note 110.

114. See *id.* (noting that in 1960, Devol sold Unimate to General Motors); Hockstein, *supra* note 111, at 114 (noting that General Motors introduced Unimate into assembly lines in 1961).

115. Carey & Clarke, *supra* note 110.

In the decades that followed the use of robots in industrial applications grew exponentially.<sup>116</sup> Today, the colloquial term “robot” can be used to describe an expansive array of devices,<sup>117</sup> including automated arms, mobile devices, mills, and telerobotic devices.<sup>118</sup> Moreover, modern robots can be further characterized as “active” or “semiaactive” devices, which can carry out tasks independent of, or dependent on, operator oversight, respectively.<sup>119</sup> Today, active and semiaactive robots are used throughout the world in nearly all industries as a way to duplicate repetitive tasks, improve upon human functions, or offer services in situations that are too hazardous for direct human work.<sup>120</sup>

## 2. Robotic Technology’s Use in the Medical Industry

Compared to other industries, the healthcare industry has been relatively slow to implement robotic technologies.<sup>121</sup> Initially, active devices were theorized to have utility in clinical applications;<sup>122</sup> however, it was not until the mid-1980s that robots were first utilized in surgical procedures.<sup>123</sup> Additionally, it was

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116. *See id.* (noting that in 1966 Stanford Research Institute developed “Shakey” the robot, which represented the first robotic blending of hardware and software so as to enable a robot to perceive its surroundings); *see also id.* (noting that in 2000 Honda released its Advanced Step in Innovative Mobility, a humanoid robot designed to be a personal assistant that understands voice commands, gestures, and can engage with its surroundings).

117. Hockstein, *supra* note 111, at 114 (noting that a variety of classifications or categories of devices can be used to describe the heterogeneous nature of robots).

118. *Id.*

119. *See id.* (describing active devices as programmable devices that carry out tasks independent of an operator’s oversight, and semiaactive devices as devices that typically translate movements from an operator’s hands into powered or unpowered movements of the robot end-effector arms).

120. *Id.* (noting that robots have been used in deep sea and space exploration, military use, and rescue missions).

121. *Compare* Carey & Clarke, *supra* note 110 (indicating that robots were first introduced into the manufacturing industry in the early 1960s), *with* Hockstein, *supra* note 111, at 114 (noting that it was not until the mid-1980s that robots were first implemented in the healthcare industry).

122. Hockstein, *supra* note 111, at 114 (noting pre-programmed data and computer algorithms could be used in surgical applications without real time operator input).

123. *See id.* (noting that in 1985, the first robotic surgery was performed, which utilized a modified robotic arm to perform a stereotactic brain biopsy). *See generally Stereotactic Brain Biopsy*, AM. ASS’N NEUROLOGICAL SURGEONS (Nov. 14, 2018), <https://www.aans.org/Patients/Neurosurgical-Conditions-and>

not until the 1980s, following developments by the National Aeronautics and Space Administration (NASA),<sup>124</sup> that academics and surgeons theorized the concept of telepresence<sup>125</sup> surgery, where surgeons could be virtually inserted into an operating field and complete surgical tasks by controlling remote robotic arms.<sup>126</sup>

Then in the late 1980s, as the field of robotic surgery continued to grow, the concept of integrating telepresence technology into the surgical field was fully realized.<sup>127</sup> Initially, the Pentagon's Defense Advanced Research Projects Agency (DARPA) developed an automated endoscopic system for optimal positioning (AESOP), which utilized a robotic arm for endoscopic<sup>128</sup> camera control,<sup>129</sup> coupled with the Hermes voice-activation system,

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-Treatments/Stereotactic-Brain-Biopsy [<https://perma.cc/6EYD-ACHP>] (defining stereotactic brain biopsy as a procedure that allows surgeons to diagnose brain abnormalities by removing a small piece of the outermost brain tissue). In the years that followed, active devices were progressively used in other surgical applications. Hockstein, *supra* note 111, at 114 (noting that a few years later a computer-guided mill was used to core the femoral head, to receive a hip replacement prosthesis, in a hip replacement surgery). *See generally Femoral Head*, SAUNDERS COMPREHENSIVE VETERINARY DICTIONARY (3d ed. 2007) (describing the femoral head as the rounded, uppermost portion of the femur, which moves in the hip joint); *Prosthesis*, SAUNDERS COMPREHENSIVE VETERINARY DICTIONARY (3d ed. 2007) (describing a prosthesis as an artificial substitute for a missing part, used for functional or cosmetic reasons, or both); *Milling Machine Definition, Process & Types*, ENG'G ARTICLES (Aug. 7, 2015), <http://www.engineeringarticles.org/milling-machine-definition-process-types/> [<https://perma.cc/FU25-7W2U>] (defining milling as a process where machine cutters rotate to remove material from a work piece).

124. *See* Hockstein, *supra* note 111, at 115 (noting that NASA began developing a head-mounted virtual-reality display that would allow users to immerse themselves with large sets of data transmitted from aerospace missions).

125. *See generally Telepresence*, TECHOPEDIA (Oct. 15, 2018), <https://www.techopedia.com/definition/14600/telepresence> [<https://perma.cc/9JMD-UFDS>] (defining telepresence as technology that allows a user to appear to be present, feel like they are present, or have some effect in a space that the person does not physically inhabit).

126. *See* Hockstein, *supra* note 111, at 115 (noting that Scott Fisher, Ph.D. and Joe Rosen, MD initially collaborated with Phil Green, Ph.D. of the Stanford Research Institute to cultivate the telepresence system and robotic arms).

127. *Id.*

128. William C. Shiel Jr., *Medical Definition of Endoscope*, MEDICINET, <https://www.medicinenet.com/script/main/art.asp?articlekey=3244> [<https://perma.cc/N7MJ-XB9G>] (defining an endoscope as a rigid or flexible instrument that is used to look deep inside the body).

129. Hockstein, *supra* note 111, at 115.

which allowed endoscope control by voice command.<sup>130</sup> Then, in 1995 the licensing rights for the AESOP systems were acquired by, inter alia, Intuitive Surgical, Inc. (Intuitive),<sup>131</sup> and in 1997 widespread clinical use of telepresence devices was achieved when Intuitive introduced its daVinci surgical system.<sup>132</sup> The system consisted of a remote surgeon console<sup>133</sup> and three robotically controlled instruments.<sup>134</sup> Building off Intuitive, Computer Motion Inc. introduced the Zeus surgical system in 1999,<sup>135</sup> and in a monumental step for telepresence surgery, the Zeus system was used to complete the first ever transatlantic surgical procedure in 2001.<sup>136</sup> Zeus was used to perform a cholecystectomy<sup>137</sup> on a patient in France by a surgeon seated 3,800 miles away in New York.<sup>138</sup>

In 2003, Computer Motion was acquired by Intuitive<sup>139</sup> and, over the past several decades, numerous improvements have been made to the daVinci system.<sup>140</sup> Today, the daVinci system has been Food and Drug Administration (FDA) approved for a

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130. *Id.* (noting that in 1994, the AESOP/Hermes platform achieved Food and Drug Administration approval, and was the first actively marketed telerobotic system).

131. *Id.*

132. *Id.*

133. *See id.* (describing the surgeon console as consisting of two viewers, one for each eye, which provide a three-dimensional view of the operating field).

134. *See id.* (describing the three robotically controlled instruments as consisting of a tower, with three multiply jointed [sic] arms; two of the arms controlled a variety of small surgical instruments and the third arm controlled a binocular video endoscope).

135. *See id.* at 116 (noting that the Zeus system differed from the daVinci system primarily in the configuration of the surgeon's workstation, allowing the surgeon to sit at a console and wear polarized goggles to view the operative field in three dimensions).

136. *Id.*

137. *Cholecystectomy (Gallbladder Removal)*, MAYO CLINIC (Nov. 10, 2018), <https://www.mayoclinic.org/tests-procedures/cholecystectomy/about/pac-20384818> [<https://perma.cc/93U6-Z34W>] (defining a cholecystectomy as a surgical procedure to remove the gallbladder, an organ that sits just below the liver on the upper right side of the abdomen).

138. Hockstein, *supra* note 111, at 116.

139. *Id.* (mentioning that after Computer Motion was acquired by Intuitive, the Zeus system was no longer commercially available).

140. *Id.* (noting that improvements to the daVinci system include the addition of a fourth robotic arm that allows surgeons to toggle between instruments, an increased number of surgical instruments that can be used in combination with the system, and the addition of an interactive video display).

variety of general, cardiac, and urologic procedures,<sup>141</sup> and its streamlined platform, small instrumentation, and remote tele-monitoring has been described as offering the potential for the healthcare industry to truly attain minimally invasive surgery.<sup>142</sup>

Ultimately, in the century following robots' initial introduction into society through literary works, unimaginable advances of the "second Industrial Revolution" have transformed what was once viewed as science fiction into today's reality. Correspondingly, as the healthcare industry has aimed to leverage the prospective benefits of telepresence surgical robotics, the legal field has faced complex questions surrounding the applicability of existing products liability doctrines, and has been tasked with determining whether there is a need for existing doctrines to evolve in response.

## II. THE MALFUNCTION THEORY OF PRODUCTS LIABILITY AND ITS DIVERSE DOCTRINAL FRAMEWORK OVER THE PAST FIFTY YEARS

Analogous to the historic developments of many of the doctrines that surround products liability law, technological advances over the past century have significantly impacted the malfunction theory of products liability.<sup>143</sup> This Part explores the current legal landscape surrounding the malfunction theory, first by describing the theory's diverse doctrinal framework, and then specifically outlining how the doctrine has been applied in medical device cases. Section A outlines instances where malfunction theory concepts have been applied broadly, narrowly, and in a nuanced manner. Then, Section B examines the sparse case law surrounding the applicability of the malfunction theory to medical device cases, highlights some of the evidentiary

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141. *Id.*

142. *See id.* at 116–17 (noting that the healthcare industry policies surrounding clinical outcomes research and “do[ing] no harm” will likely promote further research and development in the field of surgical robotics for years to come).

143. *See generally* Raymond & Allen, *supra* note 85, at 299–305 (illustrating differences in malfunction theory cases over the past century, and noting that the RESTATEMENT (THIRD) OF TORTS, PRODUCTS LIABILITY has informed the development of the malfunction theory).

boundaries that courts have delineated in those cases, and concludes by examining the applicability of the theory to surgical robotics.

A. THE BROAD AND NARROW FRAMEWORKS SURROUNDING THE MALFUNCTION THEORY OF PRODUCTS LIABILITY AND THE MODERN TREND TOWARD A MORE NUANCED APPROACH

As aforementioned, the three-pronged malfunction theory test allows a plaintiff to establish a prima facie case, and the factfinder may infer a product defect, with evidence that shows a malfunction, eliminates abnormal use, and eliminates reasonable secondary causes.<sup>144</sup> Since the malfunction theory allows a plaintiff to present circumstantial evidence to establish a prima facie case, the theory operates like a quasi-rule of evidence.<sup>145</sup> As a result, courts' interpretations of the rules of evidence, their perspectives on *Restatement (Second) of Torts* and *Restatement (Third) of Torts: Products Liability*,<sup>146</sup> and their evidentiary assessments as to whether a defect was most likely attributable to the manufacturer, improper maintenance by the user, another party's negligence, and/or simply the result of an accident, has resulted in a spectrum of cases that illustrate that this area of law remains unsettled.<sup>147</sup>

1. Cases Supporting a Broad Application of the Malfunction Theory of Products Liability

Advances over the years have not only resulted in increasingly complex products, but also in a subsequent body of law that supports a broad application of the malfunction theory.<sup>148</sup> Rooted

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144. *Id.* at 298–99.

145. *See id.* at 299 (noting that the malfunction theory implicates permissible inferences for the factfinder absent direct evidence, and the theory essentially operates as a rule of evidence).

146. *See id.* (noting that the rules of evidence and the RESTATEMENT (THIRD) OF TORTS, PRODUCTS LIABILITY have contributed to the development of the malfunction theory). *See generally* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 3 (AM. LAW INST. 1998) (permitting circumstantial evidence to be used to support an inference of a product defect); RESTATEMENT (SECOND) OF TORTS § 328D (AM. LAW INST. 1965) (permitting the factfinder to infer that the harm suffered by a plaintiff was caused by the negligence of the manufacturer).

147. *See* Raymond & Allen, *supra* note 85, at 300 (stating that the malfunction theory has been applied both narrowly and broadly by different courts, and the state of the doctrine remains in flux).

148. For an in-depth analysis of cases that implicate analogous malfunction

in strong policy considerations, akin to *res ipsa loquitur*, and influenced by § 328D of the *Restatement (Second) of Torts*, courts have historically demonstrated a willingness to allow cases involving complex products and remote plaintiffs to proceed to the jury, absent proof of any specific defect.<sup>149</sup> Furthermore, courts have also traditionally exhibited a willingness to allow these cases to proceed, despite remote plaintiffs' inability to eliminate other reasonable secondary causes of a malfunction.<sup>150</sup>

For example, in *Lindsay v. McDonnell Douglas Aircraft Corp.*, the Eighth Circuit reversed a judgment for defendant aircraft manufacturer, despite an accident report that listed three possible causes of a fatal crash.<sup>151</sup> The court stated that there is no "requirement that [the plaintiff] show the specific defect which caused the crash . . . [i]f [the plaintiff] can show that the crash was caused by some unspecified defect and that no other cause is likely, [they have] made a submissible case."<sup>152</sup> Although the aircraft manufacturer offered testimony that supported the pilot's disorientation was an alternative cause,<sup>153</sup> the

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theory concepts, and support a broad application see the discussion in *id.* at 300–01.

149. See, e.g., *Welge v. Planters Lifesavers Co.*, 17 F.3d 209, 212 (7th Cir. 1994) (reversing the district court's grant of summary judgment and remanding a strict products liability case, despite the plaintiff's inability to prove a specific defect that caused a jar of peanuts to shatter as the plaintiff was replacing the cap); *Liberty Mut. Co. v. Sears, Roebuck & Co.*, 406 A.2d 1254, 1254 (Conn. Super. Ct. 1979) (affirming the trial court's decision to allow a strict products liability case to proceed to the jury, despite an unspecified defect); *Cassisi v. Maytag Co.*, 396 So. 2d 1140, 1150 (Fla. Dist. Ct. App. 1981) (remanding for further proceedings a strict products liability action based on a malfunction itself, despite the plaintiff's inability to identify a specific defect); *Moraca v. Ford*, 332 A.2d 599, 601 (N.J. 1975) (affirming the Appellate Division's remand to permit a products liability case to proceed to the jury, despite the plaintiff's inability to point to a specific defect).

150. See *Welge*, 17 F.3d at 211 (stating that a "plaintiff in a products liability suit is not required to exclude every possibility . . . that the defect which led to the accident was caused by someone other than one of the defendants," and remanding the case despite facts supporting alternative causes); *Cassisi*, 396 So. 2d at 1142–43 (reversing the grant of summary judgment for the defendant, and allowing the case to proceed to the jury, despite the plaintiff's expert being unable to negate other causes of a dryer fire).

151. 460 F.2d 631, 634 (8th Cir. 1972); see also *id.* at 634 n.2 (noting that the report concluded that the cause of the accident was undetermined, but that three possible causes existed, including pilot disorientation, stall/spin, and material failure).

152. *Id.* at 640.

153. *Id.* at 634 n.2.



Eighth Circuit indicated that the lower court was correct in allowing the case to proceed to the jury, stating that it is the factfinder's job to "evaluat[e] and weigh[] . . . competing and often conflicting circumstances."<sup>154</sup> The court stressed that there would be "little gain to the consuming public if the courts would establish a form of recovery with one hand and take it away with the other by establishing impossible standards of proof."<sup>155</sup>

Similarly, in *Stewart v. Budget Rent-A-Car Corp.*, the Supreme Court of Hawaii reversed a directed verdict for defendants, an automobile distributor and a manufacturer, despite a rental agency admitting to pre-rental vehicle inspections that were limited to fifteen minutes.<sup>156</sup> The court stated that although "[t]he most convincing evidence is an expert's pinpointing the defect . . . [i]f no such opinion is possible . . . the user's testimony on what happened is another method of proving that the product was defective."<sup>157</sup> Although evidence was introduced that indicated that the rental agency had not performed maintenance tests on the steering assembly prior to renting,<sup>158</sup> the court stated that a "directed verdict may be granted only when after . . . indulging every legitimate inference which may be drawn . . . in [the] plaintiff's favor, it can be said that there is no evidence to support a jury verdict in [the plaintiff's] favor."<sup>159</sup> The court concluded the "quantum of evidence . . . was sufficient to go to the jury," and it was for the jury, not the court, to decide whether a defect in the car was attributable to the manufacturer or distributor, or alternatively, was the result of failure to maintain the car on the part of the rental agency.<sup>160</sup>

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154. *Id.* at 640.

155. *Id.* at 639; *see also id.* (stating that the proof required in a strict liability case must be realistically tailored to the circumstances which caused the form of action to be created).

156. *See* 470 P.2d 240, 242 (Haw. 1970) (stating that the rental car company testified that they had "thoroughly" inspected and serviced the car upon acquiring it, but later general inspections were limited to fifteen to twenty minutes in length).

157. *Id.* at 243; *see also id.* at 242 (noting that the expert mechanic stated that the accident "might well have caused the damage to the parts or, conversely, their failure might have caused the accident").

158. *See id.* at 242 (stating that later general inspections were limited to fifteen to twenty minutes in length).

159. *Id.* at 244.

160. *Id.* at 244–45.

As *Lindsay*, *Stewart*, and other cases like them indicate, over the past half-century courts have historically demonstrated a willingness to adopt a *res ipsa loquitur*-like approach to the malfunction theory in cases involving industrially complex products and remote users. In these cases, courts embrace a *res ipsa loquitur*-like inference that a product defect “speaks for itself,” based on the attenuated relationship between manufacturers and end users, the presence of inter-industry intermediaries, and the innate complexities of the products. Moreover, founded on *res ipsa loquitur*-like policy concerns regarding “establishing impossible standards of proof,”<sup>161</sup> courts in these cases have traditionally allowed the case to proceed to the jury despite plaintiffs’ failure to identify a specific defect and/or eliminate all potential secondary causes.<sup>162</sup>

## 2. Cases Supporting a Narrow Application of the Malfunction Theory of Products Liability

In contrast to cases like *Lindsay* and *Stewart*, recently scholars have advocated for,<sup>163</sup> and courts have adopted,<sup>164</sup> a much narrower approach to the malfunction theory. Founded on strong policy concerns regarding converting product sellers into product insurers,<sup>165</sup> and influenced by a strict reading of § 3 of the *Restatement (Third) of Torts*,<sup>166</sup> courts over the past several decades have shown a reluctance in allowing cases to proceed based

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161. *Lindsay v. McDonnell Douglas Aircraft Corp.*, 460 F.2d 631, 639 (8th Cir. 1972).

162. *See Menage, supra* note 83, at 366–67.

163. *See Raymond & Allen, supra* note 85, at 302 (noting that the opinion of the authors is that a more restrictive application of the malfunction theory is the better-reasoned approach).

164. *See generally Walker v. Gen. Elec. Co.*, 968 F.2d 116, 120 (1st Cir. 1992) (affirming the decision of the district court to grant defendant summary judgment, reasoning that the plaintiff failed to meet their burden of eliminating secondary reasonable causes for a toaster malfunction).

165. *See Raymond & Allen, supra* note 85, at 302 (stating that there is a danger that broad application of the malfunction theory may have the effect of converting product sellers into “insurers”). This contention is founded on the risk spreading theory of products liability, which purports that if courts impose liability on manufactures for a broader range of product injuries, manufacturers will in turn increase the price of products so as to spread the cost of losses to the purchaser; thus, the increased pricing acts as an insurance premium for consumers. Robert F. Cochran, Jr., *Dangerous Products and Injured Bystanders*, 81 KY. L.J. 687, 705 (1992).

166. *See Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 601–02 (Tex. 2004)

on circumstantial evidence.<sup>167</sup> Moreover, more recently courts have also demonstrated an unwillingness to allow cases involving remote plaintiffs to proceed to the jury, absent sufficient evidence to eliminate all reasonable secondary causes of a product malfunction.<sup>168</sup>

For example, in *Martin v. E-Z Mart Stores, Inc.*, the Eighth Circuit affirmed a grant of summary judgment for a distributor, and held that the plaintiff had failed to offer sufficient evidence to survive a motion for summary judgment in a case involving a lighter that caught fire in the plaintiff's pocket.<sup>169</sup> Although the Eighth Circuit reiterated that a plaintiff is not required to point to a specific defect in order to survive a motion for summary judgment,<sup>170</sup> the court stated that because the plaintiff failed to offer sufficient evidence to "answer the basic question of whether the accident occurred because of a potential defect in the lighter, or because of something like wear and tear or misuse" summary judgment was proper.<sup>171</sup> The court noted that unless the evidence presented "induce the mind to pass beyond conjecture as to liability for a defect," a case cannot be made for the trier of facts.<sup>172</sup>

Similarly, in *Ford Motor Co. v. Ridgway*, the Supreme Court of Texas affirmed a grant of summary judgment for an automobile manufacturer in a case involving a pick-up truck that started on fire, resulting in second-degree burns to the plaintiff.<sup>173</sup> Although the court noted that only a "scintilla of evidence"

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(citing § 3 and noting that the drafters of the Restatement were aware of temporal limitations on the malfunction theory and the importance of eliminating alternative causes).

167. For an in-depth discussion of cases where courts were hesitant to allow cases to proceed based on circumstantial evidence see Raymond & Allen, *supra* note 85, at 302 n.21.

168. See generally *Ruminer v. Gen. Motors Corp.*, 483 F.3d 561, 561–65 (8th Cir. 2007) (upholding the district court's grant of summary judgment in favor of defendant car manufacturer because the plaintiffs did not offer sufficient evidence to eliminate other potential causes, including the plaintiff not wearing their seat belt properly, wear and tear, or "some other condition arising after the vehicle left the control of General Motors.").

169. 464 F.3d 827, 831 (8th Cir. 2006).

170. See *id.* at 830 ("While proof of the specific defect may not be required, the mere fact of an accident, standing alone, does not make out a case that the product was defective." (citations omitted)).

171. *Id.*

172. *Id.* at 831 (citations omitted).

173. See *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 599 (Tex. 2004) (stating

is needed to survive a motion for summary judgment,<sup>174</sup> the court discredited the plaintiff's circumstantial evidence<sup>175</sup> and concluded that because the plaintiff failed to provide direct evidence relating to the cause of the fire, the evidence was insufficient to survive a motion for summary judgment.<sup>176</sup> The court stated that because the plaintiff "could not rule out part of the fuel system as a possible cause" of the fire, and because "the product's age [and the] presence of modifications or repairs" did not support an inference of a product defect,<sup>177</sup> the plaintiff failed to meet the burden necessary to survive a motion for summary judgment.<sup>178</sup>

As *Martin*, *Ridgway*, and more recent cases like them illustrate, technological advances, increases in inter-industrial interactions, and the underlying principles embodied in § 3 have led courts over more recent years to adopt a much stricter approach to the malfunction theory.<sup>179</sup> In these cases, courts are reluctant to rely on circumstantial evidence to infer a product defect absent sufficient evidence to eliminate wear and tear, a product's age, or the presence of repairs as possible secondary causes of a malfunction.<sup>180</sup> Moreover, founded on strong concerns surrounding imposing liability on manufactures for a broader range of product injuries, courts have become more hesitant to allow cases involving remote plaintiffs to proceed to the jury based on circumstantial evidence and/or absent evidence to eliminate all reasonable secondary causes.<sup>181</sup>

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that the accident occurred when the plaintiff was driving home, below the speed limit, on a paved road).

174. *Id.* at 600.

175. *Id.* at 601 (stating simply that the plaintiff's circumstantial evidence does not exceed a scintilla).

176. *Id.*

177. *Id.* at 601–02.

178. *See id.* at 602; *see also id.* at 600 (stating that the plaintiff's expert concluded the fire originated in the engine compartment and opined it was a malfunction of the electrical system; but failed to eliminate portions of the fuel system as a possible cause of the accident).

179. *See, e.g., id.* at 601–02 (refusing to use circumstantial evidence and § 3 of RESTATEMENT (THIRD) OF TORTS).

180. *Martin v. E-Z Mart Stores, Inc.*, 464 F.3d 827, 830 (8th Cir. 2006); *Ridgway*, 135 S.W.3d at 601.

181. *See Raymond & Allen*, *supra* note 85, at 302 n.21 (citing cases where courts have been unwilling to allow cases to proceed based on circumstantial evidence, or instances where plaintiffs have not sufficiently eliminated reasonable secondary causes).

### 3. A More Moderate Approach to the Malfunction Theory of Products Liability

As the foregoing analysis illustrates, although the utility of the malfunction theory has remained in flux over the years, one thing that has remained constant is courts' willingness to look to the Restatements for guidance.<sup>182</sup> Some courts and scholars have opined that § 3 of the *Restatement (Third) of Torts: Products Liability* indicates that circumstantial evidence, and the malfunction theory, is only applicable in cases that involve new products<sup>183</sup> that have not been subject to subsequent maintenance or repairs,<sup>184</sup> and where the possibility of third-party or user negligence have been sufficiently ruled out as an alternative cause.<sup>185</sup> However, other courts have considered § 3 and its comments, and adopted a more flexible "totality of the circumstances" approach to the malfunction theory.<sup>186</sup>

For example, in *Metropolitan Property & Casualty Insurance Co. v. Deere & Co.* the Supreme Court of Connecticut reversed the lower court's finding in a case involving a tractor fire that destroyed the insured's home, and held that the insurer did not provide sufficient evidence to survive a motion for summary judgment.<sup>187</sup> In coming to its decision the court articulated a more nuanced approach to the malfunction theory,<sup>188</sup> stating

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182. See *Ridgway*, 135 S.W.3d at 603 (noting that comments to § 3 and the cases cited in support of it illustrate the kinds of considerations courts have taken into account in deciding whether to allow an inference of pre-sale defect in a product).

183. See *Raymond & Allen*, *supra* note 85, at 304 n.24 (noting that "[n]otwithstanding the vagueness in the *Restatement (Third)*, it is noteworthy that, in every illustration in the commentary to § 3 in which the *Restatement (Third)* indicates that liability is warranted, the accident involves a new product."); see also *Jarvis v. Ford Motor Co.*, 283 F.3d 33, 43–44 (2d Cir. 2002) (applying New York's law similar to § 3 to excuse a plaintiff from proving a specific defect, instead inferring a defect from proof that a six-day-old vehicle did not perform as intended); *Myrlak v. Port Auth.*, 723 A.2d 45, 56 (N.J. 1999) (adopting § 3 in a case involving a collapsed five-week-old chair); *Ridgway*, 135 S.W.3d at 601 (noting that even if § 3 were Texas law, "it would generally apply only to new or almost new products").

184. *Ridgway*, 135 S.W.3d at 600–01.

185. *Id.* at 600.

186. See *Metro. Prop. & Cas. Ins. Co. v. Deere & Co.*, 25 A.3d 571, 588 n.15 (Conn. 2011) (noting "that this approach is different from the approach taken by the *Restatement (Third) of Torts, Products Liability*, § 3").

187. *Id.* at 571.

188. *Id.* at 583–84 ("[A] jury may rely on circumstantial evidence to infer

that a plaintiff may prove a product defect through various forms of circumstantial evidence, including history and use of the particular product, the manner in which the product malfunctioned, similar malfunctions in similar products that negate the possibility of other causes, the age of the product in relation to its life expectancy, and the most likely causes of the malfunction.<sup>189</sup> The court noted that when the totality of the plaintiff's evidence is "sufficient to establish that it is more probable than not that the plaintiff's injury was caused by a defect . . . that can fairly be attributed to the manufacturer," cases relying on the malfunction theory should proceed to the jury.<sup>190</sup> Although the insurer in *Metropolitan* was unable to provide sufficient evidence to eliminate reasonable secondary causes,<sup>191</sup> *Metropolitan* and cases like it<sup>192</sup> indicate that in cases involving complex products and interconnected parties, some more progressive courts are willing to adopt a more nuanced approach to the malfunction theory and the use of circumstantial evidence.<sup>193</sup>

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that a product that malfunctioned was defective at the time it left the manufacturer's or seller's control if the plaintiff presents evidence establishing that (1) the incident that caused the plaintiff's harm was of a kind that ordinarily does not occur in the absence of a product defect, and (2) any defect most likely existed at the time the product left the manufacturer's or seller's control and was not the result of other reasonably possible causes not attributable to the manufacturer or seller.").

189. *Id.* at 584.

190. *Id.* at 589.

191. *See id.* at 590–92 (noting that the dealer's technician testified that he performed a tune-up and found no problems or deficiencies, and that the tune-up was performed according to manufacturer specification supplied by the defendant; however, the court concluded that the plaintiff failed to remove the possibility that the "work performed on the tractor could not have damaged or caused problems with the tractor's electrical system").

192. *See, e.g.,* *Karazin v. Wright Med. Tech., Inc.*, 3:17-cv-823 (JBA), 2018 WL 4398250, at \*5 (D. Conn. Sept. 14, 2018) (applying the *Metropolitan* framework in a case surrounding the malfunction of an artificial hip replacement device); *Merrimack Mut. Fire Ins. Co. v. Watkins Mfg. Co.*, 3:13-cv-123 (JBA), 2015 WL 3397844, at \*8 (D. Conn. May 26, 2015) (applying the *Metropolitan* approach in a case surrounding a house fire that was caused by a hot tub malfunction); *Ace Am. Ins. Co. v. Eaton Elec., Inc.*, 3:11-cv-1741 (CSH), 2015 WL 233032, at \*8–10 (D. Conn. Jan. 16, 2015) (applying the *Metropolitan* "totality of the circumstances" framework to a case surrounding a house fire resulting from a faulty electricity circuit meter).

193. *See generally* *Raymond & Allen*, *supra* note 85, at 303–05 (noting that *Metropolitan* represented a more recent, nuanced approach to the malfunction theory).

B. THE SPARSE CASE LAW SURROUNDING THE MALFUNCTION THEORY IN MEDICAL DEVICE CASES AND ITS APPLICATION TO SURGICAL ROBOTICS

Ironically, scholars have noted that the malfunction theory and subsequently § 3 of the *Restatement (Third) of Torts: Products Liability* emanated from a seminal medical device case.<sup>194</sup> However, unlike the doctrinal boundaries and vast body of case law that have developed in other industries,<sup>195</sup> courts have had limited opportunities<sup>196</sup> to evaluate the applicability of the malfunction theory and subsequently § 3 in medical device cases.<sup>197</sup> Furthermore, unlike other industries, the complexities surrounding medical devices, physician-patient interactions, and the nature of the human body have inevitably strained courts to make difficult evidentiary determinations on whether product defects and resulting injuries are attributable to device manufacturers, improper maintenance by healthcare providers, physician negligence, and/or simply the result of a patients' anatomy. As a result, over the years courts have struggled to consistently apply the malfunction theory in medical device cases.

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194. Earlier drafts of the *Restatement (Third) of Torts* stems principally from Pennsylvania law, specifically *Rogers v. Johnson & Johnson Products, Inc.*, 565 A.2d 751 (Pa. 1989), a case in which the court first articulated the malfunction theory of products liability. See Jonathan M. Hoffman, *Res Ipsa Loquitur and Indeterminate Product Defects: If They Speak for Themselves, What Are They Saying?*, 36 S. TEX. L. REV. 353, 371 (1995).

195. See generally *Martin v. E-Z Mart Stores, Inc.*, 464 F.3d 827, 828 (8th Cir. 2006) (relating to a cigarette lighter defect); *Metro. Prop. & Cas. Ins. Co. v. Deere & Co.*, 25 A.3d 571, 577–78 (Conn. 2011) (relating to a tractor electrical defect); *Liberty Mutual Co. v. Sears, Roebuck & Co.*, 406 A.2d 1254, 1255–56 (Conn. Super. Ct. 1979) (relating to a television defect); *Cassisi v. Maytag Co.*, 396 So. 2d 1140, 1143 (Fla. Dist. Ct. App. 1981) (relating to a dryer defect); *Moraca v. Ford Motor Co.*, 332 A.2d 599, 600 (N.J. 1975) (relating to automobile defect).

196. See generally *Rogers*, 565 A.2d at 754 (representing the first case where the malfunction theory was adopted, specifically in a medical device case). It is also important to note that a Westlaw search of citing references to *Rogers v. Johnson & Johnson* revealed that only sixteen citing cases contained the words “medical” and/or “device” in them as of January 10, 2019.

197. *Id.* It is also important to note that a refined Westlaw search of the cases that cited *Rogers v. Johnson & Johnson* and also included the words “medical” and “circumstantial” was limited to ten cases as of January 10, 2019.

### 1. The Malfunction Theory and Its Diverse Application in Medical Device Cases

The Supreme Court of Pennsylvania first articulated the malfunction theory of strict products liability in *Rogers v. Johnson & Johnson*,<sup>198</sup> a case involving a patient that was burned by plaster used to temporarily set his leg.<sup>199</sup> Despite the manufacturer introducing evidence of physician negligence, the Supreme Court of Pennsylvania reversed the lower court's decision,<sup>200</sup> and stated that a medical device manufacturer is not entitled to a directed verdict on the malfunction theory when it introduces "evidence of secondary causation, i.e., medical malpractice . . . ."<sup>201</sup> The court reasoned that it was "altogether possible that a plaintiff's injuries could be caused jointly by a defective product, and also by third party negligence, so long as the negligence does not constitute a supervening cause of the malfunction."<sup>202</sup> A dissenting judge harshly criticized the majority's holding as being a "res ipsa loquitur"-type approach, and stated that the survival of a plaintiff's "cause of action depends upon [] establishing that nothing outside of the product itself caused the malfunction . . . ."<sup>203</sup> The judge reasoned that evidence of physician negligence should be considered fatal because "if a 'secondary cause' created the malfunction, the product itself was not defective and the products liability claim would fail."<sup>204</sup> Ultimately, this tension between the majority and dissenting opinions in

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198. *Id.* at 754 (articulating the malfunction theory as allowing a plaintiff to "prove a defect in a product with evidence of the occurrence of a malfunction and with evidence eliminating abnormal use or reasonable, secondary causes for the malfunction"); *see also id.* at 753–54 (stating that although the superior court has considered the malfunction theory of strict liability, the supreme court had never fully adopted it prior to their current decision).

199. *Id.* at 752.

200. *See id.* at 751 (noting that the superior court reversed the lower court's decision to allow the case to proceed to the jury, and held that the case should not have been submitted to the jury in light of evidence of negligence on the part of the physicians).

201. *See id.* at 754 (stating that the supreme court "cannot agree with this circular logic as it essentially mandates the grant of a directed verdict should the defendant manufacturer produce any evidence of reasonable, secondary causation").

202. *Id.* at 755.

203. *See id.* at 755–56 (Flaherty, J., dissenting) (criticizing the majority as using a "res ipsa loquitur"-type approach in its analysis, and emphasizing a narrow application of the malfunction theory).

204. *Id.* at 756.



*Rogers* foreshadowed decades of seemingly similar medical device cases that proceeded to markedly different stages of litigation, largely based on courts' differing approaches to the malfunction theory and the evidentiary requirements needed to permit an inference of a product defect.

For example, in *Wiggins v. Synthes (U.S.A.)*, a case involving surgical screws that broke in a patient's leg, the Superior Court of Pennsylvania affirmed the lower court's judgment in favor of the patient, despite evidence of secondary causes.<sup>205</sup> Although the manufacturer introduced evidence indicating that the patient's non-union of bones could have caused the surgical screws to be "ineffective," rather than defective,<sup>206</sup> the superior court indicated that the lower court was correct in allowing the case to proceed to the jury.<sup>207</sup> The court reasoned that there was enough "evidence to support a conclusion . . . that the non-union of the bones did not cause the surgical screws to break," and concluded that the evidence supported the finding that the screws failed to perform as reasonably expected.<sup>208</sup> Similarly, in *Banks v. Coloplast Corp.*, a case concerning the malfunction of an implanted inflatable prosthesis, the court denied the manufacturer's motion for summary judgment, despite allegations of patient misuse and surgical team negligence.<sup>209</sup> Although the manufacturer alleged that the prosthetic device was implanted by a surgical team, and it was possible that the device was damaged or implanted incorrectly, the court concluded that the argument "merely raise[d] a genuine issue of material fact . . . [that did] not support an entry of summary judgment . . ."<sup>210</sup>

Conversely, in *Moeller v. Danek Medical, Inc.*, a case involving a pedicle screw that broke in a patient's spine, the District Court of Pennsylvania granted the manufacturer's motion for summary judgment based on the patient's inability to eliminate a possible secondary cause.<sup>211</sup> The manufacturer presented evi-

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205. 29 A.3d 9, 9 (Pa. Super. Ct. 2011).

206. *Id.* at 15.

207. *Id.* at 17.

208. *Id.* at 16–18.

209. CIV. A. 10-5048, 2012 WL 651867, at \*6 (E.D. Pa. Feb. 28, 2012).

210. *Id.* at \*4.

211. CIV.A. 94-967, 1997 WL 1039333, at \*3–4 (W.D. Pa. Dec. 1, 1997), *aff'd*, 166 F.3d 1205 (3d Cir. 1998).

dence indicating that the patient had engaged in physical activity months after the surgery,<sup>212</sup> and the court concluded that the patient did not meet the burden of proving the “absence of abnormal use or reasonable secondary causes” so as to allow the case to proceed to the jury.<sup>213</sup> Moreover, in *Bowman v. American Medical Systems, Inc.*, a case concerning a penile prosthesis that malfunctioned and was removed, the district court granted the manufacturer’s motion for summary judgment based on spoliation of evidence.<sup>214</sup> The court concluded that because the attending physician “spoliated the removed [p]rosthesis,”<sup>215</sup> and the manufacturer did not have an opportunity to examine the device for “damage between the time of manufacture and the time of the implantation procedure,” nor an opportunity to examine whether “the alleged failure . . . was caused by improper implantation of the device,” the manufacturer was “severely prejudiced” and entitled to a grant of summary judgment.<sup>216</sup>

A comparison of *Wiggins*, *Banks*, *Moeller*, and *Bowman* illustrates that over the years courts have struggled to consistently apply the malfunction theory in medical device cases. In cases like *Wiggins* and *Banks*, courts have adopted a *Rogers* majority-like approach and have allowed cases to proceed based on evidence indicating that a malfunction may be the result of a defective product, but also a concurrent cause, including physiological factors, patient misuse, or surgical team negligence. Conversely, in cases like *Moeller* and *Bowman*, courts have adopted a *Rogers* dissent-like approach and have only allowed cases to proceed if there is sufficient evidence to eliminate other reasonable secondary causes of a malfunction, including patient misuse, physician negligence, and/or improper implantation. Ultimately, as foreshadowed by *Rogers*, the differing judicial approaches to the malfunction theory have resulted in decades of similar medical device cases that have proceeded to different

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212. *See id.* at \*3 (stating that the doctor told the patient not to do any heavy lifting following his surgery; however, months later the plaintiff attempted to lift a bench).

213. *Id.* at \*4.

214. CIV. A. 96-7871, 1998 WL 721079, at \*1 (E.D. Pa. Oct. 9, 1998).

215. *Id.* at \*1; *see also id.* (noting that the patient requested that the physician preserve the prosthesis so it could be examined to determine the cause of it breaking; however, the physician spoiled the prosthesis before any examination could be performed).

216. *Id.* at \*3–6.

stages of litigation, resulting in a body of law that still remains unclear today.

## 2. The Malfunction Theory and Its Application in a Surgical Robotic Setting

As previously indicated, the complexities surrounding medical devices, physician-to-patient interaction, and the nature of the human body, combined with the difficult evidentiary determinations surrounding whether product defects and resulting injuries are attributable to medical device manufacturers, healthcare providers, attending physicians, and/or patients have inevitably led to a range of applications of the malfunction theory in the medical field.<sup>217</sup> Moreover, recently an additional factor has been added to these complexities: robotics.<sup>218</sup> As a result, modern advances in surgical robotics and the gradual adoption of telepresence surgical techniques have recently challenged courts to test the applicability of the malfunction theory and its adjacent concepts in cases involving telepresence surgical robots.<sup>219</sup>

One of the first cases to explore the applicability of the malfunction theory to the field of telepresence surgical robotics was *Mracek v. Bryn Mawr Hospital*.<sup>220</sup> In *Mracek*, Roland Mracek sued robot manufacturer, Intuitive Surgical, Inc., after the daVinci surgical system failed to function during a routine prostatectomy.<sup>221</sup> Roland argued that a product defect could be inferred from the daVinci's repeated "error" messages, and the surgical and manufacturing teams' inability to restart the system.<sup>222</sup> Although the district court stated that the "malfunction theory does not require a plaintiff to proffer expert testimony to prove how the product was defective,"<sup>223</sup> the court rejected Roland's contention that a defect was "obvious."<sup>224</sup> Instead, the

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217. *See supra* Part II.B.1.

218. *See generally supra* Part I.C.2. (discussing recent advances in robotics within the medical field, specifically in the field of surgical robotics).

219. *See, e.g.*, *Mracek v. Bryn Mawr Hosp.*, 363 F. App'x 925 (3d Cir. 2010) (suing a surgical robot manufacturer).

220. 610 F. Supp. 2d 401 (E.D. Pa. 2009), *aff'd*, 363 F. App'x 925 (3d Cir. 2010).

221. *Id.* at 403.

222. *Id.* at 405.

223. *Id.* at 408.

224. *Id.* at 407.

court relied on Intuitive's assertion that the "use and timing of various ancillary medical equipment in connection with this . . . complex procedure reinforces that any number of reasonable secondary causes could or were responsible for the alleged damages,"<sup>225</sup> and concluded that Roland had failed to offer sufficient evidence to "eliminate any reasonable secondary causes."<sup>226</sup> In addition, the court noted that what was also "fatal to Mracek's cause of action"<sup>227</sup> was the fact that the attending physician's operative report did not "include any causation between the problems with the robot and Mracek's erectile dysfunction."<sup>228</sup>

On appeal, the Third Circuit affirmed the district court's grant of summary judgment, and simply stated that "summary judgment was proper because [the plaintiff had] . . . failed to demonstrate a genuine dispute of material fact."<sup>229</sup> Although the Third Circuit noted that expert evidence is "unnecessary where testimony . . . may enable the jury to clearly see the construction of the machine and the manner of its use,"<sup>230</sup> the court indicated that Roland's evidence of repeated "error" messages was insufficient to permit the jury to "clearly see" a product defect.<sup>231</sup> Interestingly, the Third Circuit appeared to gloss over the sufficiency of Roland's evidence regarding proof of a product defect, and focused much of its analysis on proof of causation, stating that there was insufficient evidence to "permit a jury to infer [the plaintiff's injuries] were caused by the robot's alleged malfunction."<sup>232</sup>

Given the different points of emphasis between the district court and Third Circuit's analyses, combined with the uncertainties surrounding the amount of evidence necessary to survive a motion for summary judgment in surgical robotics cases following *Mracek*, the legal field will inevitably be forced to evaluate

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225. *Id.* at 408.

226. *Id.*

227. *Id.* at 406.

228. *Id.* at 407.

229. *Mracek v. Bryn Mawr Hosp.*, 363 F. App'x 925, 927 (3d Cir. 2010) (noting that separate from whether summary judgment was proper because the plaintiff failed to produce expert reports, it was proper because he failed to demonstrate a genuine dispute of material facts).

230. *Id.* (quoting *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 415–16 (3d Cir. 1999)).

231. *Id.*

232. *Id.*

the applicability of the malfunction theory to surgical robotics cases involving remote plaintiffs as telepresence surgery becomes increasingly common. Furthermore, in light of recent Supreme Court decisions involving plaintiffs' ability to bring state-law tort claims against medical device manufacturers<sup>233</sup> and uncertainties surrounding the preemptive reach of the Medical Device Amendments of 1976,<sup>234</sup> the legal field will be forced to reevaluate the utility of existing products liability doctrines in cases involving telepresence surgical robotics as surgical robot manufacturers continue to develop new and innovative products.

### III. A NEW MALFUNCTION THEORY FOR STRICT PRODUCTS LIABILITY IN SURGICAL ROBOTICS CASES

Similar to the way the first Industrial Revolution thrust society and products liability law into monumental transformations,<sup>235</sup> recent advances in computers and robotics have thrust society into a "second Industrial Revolution,"<sup>236</sup> one which

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233. See CONG. RESEARCH SERV., R43218, PREEMPTION OF DRUG AND MEDICAL DEVICE CLAIMS: A LEGAL OVERVIEW 22 (2013), [https://www.everycrsreport.com/files/20130910\\_R43218\\_293d4299414c684a953eaae095aa422d603ff682.pdf](https://www.everycrsreport.com/files/20130910_R43218_293d4299414c684a953eaae095aa422d603ff682.pdf) [<https://perma.cc/846E-9Z2V>] (noting that following *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), lower courts have often concluded that consumers of Class III medical devices are preempted from suing device manufacturers on most state common law claims if the device receives premarket approval).

234. 21 U.S.C. § 360k(a) (2012) (stating that "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter"); see also CONG. RESEARCH SERV., *supra* note 233 (stating that the Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) indicated that state-law claims that are "parallel" to, rather than add to, federal requirements are not expressly preempted by the Medical Device Amendments of 1976). Although the Court has expressly stated that parallel claims include those that provide for "damages remedy for claims premised on a violation of FDA regulations," it has yet to address other state-law tort claims that survive federal preemption. *Id.*

235. See, e.g., Zidich, *supra* note 107, at 919 (noting that the Industrial Revolution presented a conundrum for society, but changed the way people lived and worked); see also *supra* Parts I.A.2–3. (illustrating the developments in products liability law and demonstrating how the Industrial Revolution changed not only society, but also products liability law).

236. Zidich, *supra* note 107, at 919.

requires that products liability law respond accordingly. Although the malfunction theory has exhibited minor transformations over the past several decades,<sup>237</sup> the foregoing analysis indicates a more progressive approach is needed in order to adequately address the complex legal and technological issues posed by contemporary surgical robotics.

Part III argues that although the court in *Mracek* applied a legal standard that aligns with existing malfunction theory jurisprudence, a new standard is needed in the field of surgical robotics. Section A begins by proposing that state courts should adopt a new malfunction theory incorporating the use of circumstantial evidence and a rebuttable presumption, and further explains how the proposed doctrine incorporates the ideals that prompted historic changes in products liability law into twenty-first century surgical robotics products liability. Section B frames some of the practical concerns surrounding the proposed theory, then argues the proposed doctrine best furthers sound legal policies and technological improvements in the field of surgical robotics. Finally, Section C applies the proposed doctrine to the facts of *Mracek* and opines as to how the case may have come out using the new approach to products liability law.

A. FROM PAST TO PRESENT: A NEW MALFUNCTION THEORY FOR SURGICAL ROBOTICS WHICH USES CIRCUMSTANTIAL EVIDENCE AND AFFORDS A REBUTTABLE PRESUMPTION

Although the court in *Mracek* articulated a formulation of the malfunction theory that aligns with existing jurisprudence,<sup>238</sup> an examination of the differences between the district court and Third Circuit's analysis illustrates this area of law still remains unclear.<sup>239</sup> As a result, this Note proposes that state

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237. See generally *supra* Part I.B. (discussing the advent of proving a product defect through circumstantial evidence, and the influence of the *Restatement (Third) of Torts: Products Liability*).

238. See *Mracek v. Bryn Mawr Hosp.*, 610 F. Supp. 2d 401, 408 (E.D. Pa. 2009), *aff'd*, 363 F. App'x 925 (3d Cir. 2010). (defining the malfunction theory as permitting "a plaintiff to prove a defect through circumstantial evidence. Plaintiff may raise a supportable inference of defect through: (1) evidence of the occurrence of a malfunction; (2) evidence eliminating abnormal use; and (3) evidence eliminating reasonable secondary causes for the accident").

239. As this Note indicates, complexities surrounding surgical robotics, physician-to-patient interaction, and the nature of the human body, combined with difficult evidentiary determinations surrounding whether product defects are attributable to medical device manufacturers, healthcare providers, attending

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courts should adopt a new malfunction theory in the field of surgical robotics, which addresses the issues posed by technological advances, in light of the underlying social policies that have historically influenced products liability law.

1. State Courts Should Adopt a New Burden Shifting Mechanism to the Malfunction Theory that Permits the Use of Circumstantial Evidence and Affords a Rebuttable Presumption

This Note proposes that, in applying the malfunction theory of products liability to surgical robotics, state courts should permit a factfinder to infer a product defect through the occurrence of a malfunction in the absence of abnormal use and afford a rebuttable presumption that there were no reasonable secondary causes of the malfunction. Ultimately, the proposed doctrine adopts much of the existing jurisprudential framework surrounding the malfunction theory of products liability; however, it proposes that state courts should adopt a burden shifting mechanism in surgical robotics cases. Although several alternatives exist that could effectuate such change, including the Supreme Court interpreting the proposed theory as representing a “parallel claim”<sup>240</sup> to existing post-market requirements,<sup>241</sup> a model statute that adopts the proposed doctrine, or a modification to the *Restatement (Third) of Torts: Products Liability*,<sup>242</sup>

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physicians, and/or patients, has led courts to formulate different interpretations of the malfunction theory and different evidentiary requirements. See *supra* Part II.B.2. Compare *Mracek v. Bryn Mawr Hosp.*, 363 F. App’x 925 (focusing primarily on the plaintiff’s inability to prove the causation element), with *Mracek*, 610 F. Supp. 2d at 408 (focusing primarily on the plaintiff’s inability to eliminate reasonable secondary causes of the malfunction).

240. See CONG. RESEARCH SERV., *supra* note 233 (noting the Court has stated “parallel claims,” which parallel existing federal regulations rather than add to them, include those that provide for “damages remedy;” however, the Court has yet to definitively outline alternative “parallel claims” that survive federal preemption). Some federal courts have held that state claims surrounding violations of the Medical Device Amendments of 1976 that occur outside of the premarket approval process are not preempted by federal regulations; however, other courts have addressed the same issue and come to varying conclusions. *Id.* at 23.

241. See *generally id.* (noting that once approved for marketing, manufacturers of medical devices must comply with various regulations on labeling and advertising, manufacturing, and post-marketing surveillance).

242. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. (AM. LAW INST. 1998).

given the malfunction theory's diverse jurisprudential framework, and because products liability is ultimately a matter of state tort law, this Note recommends state courts should progressively adopt the proposed theory. In doing so, state courts will act to test the viability of the proposed theory on a small scale, allowing for doctrinal modifications or refinements, which may ultimately spur more expansive federal, legislative, or treatise changes.

Much like existing malfunction theory jurisprudence, the proposed theory does not relieve a plaintiff of the burden of proving all the elements of a product liability claim.<sup>243</sup> Rather, it permits the factfinder to infer a product defect attributable to the manufacturer through circumstantial evidence.<sup>244</sup> Moreover, similar to malfunction theory jurisprudence, before a case is permitted to go to the jury, the court must be satisfied the plaintiff's evidence is sufficient to establish the probability, and not the mere possibility, that the plaintiff's injury resulted from a product defect attributable to the manufacturer.<sup>245</sup>

However, unlike existing malfunction theory jurisprudence, and § 3 of *Restatement (Third) of Torts*,<sup>246</sup> the proposed theory permits the factfinder to infer a product defect merely from the occurrence of a malfunction in the absence of abnormal use. It does not require that a plaintiff eliminate reasonable secondary causes,<sup>247</sup> nor prove "the incident . . . was not . . . solely the result of causes other than product defect existing at the time of sale or distribution."<sup>248</sup> Rather, it requires that a robot manufacturer demonstrate the existence of a specified secondary cause, either through direct evidence or the "totality of the circumstances" approach.<sup>249</sup>

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243. See *Metro. Prop. & Cas. Ins. Co. v. Deere & Co.*, 25 A.3d 571, 579–81 (Conn. 2011) (reciting the elements of a products liability claim, and quoting RESTATEMENT (SECOND) OF TORTS § 402A).

244. See *id.* at 580 (noting that the malfunction theory allows the jury to infer the existence of a defect using circumstantial evidence).

245. *Id.* at 583.

246. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 3.

247. See *Mracek v. Bryn Mawr Hosp.*, 610 F. Supp. 2d 401, 408 (E.D. Pa. 2009), *aff'd*, 363 F. App'x 925 (3d Cir. 2010) (allowing a plaintiff to raise a supportable inference of defect through, inter alia, evidence eliminating reasonable secondary causes for the accident).

248. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 3.

249. See *Metro. Prop.*, 25 A.3d at 584 (stating that another approach to the malfunction theory is to permit a plaintiff to establish a product defect through



## 2. The Proposed Malfunction Theory Integrates the Same Ideals that Induced Historic Changes in Products Liability Law into Modern Surgical Robotics

Similar to the changes in products liability law that resulted from the advances of the first Industrial Revolution,<sup>250</sup> the proposed malfunction theory incorporates the ideals that influenced the evolution of historic doctrinal developments into today's surgical robotic products liability law.

Much like the industrial changes in the late 1800s that led U.S. courts to transition from caveat emptor to recognizing implied warranties of merchantability,<sup>251</sup> the exponential growth of robotic technology in the twenty-first century necessitates the balance between technological growth and consumer safety weigh more in favor of consumers. Analogous to the way U.S. courts gradually prioritized consumer safety and reduced the doctrinal burdens placed on consumers,<sup>252</sup> the proposed theory reduces the burden placed on innocent patients by affording a rebuttable presumption that there were no reasonable secondary causes of a robotic malfunction.

Similarly, much like the industrial advances of the nineteenth century that led the court in *MacPherson* to diverge from its general rule of privity framework,<sup>253</sup> advances in surgical robotics, combined with the innate complexities of human-robot interactions, medical procedures, and the nature of the human body, demand that end patients be afforded greater protection from the inherent dangers of surgical robots.<sup>254</sup> Analogous to the

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evidence of “(1) the history and use of the particular product, (2) the manner in which the product malfunctioned, (3) similar malfunctions in similar products that may negate the possibility of other causes, (4) the age of the product in relation to its life expectancy, and (5) the most likely other causes”.

250. See *generally supra* Parts I.A.2–3. (illustrating how the industrial revolution influenced not only society, but products liability law).

251. See *generally supra* Part I.A.1 (illustrating how expansive industrial changes and consumer's naiveté led to doctrinal changes in U.S. products liability law that favored consumer safety).

252. In the late 1800s, U.S. courts exhibited a modest shift toward consumer safety by recognizing implied warranties in products liability cases. See *supra* Part I.A.1.

253. *MacPherson v. Buick Motor Co.*, 111 N.E. 1050 (1916). Throughout the 1900s, the rise of mass production, introduction of intermediaries into supply chain, and expansion of advertising placed a distance between the makers and users of products; thus, courts gradually adopted more progressive attitudes toward products liability cases. See *supra* Part I.A.2.

254. In the decades following *Winterbottom*, U.S. courts slowly began to

way the court in *MacPherson* sought to afford additional protection to those that were foreseeably expected to suffer an injury as a result of a defective product,<sup>255</sup> the proposed doctrine employs a rebuttable presumption, which lessens the burden on patients, so as to afford increased protection to end patients who may foreseeably suffer as a result of a defective robot.

In addition, much like the commercial transformations of the mid-1900s that spurred the development of strict products liability,<sup>256</sup> recent advances in the healthcare industry have created an equally attenuated divide between surgical robot manufacturers and end patients who are subject to a robot's use. Comparable to William Prosser's views throughout the 1900s,<sup>257</sup> social policy demands that surgical robot manufacturers, not innocent end patients, should bear greater responsibility for accidental injuries caused by robots. In light of Prosser's concerns surrounding the social implications of placing excessive burdens on product users, the proposed theory affords those that are "entitled to the maximum of protection," innocent end patients, increased protection by shifting more of the onus back to those that are "practically and morally, the one[s] to provide it," surgical robot manufacturers.<sup>258</sup>

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grant exceptions to the general rule of privity. Initially, courts granted exceptions in cases involving products that were imminently or inherently dangerous, then in cases where sellers knew a product was inherently dangerous but failed to disclose the danger to an unknowing buyer. *See supra* Part I.A.2. (citing *Winterbottom v. Wright*, (1842) 152 Eng. Rep. 402).

255. *See generally supra* Part I.A.2. (explaining how *MacPherson* expanded the general rule of privity's inherently dangerous product exception to include things "that [are] reasonably certain to place life and limb in peril when negligently made," which opened the courtroom to anyone foreseeably expected to suffer an injury as a result of a defective product (quoting *MacPherson*, 111 N.E. at 1053)).

256. Throughout the 1900s, the rise of mass production, introduction of intermediaries into the supply chain, and expansion of advertising placed a distance between the makers and users of products; thus, courts gradually adopted more progressive attitudes toward products liability cases. *See supra* Part I.A.2.

257. It was "an increased feeling that social policy demands that the burden of accidental injuries caused by defective chattels be placed upon the producer" that led William Prosser to propose the idea of imposing strict products liability in tort law, rather than theories grounded in contract law, implied warranties, or negligence. *See PROSSER, supra* note 61, at 689; *supra* Part I.A.3.

258. PROSSER, *supra* note 61; *see also supra* Part I.A.3.

Finally, much like the equitable concerns that inspired courts in the late-1900s to extend strict products liability protection to third-party bystanders,<sup>259</sup> the proposed theory aims to “provide greater protection” to innocent, bystander-esque patients by shifting the burden of demonstrating a reasonable secondary cause to those that have the greatest opportunity to inspect surgical robots for defects: robot manufacturers.

B. THE NEW MALFUNCTION THEORY: PRACTICAL CONCERNS AND WHY THE NEW DOCTRINE BETTER FURTHERS SOUND LEGAL POLICIES AND TECHNOLOGICAL ADVANCES IN THE FIELD OF SURGICAL ROBOTICS

Although the proposed malfunction theory contemplates many of the same social concerns that influenced historic developments in products liability law, it is important to recognize that these developments did not occur without resistance.<sup>260</sup> As a result, this Section aims to address some of the concerns surrounding the proposed theory, and argues the proposed doctrine best promotes the underlying principles of the malfunction theory and the strict products liability doctrines, as well as clinical and technological advances in the field of surgical robotics.

1. Manufacturers of Surgical Robots Would Not Turn into Insurers, but Rather, Responsible Manufacturers

One of the most prominent concerns surrounding a broad application of the malfunction theory, and analogously the proposed theory’s burden shifting mechanism, is the concern that “broad application . . . may have the effect of converting product sellers into ‘insurers.’”<sup>261</sup> This contention is rooted in the risk spreading theory of products liability, which purports that if courts impose liability on manufacturers for a broader range of

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259. As this Note indicates, bystanders are entitled to greater protection than consumers or users since the consumer and users have at least the opportunity to inspect for defects and to limit their purchases to articles that are manufactured by reputable manufacturers and sold by reputable dealers, whereas a bystander ordinarily has no such opportunity. *Elmore v. Am. Motors Corp.*, 451 P.2d 84, 89 (Cal. 1969) (en banc); *supra* Part I.A.3.

260. See generally William L. Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1099 (1960) (quoting Chief Justice Cardozo who stated “[t]he assault upon the citadel of privity is proceeding in these days apace” and commenting that in the thirty years that followed a good part of the citadel held out, despite the continued assault).

261. Raymond & Allen, *supra* note 85, at 302.

product injuries, manufacturers will in turn increase the price of products so as to spread the cost of losses to the purchasers.<sup>262</sup> Although this concern may ultimately have some validity on the whole,<sup>263</sup> and in some industries expansive liability and subsequent risk-spreading measures may adversely affect consumers,<sup>264</sup> in the field of surgical robotics, this proposition is largely inappropriate. Instead, the proposed theory would likely result in surgical robot manufacturers being held more responsible for injuries caused by defective devices.

More specifically, in light of the healthcare industry's recent adoption of value-based purchasing methods, which reward hospitals with incentive payments based on the quality of care that is provided,<sup>265</sup> and the advent of risk-based contracting between device manufacturers and healthcare providers, which contractually allocate more financial risk to manufacturers who do not satisfy certain performance or clinical outcomes,<sup>266</sup> surgical robot manufacturers are significantly hindered, either commercially or contractually, in their ability to "spread risk" to end patients. Unlike other industries where there is a quantitatively higher likelihood of products liability cases and where expansive liability could realistically turn wholesale manufacturers into product insurers,<sup>267</sup> the ALI has indicated that indeterminate

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262. Cochran, *supra* note 165, at 705.

263. See, e.g., Prosser, *supra* note 260, at 1110–11 (indicating courts were hesitant to apply the doctrine of strict liability to certain industries, including tires, pumps, insecticides, and lumber).

264. See Cochran, *supra* note 165, at 705–06 (noting second-order effects that negatively impact consumer choice, including the possibility of manufacturers withdrawing products from the market that are not profitable, or adding significant "insurance premiums" to product prices that would disproportionately affect low income consumers).

265. See Scott Hodgin, *Value-Based Purchasing: What Is It?*, TXCIN (May 7, 2018), <http://www.insight-txcin.org/post/what-is-value-based-purchasing> [<https://perma.cc/KNX6-Z6ZU>] (describing value-based purchasing as a purchasing approach that assesses annual device and system purchasing based on clinical outcomes).

266. See Jaimy Lee, *Devicemakers Explore Risk Contracts with Hospitals*, MOD. HEALTHCARE (Dec. 6, 2014), <https://www.modernhealthcare.com/article/20141206/MAGAZINE/312069964/devicemakers-explore-risk-contracts-with-hospitals> [<https://perma.cc/4CJ2-WCLA>] (discussing the trend in the healthcare industry for large medical device companies to explore risk-based deals).

267. See Prosser, *supra* note 260, at 1110–11 (noting industries where courts were hesitant to apply strict liability out of economic concerns).

product defect cases represent a “small number of cases.”<sup>268</sup> Research shows medical device and surgical robotics cases represent an even smaller number of those cases.<sup>269</sup> As a result, in the presently emerging field of surgical robotics, where commercial and contractual limitations obviate risk spreading, and the number of products liability cases is minimal, the contention that broad application of the proposed malfunction theory would have the effect of converting surgical robot manufacturers into insurers is likely inaccurate.

Rather, more appropriately, it is important to remember that from a law and public policy perspective, courts and commentators have repeatedly emphasized that the underlying purpose of strict products liability 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.”<sup>270</sup> Given this understanding, circumstantial evidence and the malfunction theory have historically functioned as ways for plaintiffs to offer evidence of a product defect,<sup>271</sup> so as to ensure that manufacturers bear more responsibility associated with product malfunctions. As cases like *Lindsay* and *Stewart*<sup>272</sup> illustrate, in situations where remote users are “powerless” to guarantee the maintenance and/or safety of the products they use, a broad application of the malfunction theory effectively furthers the underlying purpose of strict liability by ensuring that more responsibility is borne by the manufacturer. Unfortunately, as recent medical device cases like *Bowman*, *Moeller*, and *Mracek*<sup>273</sup> indicate, a narrow application of the malfunction theory, combined

268. *Thursday Morning Session – May 18, 1995*, *supra* note 93.

269. See *supra* Part II.B. (noting the case law regarding the applicability of the malfunction theory to medical device cases is limited); see also *supra* Part II.B.2. (discussing the only case surrounding the applicability of the malfunction theory to surgical robotics).

270. *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1963); see also *Prosser*, *supra* note 260, at 1122–24.

271. *Menage*, *supra* note 83, at 379.

272. See *supra* Part II.A. (citing *Lindsay v. McDonnell Douglas Aircraft Corp.*, 460 F.2d 634 (8th Cir. 1972); *Stewart v. Budget Rent-A-Car Corp.*, 470 P.2d 240 (Haw. 1970)).

273. See *supra* Part II.B. (citing *Mracek v. Bryn Mawr Hosp.*, 610 F. Supp. 2d 401 (E.D. Pa. 2009), *aff'd*, 363 Fed. App'x. 925 (3d Cir. 2010); *Bowman v. Am. Med. Sys., Inc.*, No. CIV. A. 96–7871, 1998 WL 721079 (E.D. Pa. Oct. 9, 1998); *Moeller v. Danek Med., Inc.*, No. CIV. A. 94–967, 1997 WL 1039333 (W.D. Pa. Dec. 1, 1997), *aff'd*, 166 F.3d 1205 (3d Cir. 1998)).

with the inherently difficult evidentiary determinations surrounding whether medical device defects and resulting injuries are attributable to device manufacturers, healthcare providers, attending physicians, and/or patients, inevitably leaves end patients to bear the devastating costs of medical device malfunctions.<sup>274</sup> As a result, unlike in other industries, the complexities surrounding surgical robotics, physician-patient interactions, and the nature of the human body necessitate that the malfunction theory be reevaluated in light of the underlying purpose of strict products liability. In furtherance of this purpose, the proposed theory's burden shifting mechanism effectively shifts more of the equitable and social costs, as well as responsibility, associated with malfunctions away from those that are "powerless to protect themselves," end patients, and back to those "that put such products on the market," surgical robot manufacturers.<sup>275</sup> After all, as the Eighth Circuit has stated, there would be "little to gain to the consuming public if the courts would establish a form of recovery with one hand and take it away with the other by establishing impossible standards of proof."<sup>276</sup>

## 2. The Proposed Doctrine Would Not Deter Technological Advances nor Adoption but Rather Would Ensure Safe Advances and Safe Adoptions

Another concern surrounding broad application of the malfunction theory and analogously the proposed theory's burden shifting mechanism is that broad application would deter experimental and technological advances, as well as clinical adoption. Although these contentions may be founded on realistic concerns,<sup>277</sup> in light of the healthcare industry's existing standards

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274. See *Mracek*, 610 F. Supp. 2d at 408 (granting summary judgment against the patient for failure to eliminate reasonable secondary causes for a surgical robot malfunction during a prostatectomy).

275. *Greenman*, 377 P.2d at 901.

276. *Lindsay*, 460 F.2d at 639.

277. See, e.g., David R. Geiger, *Federal Court Holds Manufacturer of Investigational Drug and Medical Device Responsible for Clinical Trial Investigator's Allegedly Inadequate Informed Consent Form*, FOLEY HOAG (July 16, 2014), <https://foleyhoag.com/publications/alerts-and-updates/2014/july/manufacturer-of-investigational-drug-and-medical-device-responsible-for-clinical-trial> [<https://perma.cc/K4XS-DSAG>] (noting the U.S. District Court of Massachusetts refused to dismiss a suit against the manufacturer of an investigational drug based on allegedly inadequate warnings the trial investigator provided to patients).

and safeguards, combined with the advent of value-based purchasing and risk-based contracts,<sup>278</sup> a heightened risk of liability to manufacturers under the proposed theory would act to ensure, not deter, safe advances and adoption of surgical robotics.

As a general framework, over the past several decades the FDA has established an expansive set of regulations surrounding the safety and effectiveness of medical devices in the United States.<sup>279</sup> For certain devices,<sup>280</sup> like surgical robots, the FDA has determined general controls are insufficient and require the “most stringent” approval processes.<sup>281</sup> The FDA has recognized that certain devices “present a potential, unreasonable risk of illness or injury,”<sup>282</sup> and impose stricter premarket approval<sup>283</sup> and post-market review<sup>284</sup> requirements on device manufacturers.

In light of these existing regulations and contractual arrangements, the contention that the proposed doctrine would deter technological advances is likely inappropriate. To begin, the proposed doctrine would not impose any additional premarket

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278. See Hodgin, *supra* note 265; see also Lee, *supra* note 266.

279. See *Overview of Device Regulation*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation> [<https://perma.cc/64MM-ZK7U>] (outlining regulatory requirements for medical devices distributed in the United States).

280. See *Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma> [<https://perma.cc/VD3X-VM7L>] (noting Class III devices are those which support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury).

281. *Id.*

282. See *id.* (defining Class III medical devices).

283. See *Overview of Device Regulation*, *supra* note 279 (outlining the FDA approval process); see also CONG. RESEARCH SERV., *supra* note 233 (noting the premarket approval process is often described as rigorous and time-consuming, requiring submissions to the FDA of information regarding proposed labeling, reports of information concerning investigations which have been made to show whether or not the device is safe and effective, a description of the manufacturing processes and methods, samples of the device and its components, and information regarding the components, ingredients, and operating principles of the device).

284. See JUDITH A. JOHNSON, CONG. RESEARCH SERV., R42130, FDA REGULATION OF MEDICAL DEVICES (2016), <https://fas.org/sgp/crs/misc/R42130.pdf> [<https://perma.cc/8UQ5-3T2S>] (noting the medical device post-market surveillance system includes medical device reporting, post-approval studies, post-market surveillance studies, and FDA discretionary studies).

restrictions on device researchers or manufacturers.<sup>285</sup> Rather, the proposed doctrine would merely shift the burden to the manufacturer during the post-market stage and impose an obligation on the manufacturer to demonstrate the device remained compliant with the FDA's preexisting regulations. In addition, given recent trends in the healthcare industry toward value-based purchasing and risk-based agreements, which aim to foster transparency between device manufacturers and healthcare providers regarding clinical outcomes<sup>286</sup> and post-market device performance,<sup>287</sup> the proposed theory's burden shifting mechanism would supplement existing contractual frameworks, induce more intra-industry transparency during the post-market stage, and promote more informed second-generation device research and development. As a result, in cases like *Mracek*<sup>288</sup> the proposed theory would not only impose on "the manufacturers . . . rather than the injured persons"<sup>289</sup> the burden of demonstrating the existence of a specific reasonable secondary cause, but also the tangential burden of demonstrating compliance with the FDA's post-market requirements.<sup>290</sup> In such cases, which involve numerous physician-robot and physician-patient interactions, the robot manufacturer would be most likely to provide evidence surrounding the history and use of the robot, the manner in which it malfunctioned, whether there have been similar malfunctions in the same or similar robots, and/or the age of the robot in relation to its life expectancy,<sup>291</sup> as well as evidence sur-

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285. As this Note recognizes, in light of the Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), many lower courts have often concluded that consumers of Class III medical devices are prevented from suing device manufacturers on state common law claims if the device receives pre-market approval. See CONG. RESEARCH SERV., *supra* note 233. However, it can be argued that strict products liability claims are "parallel" to, rather than in addition to, federal requirements surrounding post-market compliance with FDA regulations, an issue the Supreme Court has yet to decide.

286. See Hodgin, *supra* note 265.

287. See Lee, *supra* note 266.

288. See *supra* Part II.B. (citing *Mracek v. Bryn Mawr Hosp.*, 610 F. Supp. 2d 401 (E.D. Pa. 2009), *aff'd*, 363 F. App'x 925 (3d Cir. 2010)).

289. *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1963).

290. See *supra* note 285 and accompanying text.

291. See *Metro. Prop. & Cas. Ins. Co. v. Deere & Co.*, 25 A.3d 571, 583–85 (Conn. 2011) (discussing an approach to establishing liability under malfunction theory and the factors that can be used to infer a product defect through the "totality of the circumstances").



rounding the conduct of the healthcare provider and/or attending physicians. This evidence, both qualitatively and quantitatively, is likely to be more exhaustive and more informative than evidence offered by an injured patient. Thus, ultimately the proposed theory's burden shifting mechanism would likely result in more valuable evidence surrounding a surgical robot malfunction, which would likely not deter technological advances, but rather foster intra-industry transparency regarding post-market device performance and encourage more informed device research and development.

Similarly, in light of the FDA's extensive premarket and post-market safety standards,<sup>292</sup> the clinical and social advantages of minimally invasive surgery touted by surgical robot manufacturers,<sup>293</sup> and the minute number of surgical robotics cases,<sup>294</sup> the contention that the proposed doctrine's heightened risk of liability has the potential to deter clinical adoption is also likely improper. With the understanding that the proposed doctrine acts as a safeguard to ensure manufacturers market surgical robots that comply with the FDA's post-market requirements, the proposed theory in essence acts to ensure that healthcare providers purchase robots that are safe, effective, and remain FDA compliant. Moreover, in light of the rise of value-based purchasing<sup>295</sup> and risk-based contracts,<sup>296</sup> the proposed theory would also act to alleviate healthcare providers of some of the additional risks associated with adopting new robotic techniques. For example, in cases like *Mracek*<sup>297</sup> the proposed doctrine would require that those with the most knowledge of the robotic system, the manufacturer, not the injured patient, pro-

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292. See *Premarket Approval (PMA)*, *supra* note 280 (discussing how premarket approval requires extensive clinical data and trials).

293. See *supra* Part I.C.2. (highlighting the clinical advantages offered by the daVinci surgical system through streamlined platforms, smaller instrumentation, and remote telemonitoring).

294. See *supra* Part III.B.1. (discussing how surgical robotics cases represent a limited number of indeterminate products liability cases).

295. See Hodgin, *supra* note 265 (discussing value-based purchasing in the healthcare industry based on device value and clinical outcomes).

296. See Lee, *supra* note 266 (discussing the advent of risk-based contracts between medical device manufacturers and healthcare providers).

297. See *supra* Part II.B.

vide sufficient evidence to demonstrate that the post-market device was not in fact defective,<sup>298</sup> or alternatively, that another secondary cause was responsible for the malfunction. In such cases, the manufacturer would likely present evidence surrounding the history and use of the robot, similar malfunctions in similar robots, and the manner in which the robot malfunctioned,<sup>299</sup> which may alleviate healthcare providers of the costs and liabilities associated with a malfunction under preexisting risk-based agreements. Similarly, in cases like *Bowman*, where spoliation of evidence relieves the manufacturer of liability,<sup>300</sup> the proposed theory would shift the burden of demonstrating a reasonable secondary cause of the malfunction to the manufacturer, thus, also alleviating healthcare providers of additional costs and liabilities under risk-based agreements. As a result, given the advantages of minimally invasive robotic surgery, combined with the understanding that the proposed doctrine acts to ensure robotic systems are FDA compliant and may alleviate healthcare providers of additional risks associated with adopting new surgical techniques, the proposed theory's burden shifting mechanism will likely not deter, but rather promote safer and more expansive clinical adoption of novel surgical robotic techniques.

### C. A NEW MALFUNCTION THEORY APPLIED TO *MRACEK V. BRYN MAWR HOSPITAL* AND THE FUTURE OF THE DOCTRINE

In applying the proposed theory to the facts of *Mracek*, it is unclear whether the same court would have reached a different outcome, largely because of the limited facts provided in the record. At the district court level, the court's dismissal of Mracek's contention that a defect was "obvious because all of [the robot's] components shut down after repeatedly flashing 'error' messages,"<sup>301</sup> and reliance on Intuitive's general assertion that "[the

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298. This could likely be demonstrated through presenting evidence surrounding manufacturing standards and/or compliance with company policies.

299. See *Metro. Prop. & Cas. Ins. Co. v. Deere & Co.*, 25 A.3d 571, 583–85 (Conn. 2011) (discussing the "totality of the circumstances" approach to demonstrating a product defect and listing factors related to inferring a product defect, including history and use of the particular product, the manner in which the product malfunctioned, similar malfunctions in similar products that negate the possibility of other causes, the age of the product in relation to its life expectancy, and the most likely causes of the malfunction).

300. See *supra* Part II.B.

301. *Mracek v. Bryn Mawr Hosp.*, 610 F. Supp. 2d 401, 405 (E.D. Pa. 2009), *aff'd*, 363 F. App'x 925 (3d Cir. 2010).

surgery was] a matter of complex surgical innovation . . . [and] any number of reasonable secondary causes could or were responsible for the alleged damages,”<sup>302</sup> would likely have been insufficient grounds to grant summary judgment. In affording Mracek a rebuttable presumption that there were no reasonable secondary causes of the malfunction, the district court would have required that Intuitive submit additional evidence to demonstrate a specified reasonable secondary cause did in fact exist. In doing so, Intuitive would have likely been forced to introduce evidence surrounding the history and use of the daVinci robot, the manner in which the robot malfunctioned, similar malfunctions in similar daVinci products, the age of the robot in relation to its life expectancy, and/or had to have opined to the most likely cause of the malfunction.<sup>303</sup> As a result, the district court would have acquired additional valuable evidence surrounding the daVinci malfunction. If the court could not determine it was “more probable than not” that the malfunction could “fairly be attributed” to some other secondary cause not attributable to Intuitive, summary judgment would not have been proper.<sup>304</sup>

Interestingly, the Third Circuit did not specifically address the issue of whether reasonable secondary causes existed; rather, the court relied heavily on the insufficiency of the evidence to “permit a jury to infer [Mracek’s injuries] were caused by the robot’s alleged malfunction.”<sup>305</sup> As is often the situation in surgical cases, the complexities surrounding medical devices, physician-patient interactions, and the nature of the human body make proving causation difficult. However, in applying the proposed doctrine to the facts of *Mracek*, Intuitive would likely have had to submit additional evidence at the district court level surrounding the existence of reasonable secondary causes of the malfunction. Compared to *Mracek*, Intuitive would have been more likely to submit evidence surrounding the history of the robot itself, as well as the conduct of the healthcare provider

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302. *See id.* at 408.

303. *See Metro. Prop.*, 25 A.3d at 583–85 (discussing the “totality of the circumstances” approach to the malfunction theory and outlining factors that can be used to infer a product defect).

304. *See id.* at 589.

305. *See Mracek v. Bryn Mawr Hosp.*, 363 F. App’x at 927 (stating merely that summary judgment was proper because the plaintiff failed to demonstrate a genuine issue of material fact).

and/or the opinions of the attending physician. This evidence would have provided, both quantitatively and qualitatively, more evidence surrounding not only potential secondary causes of the malfunction but also additional information surrounding the nature of Mracek's injuries and the causation of such injuries.<sup>306</sup>

While it remains unclear whether the results of *Mracek* would have changed under the proposed malfunction theory, it is clear there is a need for fundamental change in products liability law as it applies to the field of telepresence surgical robotics. This Part advises that in assessing products liability cases involving telepresence surgical robotics, state courts should reflect on the history of products liability and the underlying social considerations that led to many of its historic doctrinal developments, and additionally should consider the expansive technological advances of the twenty-first century and how contemporary products liability law is (or is not) addressing the most prevailing issues that society faces. In doing so, this Part recommends that in the field of telepresence surgical robotics, state courts should adopt a rebuttable presumption, holding that when applying the malfunction theory of strict products liability to surgical robotics, a product defect can be inferred from the occurrence of a malfunction in the absence of abnormal use, raising a rebuttable presumption that there were no reasonable secondary causes of the malfunction.

### CONCLUSION

This Note proposes a change in the malfunction theory doctrine of strict products liability as it applies to cases involving surgical robotics. This Note advocates for a more nuanced approach to the malfunction theory, which reflects the underlying considerations, which motivated historic developments in products liability law over the past century. In light of recent advances in computers and robotics, this Note argues that in ap-

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306. The evidence presented in the case was minimal. The plaintiff did not submit expert reports or have expert testimony. As a result, it is difficult to opine how much, if any, additional information would have been received if Intuitive were required to submit additional evidence surrounding secondary cause, and how that would relate to facts surrounding causation. *See Mracek*, 363 F. App'x at 927; *Mracek*, 610 F. Supp. 2d at 408 (illustrating the evidence provided by the plaintiff at trial was minimal).

plying the malfunction theory of products liability to surgical robotics, state courts should infer a product defect from the occurrence of a malfunction in the absence of abnormal use and raise a rebuttable presumption that there were no reasonable secondary causes of the malfunction. Founded on historic developments in products liability law, the proposed theory aims to reduce the burden placed on those that are foreseeably expected to suffer as a result of a defective product, the patient, by shifting the burden to those that are most able to prevent defective robots from reaching the market, the surgical robot manufacturer. While some may contend that such a proposal will have drastic practical implications, due to the limited number of surgical robotics cases, preexisting federal regulations, and the advent of value-based purchasing and risk-based agreements in the healthcare industry. In reality, the proposed doctrine would result in more responsible manufacturers and the adoption of safer surgical robots. Ultimately, the proposed solution aims to bring some clarity to an area of the law that has remained in flux for the past several decades, with the hope that someday a deserving patient will receive their just day in court.