

# TORTS AND INNOVATION

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*This Essay exposes and analyzes a hitherto overlooked cost of tort law: its adverse effect on innovation. Tort liability for negligence, defective products, and medical malpractice is determined by reference to custom. We demonstrate that courts' reliance on custom and conventional technologies as the benchmark of liability chills innovation and distorts its path. Specifically, recourse to custom taxes innovators and subsidizes replicators of conventional technologies. We explore the causes and consequences of this phenomenon and propose two possible ways to modify tort law in order to make it more welcoming to innovation.*

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## INTRODUCTION

Innovation is a key determinant of wellbeing and economic growth.<sup>1</sup> Academic discussions of innovation are typically confined to the domains of patent and trade secret law. This Essay highlights a previously underappreciated connection between innovation and tort law.<sup>2</sup> It seeks to expose and analyze the cost the current design of our tort system imposes on innovation. The main thesis of the Essay is that courts' reliance on customs and conventional technologies as the benchmark for assigning tort liability chills innovation and distorts its path. This reliance taxes innovators and subsidizes users and replicators of conventional technologies.

The centrality of custom to our torts system can best be seen in three main doctrines that make up tort law: negligence, product liability, and medical malpractice. Begin with negligence. In assessing a defendant's conduct, courts presume that a defendant who fails to comply with safety-related customs prevalent in her industry acts negligently. The defendant consequently needs to rebut this presumption, which may in many cases be very difficult to do. Likewise, in product liability, courts turn to custom in determining whether the defendant's product design was defective. Deviation from industry custom, therefore, runs a greater risk of a ruling that the product is unsafe. Finally, in the area of medical malpractice, courts hold doctors to the "customary care" standard. A physician's failure to comply with this standard exposes her to a higher prospect of liability.

In short, custom constitutes the benchmark against which defendants' conduct is evaluated.<sup>3</sup> The law of torts relies on custom not only directly, by associating custom with precautions against harm that a reasonable person ought to take, but also indirectly, through evidentiary rules and presumptions that bolster the centrality of custom to adjudicative determinations of fault.<sup>4</sup> Chief among those rules is the *res ipsa loquitur* presumption that creates a strong evidential association between safety and conventional

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1. See e.g., DAVID WARSH, KNOWLEDGE AND THE WEALTH OF NATIONS: A STORY OF ECONOMIC DISCOVERY (2006) (discussing the importance of innovation to economic growth).

2. This neglect is quite surprising considering the classic "rewards insight" of Steven Shavell & Tanguy van Ypersele, *Rewards versus Intellectual Property Rights*, 44 J.L. & ECON. 525 (2001). Shavell and van Ypersele have established that, under certain conditions, paying innovators for their inventions would promote the incentive to innovate in a socially much better way than giving innovators intellectual property rights. This insight calls for elimination of any *negative* rewards that innovators receive from the legal system, and rules of tort liability skewed against innovators constitute a negative reward. See generally STEVEN SHAVELL, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW 177–99 (2004) (demonstrating how overbroad liability rules chill socially beneficial activities).

3. See *infra* Part I.

4. Courts' decisions about negligence routinely rely on proxies and evidentiary devices that include custom, the *res ipsa loquitur* rule, and accepted expert opinion. See, e.g., *Twyman v. Twyman*, 855 S.W.2d 619, 633 (Tex. 1993) (Hecht, J., concurring and dissenting) ("The issue of negligence is seldom decided without guidance from some external source: custom, relevant statutes and regulations, evidentiary doctrines such as *res ipsa loquitur*, or expert testimony on alternatives." (quoting Daniel Givelber, *The Right to Minimum Social Decency and the Limits of Evenhandedness: Intentional Infliction of Emotional Distress by Outrageous Conduct*, 82 COLUM. L. REV. 42, 56 (1982))).

precautions against harm. Under this presumption, an unusual occurrence featuring an infliction of harm by an instrumentality over which the defendant exercised exclusive control prompts an inference that the defendant was negligent.<sup>5</sup> Taking conventional precautions against harm removes the occurrence from the “unusual” category.<sup>6</sup> Failure to take conventional precautions, in contrast, indicates negligence on the part of the defendant not only when she takes no precautions whatsoever, but also when she elects to employ a novel—i.e., unconventional—technology.<sup>7</sup> When *res ipsa* applies, the case goes to trial automatically and the plaintiff is entitled to a jury decision on whether the defendant acted negligently, even when she cannot point to any specific negligent act.<sup>8</sup> The ensuing prospect of losing the case puts the defendant under a serious pressure to settle.

Another rule inimical to innovation is the *Frye* doctrine<sup>9</sup> that controls the admissibility of expert evidence in many state jurisdictions.<sup>10</sup> Under *Frye*, expert testimony that falls outside of scientific or technological consensus is inadmissible as evidence and cannot be presented to fact finders. This evidential incapacitation works against innovators and in favor of users and producers of conventional technologies.

To appreciate the combined effect of these doctrines and rules on innovation, consider the following example.<sup>11</sup> Assume that Jane, a physician, invents a new method of stabilizing the heads of patients who suffer back

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5. See W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 39, at 243 (5th ed. 1984) (“In its inception the [res ipsa loquitur] principle was nothing more than a reasonable conclusion, from the circumstances of an *unusual* accident, that it was probably the defendant’s fault.” (emphasis added)); see also *id.* at 244–48 (explaining that the res ipsa rule applies predominantly to unusual events).

6. See, e.g., *Aderhold v. Lowe’s Home Ctrs., Inc.*, 643 S.E.2d 811 (Ga. Ct. App. 2007) (denying *res ipsa* to a shopper struck by a box that fell from a shelf at a home improvement store). The court noted that “the manner in which the boxes were stacked . . . did not appear to be unusual or dangerous.” *Id.* at 812. For more details see *infra* notes 47–53 and accompanying text.

7. See, e.g., *Hailey v. Otis Elevator Co.*, 636 A.2d 426, 428 (D.C. 1994) (“Given the power of *res ipsa loquitur* to satisfy without further proof the element of negligence and the consequent caution with which it should be applied, we think that where the plaintiff relies upon ‘common knowledge’ to invoke the doctrine, the fact that such events do not ‘ordinarily’ occur ‘without negligence’ must be based upon a *widespread consensus of a common understanding*.” (emphasis added)). For more details see *infra* notes 47–53 and accompanying text.

8. See *infra* notes 47–50 and accompanying text.

9. See *infra* notes 45–46, 57–58 and accompanying text.

10. The *Daubert* Trilogy, *infra* note 60, that applies in federal courts and, with some modifications, in more than half of the states attenuates the anti-innovation bias only slightly. See *infra* text accompanying notes 62–68.

11. This example is based on a true story one of us heard from a practicing physician. See also Edward P. Monico et al., *The Impact Of Evidence-Based Medicine And Evolving Technology On The Standard Of Care In Emergency Medicine*, 3(2) INTERNET J. LAW, HEALTHCARE & ETHICS (2005), <http://www.ispub.com/ostia/index.php?xmlFilePath=journals/ijlhc/vol3n2/evidence.xml> (“[T]he customary [care] standard provides a safe haven for physicians who align themselves with the status quo regardless of whether or not this affiliation reflects the latest medical information. . . . [C]ustom may contribute to the tremendous delay between discovery of effective therapies and their routine use.”). As an example of this phenomenon, Monico et al. cite physicians’ general reluctance to perform ultrasound-guided central venous access—a novel procedure presently depressed by the custom rules. *Id.*

injuries in automobile accidents. Unfortunately, it is not fail-safe: two percent of the accident victims treated with Jane's stabilization method will suffer permanent damage to the spine. Nevertheless, Jane's method is superior to the customary treatment, which injures five percent of the victims. Assume further that the cost of treating patients is the same under both methods. From a social standpoint, it is clear that Jane's method should replace the customary treatment. However, the rules of tort liability will probably prevent this socially beneficial development. Under these rules, physicians using Jane's innovative method will be exposed to a much higher risk of liability than physicians who adhere to the customary method. Indeed, it is quite possible that users of the customary method will successfully fend off all suits against them, whereas adopters of Jane's method will have to compensate the victims in all cases in which the treatment fails. Anticipating this outcome, innovators like Jane may decide in many cases to put their inventive skills to rest and forego their attempts to improve upon conventional wisdom altogether.

The custom-based design of our tort law, especially when coupled with the evidence rules used by courts, subsidizes producers and users of conventional technologies while taxing innovators. Innovation entails three distinct activities: coming up with a viable idea for a new invention, research and development ("R&D"), and commercialization or marketing the invention to the public.<sup>12</sup> Naturally, innovators critically depend on the reaction of the market to their innovation; the market success of a new technology determines the innovator's reward. Failure in the marketplace implies that investments in R&D (and the innovator's opportunity costs) will not be recuperated. As we will show, however, the market's reaction to an innovation is a function not only of the innovation's quality but also of the innovator's expected liability in torts. When an innovator cannot reduce this liability by improving the quality of her innovation, the effect of the law of torts on the incentive to innovate is perverse.

To be sure, we do not argue that tort law stops all innovators dead in their tracks; many innovations are produced even under the current regime. Yet the heightened risk of liability puts a drag on innovation and diverts its path.

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12. We are aware of the possible argument that commercialization is not really part of the inventive process, among other things because it is usually not carried out by innovators. A typical innovator sells her invention to an entrepreneur and exits the scene. However, we chose to include the commercialization stage in the inventive process for two reasons. First, successful commercialization directly influences the return from innovation and thus affects the ex ante incentives to innovate. Second, the commercial success of the invention may bear on its patentability. In deciding whether an invention has satisfied the statutory non-obviousness requirement, courts often rely on the commercial success of the invention on the market. *See, e.g., Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966) ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy."). For criticism, see Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803, 842-52 (1988).

The exact effect on innovation is a function of the magnitude of the necessary investment in R&D and the size of the improvement an innovation represents over existing alternatives. The greater the investment in R&D necessary to produce a certain innovation, the greater is the risk that the innovation will not be produced. By contrast, an innovation that substantially improves upon existing alternatives will likely be produced despite the R&D costs. Either way, the increased liability innovators face raises the total cost of producing innovations and, consequently, the price consumers must pay for new technologies and products that do reach the market.

When R&D costs are moderate or low, innovators may elect to complete the development stage, and when possible, even patent their inventions, because they expect no tort liability at these early stages. Many innovators, however, will stop short of commercializing their inventions because commercialization may lead to liability in torts. This dynamic will leave society with a list of unimplemented inventions—both patented and unpatented.

In addition to chilling innovation, the custom rules skew the direction of technological progress. The heightened risk of liability for tort damages induces innovators to limit their R&D endeavors to the conventional technological frameworks. Instead of focusing upon genuine technological breakthroughs, innovators will strive to produce incremental improvements on customary and conventional technologies.

The distortionary effect of the torts system on innovation may be rectified, however. We propose two possible reforms that achieve this goal. First, policymakers can make tort law more welcoming to innovation by eliminating the privileged status of custom and moving to a pure cost-benefit system. We term this alternative “equalizing down.” Implementation of this reform will free courts from the need to consider custom in determining defendants’ liability and allow them to compare the defendants’ conduct to other alternatives without putting a thumb on the scale. We are aware of the fact that the custom rules produce certain social benefits. Adherence to custom facilitates fact-finding, shields defendants from the juries’ whims and biases, and makes tort adjudication more consistent and predictable.<sup>13</sup> These benefits are capped, however: they can never exceed the total social value produced by all tort suits. On the other hand, the social value of innovation is virtually limitless. One successful innovation in the area of medicine, for instance, may save thousands of lives and alone outweigh the benefits of the custom rules.

Nevertheless, we recognize the fact that some may be wary of a wholesale abolition of the custom rules. For them, we propose a different and arguably more innovative reform: an “equalizing up” approach.<sup>14</sup> Instead of abolishing the custom rules, it is possible to keep them and grant certain innovations, approved by special boards of industry experts, the same privileged status as enjoyed by custom. Adoption of this proposal would require establishing special boards comprised of industry experts,

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13. See *infra* note 16 and sources cited therein; see also *infra* notes 116–119 and accompanying text.

14. See *infra* Section III.B.

who will review the safety of scientific and technological innovations in their relevant areas of expertise. Innovations that successfully pass the review will be placed on a par with conventional technologies and will receive the same deference from courts in tort actions. The review process we propose will be optional (rather than mandatory) and private (rather than state controlled). Implementation of this reform will allow the legal system to unlock much of the value the custom rules currently depress without foregoing the rules' benefits.

Structurally, this Essay unfolds in three parts. Part I demonstrates the centrality of custom rules to the design of our torts system. Part II discusses the perverse effect of custom rules on innovation. Part III proposes two possible reforms to eliminate the anti-innovation bias of tort law and analyzes the relative benefits and costs of each. A short conclusion follows.

### I. THE CENTRAL ROLE OF CUSTOM IN TORT LAW

The law of torts assigns liability for harms individuals inflict on others. Yet not all harms give rise to liability; only those resulting from behavior that falls short of socially acceptable standards will have this effect.<sup>15</sup> In deciding what behavior is socially unacceptable, courts routinely turn to custom.<sup>16</sup> Custom plays a key role in this process.<sup>17</sup>

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15. See DAN B. DOBBS, *THE LAW OF TORTS* § 8, at 12 (2000) (describing tort liability as premised on deviation from acceptable standards); KEETON ET AL., *supra* note 5, § 1, at 6 (same).

16. See KEETON ET AL., *supra* note 5, § 33, at 193–96; James A. Henderson, Jr., *Process Constraint in Tort*, 67 CORNELL L. REV. 901, 924 (1982) (calling courts' resort to customary standards "avoidance by delegation"); James A. Henderson, Jr. & John A. Siliciano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1382 (1994) (explaining and analyzing the "customary care" standard for doctor-patient relationships); Steven Hetcher, *Creating Safe Social Norms in a Dangerous World*, 73 S. CAL. L. REV. 1 (1999); Steven Hetcher, *The Jury's Out: Social Norms' Misunderstood Role in Negligence Law*, 91 GEO. L.J. 633, 646–47 (2003) ("[J]uries do not engage in [abstract cost-benefit analysis], but instead draw from their diverse array of everyday norms and customs when providing concrete substance to the abstract reasonable person standard to render a decision on the issue of negligence."); Fleming James, Jr. & David K. Sigerson, *Particularizing Standards of Conduct in Negligence Trials*, 5 VAND. L. REV. 697, 712–13 (1952) (underscoring the centrality and utility of courts' reliance on custom in determining negligence); Patrick J. Kelley, *Who Decides? Community Safety Conventions at the Heart of Tort Liability*, 38 CLEV. ST. L. REV. 315, 353–63 (1990) (arguing that, instead of relying on cost-benefit analysis, negligence decisions based on the "reasonable person" standard use customs and community norms as a benchmark); Clarence Morris, *Custom and Negligence*, 42 COLUM. L. REV. 1147 (1942) (underscoring the centrality and utility of courts' reliance on custom in determining negligence); David G. Owen, *Proving Negligence in Modern Products Liability Litigation*, 36 ARIZ. ST. L.J. 1003, 1017 (2004) ("[W]hether a person who has caused harm to another acted or failed to act as similar persons customarily act in the same situation goes to the heart of negligence determinations."); Stephen R. Perry, *Responsibility for Outcomes, Risk, and the Law of Torts*, in *PHILOSOPHY AND THE LAW OF TORTS* 72, 113–14 (Gerald J. Postema ed., 2001) (observing that harms that are actionable in torts result from deviations from a customarily accepted level of risk); David A. Urban, Comment, *Custom's Proper Role in Strict Products Liability Actions Based on Design Defect*, 38 UCLA L. REV. 439, 440 (1990) (criticizing California courts' departure from the generally accepted custom-based ascertainment of product defects for leaving judges and juries "in a vacuum"). *But see* Richard A. Epstein, *The Path to The T.J. Hooper: The Theory and History of Custom in the Law of Tort*, 21 J. LEGAL STUD. 1 (1992) (criticizing modern courts' tendency to place cost-benefit analysis ahead of custom in ascribing liability in torts).

17. See DOBBS, *supra* note 15, § 164, at 396; KEETON ET AL., *supra* note 5, § 33, at 193–96.

The centrality of custom in our torts system is most readily apparent in negligence cases, where courts associate defendants' failure to comply with relevant industry customs with negligence. Similarly, in the area of product liability, courts turn to custom in evaluating the safety of defendants' products: deviation from industry customs constitutes evidence that the defendant's product was unsafe. Finally, in medical malpractice suits, courts use "customary care" as the standard of care physicians are expected to follow when treating their patients. Provision of noncustomary care exposes physicians to a heightened prospect of liability.

Conversely, a defendant's compliance with custom substantially increases her chances to defend against negligence and defective-product allegations. In the medical malpractice area, a doctor's compliance with the "customary care" standard is virtually certain to defeat the action. Customary compliance thus separates between two categories of defendants who cause damage to another person. Defendants who violate custom are very likely to assume liability in torts; defendants who comply with custom will likely go scot-free.

The remainder of this Part analyzes the rules that establish the centrality of custom in the law of torts. We address both the substantive doctrines of liability and the evidence rules employed by courts.

#### A. Custom and Liability for Negligence

Under general negligence doctrine, failure to comply with relevant industry customs indicates that a defendant acted negligently.<sup>18</sup> In the Restatement's words, "[i]n determining whether conduct is negligent, the customs of the community, or of others under like circumstances, are factors to be taken into account, but are not controlling where a reasonable man would not follow them."<sup>19</sup> Accordingly, a defendant's deviation from the relevant industry custom constitutes evidence that she acted negligently. Although this finding, on its own, is not supposed to be dispositive and may be countered by the defendant,<sup>20</sup> as a *practical* matter, noncompliance with

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18. See DOBBS, *supra* note 15, § 164, at 397.

19. RESTATEMENT (SECOND) OF TORTS § 295A (1965); see also FED. R. EVID. 406 (customs and routine practices admissible as evidence to prove action in conformity).

20. The comments to the Restatement clarify the relevance of custom:

If the actor does what others do under like circumstances, there is at least a possible inference that he is conforming to the community standard of reasonable conduct; and if he does not do what others do, there is a possible inference that he is not so conforming. . . . [W]here there is nothing in the situation or in common experience to lead to the contrary conclusion, this inference may be so strong as to call for a directed verdict, one way or the other, on the issue of negligence.

RESTATEMENT (SECOND) OF TORTS § 295A cmt. b. The Restatement further notes that "[a]ny such custom is . . . not necessarily conclusive . . . . Customs which are entirely reasonable under the ordinary circumstances which give rise to them may become quite unreasonable in the light of a single fact in the particular case." *Id.* § 295A cmt. c.

custom often dooms defendants.<sup>21</sup> Thus, in the absence of proof to the contrary, evidence of the defendant's failure to comply with the relevant industrial custom allows the judge to give a directed verdict on the issue of negligence.<sup>22</sup>

Consider the following example.<sup>23</sup> A train passenger slips into the gap between the platform and the train and suffers serious injuries to her leg. The platform's design is customary. The passenger sues the company that owns both the train and the station for negligent operation and maintenance of the station. She produces expert testimony that the company could enhance the passengers' safety at a low cost by making the gap narrower than it was.<sup>24</sup> Will the passenger prevail? On these facts, the answer is no. The expert testimony carries no weight when it challenges the customary design of rapid transit systems, with which the company had conformed. To succeed in her lawsuit, the passenger would need to establish that this industry-wide custom was unreasonably dangerous. A mere showing of a potentially safer alternative to the custom will not do,<sup>25</sup> especially when the station, used by about three million passengers, had experienced only two similar accidents in the past.<sup>26</sup>

Courts' adherence to custom is predicated on the assumption that what is ordinarily done by actors engaged in a similar activity is what an ordinarily careful actor should do under the same circumstances.<sup>27</sup> Specifically, customs are believed to reflect the conventional assessment of the risks of harm that a given set of circumstances involves, the precautions ordinarily taken to meet those risks, the feasibility of those precautions relative to alternatives, the actor's ability to have all this information, and, finally, the general expectation that he and others will follow the conventional wisdom.<sup>28</sup>

Defeating a defendant's evidence of customary compliance is, indeed, extremely difficult.<sup>29</sup> The plaintiff may overcome custom by showing that

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21. This practice has an obvious explanation: custom integrates the conventional wisdom—a decisional shortcut which is both easy and sensible to apply without generating much controversy over the court's decision. *See* DOBBS, *supra* note 15, § 164, at 395–96; KEETON ET AL., *supra* note 5, § 33, at 193–94.

22. *See* RESTATEMENT (SECOND) OF TORTS § 295A cmt. b; *see also* Owen, *supra* note 16, at 1038 (“A defendant's violation of a relevant safety standard set . . . by the defendant's industry by custom . . . ordinarily will go far in proving a plaintiff's negligence claim.”).

23. This example is adapted from *Sledd v. Washington Metropolitan Area Transit Authority*, 439 A.2d 464 (D.C. 1981) (per curiam).

24. *Id.* at 469.

25. *See id.*

26. *Id.* (affirming grant of summary judgment on that basis).

27. RESTATEMENT (SECOND) OF TORTS § 295A cmt. b (1965); DOBBS, *supra* note 15, § 164, at 396; *see also* *Bowan ex rel. Bowan v. Express Med. Transporters, Inc.*, 135 S.W.3d 452, 460 (Mo. Ct. App. 2004), *reh'g and/or transfer denied* (May 13, 2004).

28. RESTATEMENT (SECOND) OF TORTS § 295A cmt. b.

29. Judge Learned Hand observed that “in most cases reasonable prudence is in fact common prudence.” *The T.J. Hooper*, 60 F.2d 737, 740 (2d. Cir. 1932); *see also* *Westinghouse Elec. Corp. v. Nutt*, 407 A.2d 606, 610–12 (D.C. 1979).

the circumstances of the case are so unusual as to make the customary precautions inappropriate.<sup>30</sup> This possibility is rare by definition. The plaintiff may also demonstrate that the existing custom is a product of collusive understandings within the industry to which the defendant belongs.<sup>31</sup> If the plaintiff succeeds in proving such a conspiracy, the defendant's negligence would be established instantaneously,<sup>32</sup> and the defendant would likely have to pay punitive damages as well.<sup>33</sup> Because a successful conspiracy showing exposes the entire industry to the risk of class action, evidence of conspiracy is rarely available. Firms make every effort to conceal it as well as to remove any trace of conspiratorial understandings that place the public at risk.<sup>34</sup>

The most promising way of countering the defendant's custom evidence, therefore, is to identify a readily available precaution against damage that the customary practice had missed. This strategy stems from two torts classics: *Texas & Pacific Railway Co. v. Behymer*<sup>35</sup> and *The T.J. Hooper*.<sup>36</sup> These decisions established, respectively, that "[w]hat usually is done may be evidence of what ought to be done, but what ought to be done is fixed by a standard of reasonable prudence, whether it usually is complied with or not,"<sup>37</sup> and that "in most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices."<sup>38</sup>

As attested in *The T.J. Hooper*, evidence that the industry had missed a readily available, cost-justified precaution can only be found in rare cases.<sup>39</sup> *Behymer* is one such case. There, railroad companies customarily required employees to deice railroad cars while standing on their slippery tops, without making sure that the cars did not move.<sup>40</sup> This Dickensian custom was disturbingly unsafe, which made it an easy premise for Justice Holmes's sharp differentiation between the "is" and the "ought." *The T.J. Hooper* presents another setting that one rarely comes across. There, a tugboat caught

30. See RESTATEMENT (SECOND) OF TORTS § 295A cmt. c.

31. See *id.* (noting that courts should disregard a custom resulting from a "deliberate disregard of a known risk").

32. See, e.g., *Adcock v. Brakegate, Ltd.*, 645 N.E.2d 888 (Ill. 1994) (affirming imposition of substantial liability in torts on Owens-Corning Fiberglass Corporation for conspiring with other asbestos manufacturers to conceal hazards of asbestos); *Owens-Corning Fiberglas Corp. v. Ballard*, 749 So. 2d 483, 487 (Fla. 1999) (holding Owens-Corning liable for concealing dangers of asbestos while marketing asbestos-contaminated products).

33. See *Owens-Corning*, 749 So. 2d at 485 (stating that the jury assessed thirty-one million dollars in punitive damages against Owens-Corning); DOBBS, *supra* note 15, § 381, at 1062–63.

34. See *Owens-Corning*, 749 So. 2d at 487 (describing extensive cover-up by Owens-Corning to avoid liability).

35. 189 U.S. 468 (1903).

36. 60 F.2d 737 (2d Cir. 1932).

37. *Behymer*, 189 U.S. at 470.

38. *The T.J. Hooper*, 60 F.2d at 740.

39. See *id.*

40. See *Behymer*, 189 U.S. at 469–70.

by a storm had lost a barge it was towing—damage that could easily have been prevented by notifying the boat’s operator about the impending storm. This notification could have been transmitted by radio without problems, but the industry’s custom was to allow tugboats to sail with no radio equipment on board.<sup>41</sup> For Judge Hand, this “slack” was a straightforward affront to common sense.<sup>42</sup>

Nowadays, of course, such self-incriminating industry practices rarely take place. Every modern industry makes a sustained effort to appear safe in order to boost sales and turn its customs and protocols into reliable evidence in courts of law.<sup>43</sup> Industries’ conscious effort to adopt and foster customs increases the probability that a firm that aligns with the industrial custom will escape liability for harms it causes. Correspondingly, it also increases the probability that a firm that fails to align with the custom will assume liability for these harms. This dynamic creates a powerful incentive for firms to comply with existing industrial customs and rely upon conventional technologies.

Two additional rules of evidence bolster the centrality of custom: the *res ipsa loquitur* presumption,<sup>44</sup> and the *Frye* doctrine,<sup>45</sup> which governs the admissibility of expert evidence in numerous jurisdictions.<sup>46</sup>

The *res ipsa loquitur* rule allows fact finders to hold the defendant negligent when three cumulative conditions are present: (a) the plaintiff’s damage is caused by an agency or instrumentality over which the defendant exercised exclusive control, (b) the plaintiff’s conduct does not contribute to the occurrence of that damage, and (c) the injury could not ordinarily occur without negligence.<sup>47</sup>

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41. See *The T.J. Hooper*, 60 F.2d at 740.

42. *Id.*

43. See, e.g., Clayton P. Gillette & James E. Krier, *Risk, Courts, and Agencies*, 138 U. PA. L. REV. 1027, 1038–39 (1990) (“[F]irms with an earned reputation for safety can enjoy competitive advantages in product and labor markets.”).

44. See RESTATEMENT (SECOND) OF TORTS § 328D (1965) (“It may be inferred that harm suffered by the plaintiff is caused by negligence of the defendant when . . . the event is of a kind which ordinarily does not occur in the absence of negligence . . .”). For specifics and rationales of the *res ipsa* rule, see ARIEL PORAT & ALEX STEIN, TORT LIABILITY UNDER UNCERTAINTY 84–100 (2001).

45. See *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923) (conditioning the admissibility of expert evidence upon the “standing and scientific recognition” of its underlying scientific knowledge).

46. The *Frye* doctrine continues to apply in California, New York, and numerous other states. See, e.g., *Parker v. Mobil Oil Corp.*, 857 N.E.2d 1114, 1119–20 (N.Y. 2006) (reaffirming *Frye*’s controlling status in New York law); *People v. Kelly*, 549 P.2d 1240, 1244 (Cal. 1976) (adopting *Frye*’s general acceptance standard in California law); *People v. Leahy*, 882 P.2d 321, 324–31 (Cal. 1994) (reaffirming applicability of *Kelly-Frye* standards in California courts and declining to switch to *Daubert*); see also *Christian v. Gray*, 65 P.3d 591, 595 n.2 (Okla. 2003) (listing *Frye* jurisdictions, *Daubert* jurisdictions, and undecided jurisdictions).

47. See DOBBS, *supra* note 15, § 154, at 370–71; PORAT & STEIN, *supra* note 44, at 84.

The final condition refers to courses of events that “common experience of mankind”<sup>48</sup> categorizes as ordinary. This condition of *res ipsa* privileges conventional knowledge over its rivals. By doing so, it induces firms to adhere to customary precautions: taking those precautions negates the condition. When customary or “ordinary” precautions do not prevent the plaintiff’s damage, the occurrence of that damage is not deemed an event that *ordinarily* involves negligence on the part of the defendant. Instead, courts perceive the damage as practically unavoidable.<sup>49</sup> Conversely, when the defendant’s instrumentality damages the plaintiff and the customary precautions are not taken, the *res ipsa* rule will likely apply.<sup>50</sup> This means that the negligence presumption extends to cases in which the defendant used novel technology to avoid damage to the plaintiff instead of taking the customary precautions against that damage.

The train-station accident, discussed earlier,<sup>51</sup> exemplifies how the *res ipsa* rule works. There, the customary status of the gap between the train and the platform denies *res ipsa* to the passenger whose leg was trapped in the gap. Because the train company complies with the custom of the rapid transit systems industry, the gap does not classify as unusual and cannot evidence negligence. The two other conditions of *res ipsa* are present, but two out of three is not enough. The *res ipsa* rule will not apply.

In sum, by taking customary precautions, the defendant will not always avoid the plaintiff’s damage but will always escape the consequences of *res ipsa*. This factor may be crucial to the lawsuit. When, as in the train-station example,<sup>52</sup> the plaintiff has no evidence identifying the specifics of the defendant’s negligence and cannot rely on *res ipsa*, the judge will dismiss the lawsuit.<sup>53</sup>

48. PORAT & STEIN, *supra* note 44, at 88; *see also Ex parte* Mobile Power and Light Co., 810 So.2d 756, 759 (Ala. 2001) (interpreting the “ordinary” condition of *res ipsa* as referring to “common knowledge and the experience of mankind” (quoting *Khirieh v. State Farm Mut. Auto. Ins. Co.*, 594 So.2d 1220, 1223 (Ala. 1992))).

49. *See, e.g.,* Coalite, Inc. v. Aldridge, 229 So.2d 524, 533–34 (Ala. Ct. App. 1968) (approving application of *res ipsa* in an action for damages resulting from a coal mining company’s blasting operations because the company failed to show alignment with the industry custom with respect to the amount of explosives used); *Darlington Corp. v. Finch*, 149 S.E.2d 861, 861–62 (Ga. Ct. App. 1966) (denying *res ipsa* to a plaintiff injured by an elevator’s closing doors when evidence showed that “[the elevator] had been installed in accord with the American Standard and Safety Code, sponsored by the American Institute of Architects, the National Bureau of Standards, and the American Society of Mechanical Engineers” and underwent routine inspections in the building); *Ursini v. Ky. Kingdom, Inc.*, Nos. 2002-CA-00267-MR; 2002-CA-000560-MR; 2003 WL 1948872 \*3 (Ky. Ct. App. Apr. 25, 2003) (“[The plaintiff] has failed to show that anything unusual happened during or immediately after the ride. . . . In the absence of proof that some out of the ordinary event occurred, [res ipsa loquitur] has no application.”).

50. *See, e.g.,* Buckelew v. Grossbard, 435 A.2d 1150, 1158 (N.J. 1981) (“We hold . . . that expert testimony to the effect that the medical community recognizes that an event does not ordinarily occur in the absence of negligence may afford a sufficient basis for the application of the doctrine of *res ipsa loquitur*.”).

51. *See supra* notes 23–26 and accompanying text.

52. *See supra* notes 23–28 and accompanying text.

53. *See* DOBBS, *supra* note 15, § 154, at 370–71. For a telling example featuring a plaintiff crying for help, *see Rabena v. City of New York*, 556 N.Y.S.2d 807 (Civ. Ct. 1990) (dismissing a

Now consider the following example of an elevator accident. A person inadvertently leans against an elevator's closed doors on the tenth floor. The doors open, and the person falls down the shaft to his death. His descendants sue the building's maintenance company for wrongful death. The elevator and its equipment were routinely inspected and found to be in good working condition. The company also had installed Z-brackets, which, according to conventional knowledge, substantially reduce the probability of the doors opening.<sup>54</sup> Under this scenario, as in the train-station case, the plaintiffs would not be able to rely on *res ipsa* and the company would likely be entitled to a directed verdict in its favor.

But what if the company used a new technology instead of Z-brackets? What if it installed a special control system that keeps the elevator's doors locked until the cabin's arrival to the floor?<sup>55</sup> Assume that the probability of this system's malfunction is roughly similar to that of Z-brackets' failure, but the technology used to develop the novel control system is not yet conventional knowledge. Under this set of facts, the accident would classify as an occurrence that ordinarily involves negligence on the part of the company. This is what the *res ipsa* rule says when Z-brackets are not installed. The case would consequently go to the jury, and the company would be facing a serious risk of liability.<sup>56</sup>

The second evidence rule that encourages adherence to custom is the *Frye* doctrine. Under *Frye*, testimony of a scientific or technological expert can only be admitted into evidence when the expert's opinion represents knowledge that has gained "standing and scientific recognition" in the relevant community of experts.<sup>57</sup> This doctrine, too, elevates conventional knowledge over scientific and technological innovations. To see how, return to our elevator-accident example and assume that the company calls an expert witness to testify about the advantages of the new control system. Assume further that the new technological knowledge—explaining how the novel system works and why its malfunction is as improbable as a Z-bracket's failure—has yet to receive "standing and scientific recognition." Under the orthodox understanding of *Frye*, if the expert based her testimony on novel engineering principles,

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lawsuit lacking evidence that could identify the wrongdoer or the instrumentality that caused the injury brought by a mother of a mentally retarded child who was taken unharmed on a bus from home to school and returned home with a thigh injury).

54. For a newspaper report about the Z-bracket technology, see Anahad O'Connor & Tanzina Vega, *Queens Elevator Accident Kills 2, Just After Similar Death at a Club*, N.Y. TIMES, Feb. 5, 2007, at B1.

55. This new technology does not actually exist. We made it up for purposes of our example.

56. See DOBBS, *supra* note 15, § 164, at 397–98; PORAT & STEIN, *supra* note 44, at 90.

57. *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923). As explained in 1 CHARLES TILFORD MCCORMICK ET AL., MCCORMICK ON EVIDENCE § 203, at 827 (Kenneth S. Broun ed., 6th ed. 2006), *Frye's* "general acceptance" standard requires the proponent of an expert's testimony to "show that the scientific community agrees that the principles or techniques on which the expert relies are capable of producing accurate information and conclusions." This requirement disqualifies expert testimony not aligning with conventional wisdom. See *id.* at 828 (giving examples of novel scientific findings that "have fallen prey to [*Frye's*] influence").

the judge should rule it inadmissible.<sup>58</sup> As a consequence, the company would have no defense against the lawsuit.<sup>59</sup>

Federal law and numerous states have replaced the *Frye* doctrine with a set of rules known as the “*Daubert* Trilogy.”<sup>60</sup> This change, however, does not

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58. The classic article on the subject attests that “[i]t is unresolved whether the *Frye* standard requires general acceptance of the scientific technique or of both the underlying principle and the technique applying it,” Paul Giannelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States a Half Century Later*, 80 COLUM. L. REV. 1197, 1212 (1980), and that court decisions dealing with this issue are not uniform, *id.* at 1211–14. This uncertainty originates from *Frye*’s formulation that “while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, *the thing from which the deduction is made* must be sufficiently established to have gained general acceptance in the particular field in which it belongs.” *Frye*, 293 F. at 1014 (emphasis added). For a strict version of *Frye*, see *Overton v. State*, 976 So. 2d 536, 550 (Fla. 2007) (“In utilizing the *Frye* test, the burden is on the proponent of the evidence to prove the *general acceptance* of both the underlying *scientific principle* and the *testing procedures* used to apply that principle to the facts of the case at hand.” (quoting *Ramirez v. State*, 651 So. 2d 1164, 1168 (Fla. 1995))); *Parker v. Mobil Oil Corp.*, 857 N.E.2d 1114, 1119–20 (N.Y. 2006) (“[T]he *Frye* test asks ‘whether the accepted techniques, when properly performed, *generate results accepted as reliable within the scientific community generally.*’” (citation omitted) (quoting *People v. Wesley*, 633 N.E.2d 451, 454 (N.Y. 1994) (emphasis added))); *State v. Gregory*, 147 P.3d 1201, 1238 (Wash. 2006) (“Washington has adopted the *Frye* test for evaluating the admissibility of new scientific evidence. . . . Both the scientific theory underlying the evidence and the technique or methodology used to implement it must be generally accepted in the scientific community for evidence to be admissible under *Frye*.” (citing *State v. Gore*, 21 P.3d 262, 271–72 (Wash. 2001))); *Logerquist v. McVey*, 1 P.3d 113, 133 (Ariz. 2000) (explaining that *Frye* blocks the admission of “novel scientific principles, formulae, or procedures developed by others”); *Caldwell v. State*, 393 S.E.2d 436, 441 (Ga. 1990) (“In many states, the test for admissibility of novel scientific evidence is whether the scientific principle or discovery supporting the evidence is sufficiently established to have gained general acceptance in the particular field in which it belongs. This is not the test in Georgia. . . . We hold that it is proper for the trial judge to decide whether the procedure or technique in question has reached a scientific stage of verifiable certainty . . . .” (citations and internal quotation marks omitted)); *People v. Kelly*, 549 P.2d 1240, 1245 (Cal. 1976) (“The primary advantage . . . of the *Frye* test lies in its essentially conservative nature. For a variety of reasons, *Frye* was deliberately intended to interpose a substantial obstacle to the unrestrained admission of evidence based upon new scientific principles.”). See also David L. Faigman, *Admissibility Regimes: The “Opinion Rule” and Other Oddities and Exceptions to Scientific Evidence, The Scientific Revolution, and Common Sense*, 36 SW. U. L. REV. 699, 701–02 (2008) (“*Frye*-like tests typically focus on whether experts from a particular field accept the empirical basis for the opinion . . . . A *Frye* test contemplates that judges need bring little or no knowledge of research methods to the admissibility decision. The test can be applied simply by counting the noses of members of the pertinent field. In contrast, *Daubert* requires judges to have fairly developed empirical sensibilities, since they must evaluate the methods and principles underlying the proffered expertise.” (footnotes omitted)); Joseph J. Ortego & James W. Weller, *Products Liability and the Elements of Science: Admissibility of Expert Testimony in New York and Other Frye States*, 41 TORT TRIAL & INS. PRAC. L.J. 83 (2005) (surveying *Frye* states’ restrictions on the admissibility of novel scientific and technological knowledge). For a relaxed version of *Frye*, see, for example, *Grady v. Frito-Lay, Inc.*, 839 A.2d 1038, 1045 (Pa. 2003) (“[I]n applying the *Frye* rule, we have required and continue to require that the proponent of the evidence prove that the methodology an expert used is generally accepted by scientists in the relevant field as a method for arriving at the conclusion the expert will testify to at trial. This does not mean, however, that the proponent must prove that the scientific community has also generally accepted the expert’s conclusion.” (citations omitted)).

59. *Sledd v. Washington Metro. Area Transit Auth.*, 439 A.2d 464, 469 (D.C. 1981) (per curiam), is a parallel example of an expert’s failure to challenge conventional wisdom. There, the court dismissed the plaintiff’s lawsuit summarily.

60. Cases forming this trilogy are *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993); *General Electric Co. v. Joiner*, 522 U.S. 136 (1997); and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). The trilogy substituted the *Frye* standard by a multifactor balancing test that requires the trial judge (1) to make sure that the methodology underlying the expert’s testimony can

materially affect our analysis: a defendant who chooses to use new technologies over conventional ones would hardly fare better in a *Daubert* jurisdiction.<sup>61</sup>

*Daubert*'s multifactor screening of expert testimony includes four criteria that might keep the company's expert away from court.<sup>62</sup> One of those criteria, again, is the expert's alignment with the conventional technological wisdom. This criterion is discretionary, rather than mandatory, but failure to satisfy it increases the probability that the testimony will be excluded.<sup>63</sup> Another criterion is a peer-reviewed publication of the expert's methodology.<sup>64</sup> This criterion is particularly hostile to technological innovations that are kept secret—away from imitators' eyes—for business reasons. Apart from that, peer review is often a wall erected by old-timers that innovators will find difficult to penetrate.<sup>65</sup> A similar timing problem arises in connection with two additional criteria set by *Daubert*: replicability of the new methodology<sup>66</sup> and ascertainment of its error rate.<sup>67</sup> For these criteria to be met, the new technology usually needs to undergo a long series of tests that will determine its dependability.<sup>68</sup>

Collectively, the custom rules tell firms, “if you want to minimize your prospect of paying for damages that your activities may cause, go conventional, align yourself with the custom and never stand out.”

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be tested by other experts; (2) to consider whether this methodology underwent peer review and was published in the academic or professional literature after undergoing examination for possible flaws; (3) to take into account the error rate, actual or potential, that accompanies the expert's testimony and methodology; (4) to see whether this methodology attains acceptance in the relevant scientific or professional community; (5) to examine the expert's inferences from methodology to conclusions for the presence of analytical gaps; and, finally, (6) to look into the testimony's capacity to mislead or prejudice the jury. For informative discussion of this test, see 1 McCORMICK ET AL., *supra* note 57, § 203, at 831–33.

61. See Edward K. Cheng & Albert H. Yoon, *Does Frye or Daubert Matter? A Study of Scientific Admissibility Standards*, 91 VA. L. REV. 471 (2005) (demonstrating empirically, using a jurisdiction-removal criterion for ascertaining tort defendants' revealed preferences, that the shift from *Frye* to *Daubert* has brought about no real changes on the ground in state courts).

62. *Daubert*, 509 U.S. at 592–95.

63. *Id.* at 594.

64. *Id.* at 593–94.

65. David F. Horrobin, *The Philosophical Basis of Peer Review and the Suppression of Innovation*, 263 JAMA 1438 (1990) (arguing that peer review generally favors conventional wisdom and tends to suppress innovation).

66. *Daubert*, 509 U.S. at 593.

67. *Id.* at 594.

68. Cf. 1 McCORMICK, *supra* note 57, § 203, at 832–33 (describing ways to gain acceptability in the general scientific community).

### B. Custom and Product Liability

Custom also plays a crucial role in the area of product liability.<sup>69</sup> Under the prevalent product-liability regime, a manufacturer's conformity with the relevant industrial custom<sup>70</sup> is admissible as evidence tending to prove that its product was safe and not defectively designed.<sup>71</sup> Conversely, a manufacturer's failure to conform to custom constitutes evidence—once again, inconclusive—of the presence of a defect in its product.<sup>72</sup> Custom is taken into account in the determination of design defects under both the “risk-utility”<sup>73</sup> and the “consumer expectation”<sup>74</sup> tests. Under these tests, a product classifies as defective when it creates a risk of harm that exceeds its benefits or falls far below a reasonable consumer's expectation.

The effect of these custom rules is substantial. A product that conforms to the customary design will normally classify as more beneficial than risky and as satisfying a reasonable consumer's expectation. The product consequently will be held safe and non-defective, despite the damage consumers may have suffered from using it. Conversely, a product that deviates from customary design will almost certainly fail both the “risk-utility” and the “consumer expectation” tests.<sup>75</sup> This failure will result in the classification of the product as unsafe and defective.<sup>76</sup>

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69. See David G. Owen, *Proof of Product Defect*, 93 KY. L.J. 1, 5–10 (2004) (documenting massive use of industry customs as a benchmark for determining design defects in product liability actions). Industry customs affect predominantly products' designs. We therefore do not discuss here actions complaining about manufacturing defects or inadequate instructions and warnings. Cf. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998) (specifying three distinct categories of product liability: liability for defectively designed products, liability for manufacturing defects, and liability for inadequate instructions and warnings accompanying the product).

70. Note that industrial custom is not exactly the same as the “state of art” upon which manufacturers often rely in defending against product liability lawsuits. Custom is what manufacturers habitually do in producing the product. State of art refers to a general technological ability to make a safe product. See KEETON ET AL., *supra* note 5, § 99, at 701. Manufacturers may or may not customarily utilize the state-of-art technology. Whether they do so or not is an empirical question. See Urban, Comment, *supra* note 16, at 440 n.4.

71. Owen, *supra* note 69, at 7–8.

72. *Id.* at 7.

73. See DAVID G. OWEN ET AL., 2 MADDEN & OWEN ON PRODUCTS LIABILITY § 27.6, at 823–28 (3rd ed. 2000).

74. *Id.* at 824–26.

75. *Id.* at 823–28. For recent court decisions on that issue, see *Moore ex rel. Moore v. Mississippi Valley Gas Co.*, 863 So.2d 43, 46–47 (Miss. 2003) (defendant's evidence that its water heater conformed with industry standards defeated suit for hot water burns sustained by plaintiff); and *Alfred v. Caterpillar, Inc.*, 262 F.3d 1083, 1088 (10th Cir. 2001) (holding that failure of defendant's equipment to comply with industry standards evidences presence of a defect in the equipment, although it does not yet establish that the equipment was unreasonably dangerous to ordinary consumers).

76. See OWEN ET AL., *supra* note 73, at 823–28.

Effectively, the “risk-utility” and “consumer expectation” tests institute a fault-based negligence regime for imposing liability for defective products.<sup>77</sup> They introduce the principles of negligence into liability that purports to be strict on paper.<sup>78</sup>

It should be noted that courts in California and several other jurisdictions have adopted an unmitigated strict liability regime with respect to defective products.<sup>79</sup> For that reason, they have ruled that evidence of the manufacturer’s compliance with the relevant industrial custom is irrelevant and consequently inadmissible.<sup>80</sup> This liability regime does not discourage technological innovation, and we therefore use it in Part III as a model for one of our reform proposals.

### C. Custom and Medical Malpractice

In many relationships between professionals and their clients, custom serves as a modifiable contractual default.<sup>81</sup> The doctor-patient relationship best exemplifies this “custom as default” model.<sup>82</sup> A doctor’s basic duty is to treat her patients with customary medical care.<sup>83</sup> Specifically, the doctor must follow the standards accepted by doctors practicing in the same area or specialty.<sup>84</sup> Doctors and patients are not free to downscale this “customary

77. DOBBS, *supra* note 15, § 358, at 987; *see also* Owen, *supra* note 69, at 5 (“The admissibility of customary industry standards [in product liability actions] derives from the use of this type of evidence for nearly two centuries in negligence law . . .”).

78. DOBBS, *supra* note 15, § 358, at 987.

79. *See, e.g.*, Buell-Wilson v. Ford Motor Co., 46 Cal. Rptr. 3d 147, 164 (Ct. App. 2006) (“A manufacturer cannot defend a product liability action with evidence it met its industry’s customs or standards on safety. . . . [A]dmission of such evidence is reversible error.” (citations omitted)); Grimshaw v. Ford Motor Co., 174 Cal. Rptr. 348, 378 (Ct. App. 1981) (noting that custom is irrelevant to California’s risk-benefit test for design defects and consequently inadmissible as evidence); Titus v. Bethlehem Steel Corp., 154 Cal. Rptr. 122, 126 (Ct. App. 1979) (stating that custom is inadmissible because defendant’s compliance with custom does not shield him from strict liability for defective products).

80. *See Buell-Wilson*, 46 Cal. Rptr. 3d at 164; *see also* Holloway v. J.B. Sys., Ltd., 609 F.2d 1069, 1073 (3d Cir. 1979) (holding that trade customs cannot be admitted into evidence under the Pennsylvania law of product liability). For criticism of these rulings, *see* Urban, Comment, *supra* note 16, at 463–65.

81. *See* DOBBS, *supra* note 15, § 242, at 631–32.

82. *See id.* § 242, at 631–33; *see also* Henderson & Siliciano, *supra* note 16, at 1382.

83. *See* DOBBS, *supra* note 15, § 242, at 633; Henderson & Siliciano, *supra* note 16, at 1382; *see, e.g.*, Franklin v. Gupta, 567 A.2d 524 (Md. Ct. Spec. App. 1990) (exemplifying the “customary care” standard in the medical malpractice law).

84. *See* Tunkl v. Regents of Univ. of Cal., 383 P.2d 441 (Cal. 1963) (voiding on public policy grounds an agreement incorporating patient’s waiver of tort suits for treatments falling below the “customary care” standard); Porubiansky v. Emory Univ., 275 S.E.2d 163 (Ga. Ct. App. 1980) (same); Meiman v. Rehab. Ctr., Inc., 444 S.W.2d 78 (Ky. 1969) (same); Cudnik v. William Beaumont Hosp., 525 N.W.2d 891, 894–96 (Mich. Ct. App. 1994) (same); Ash v. N.Y. Univ. Dental Ctr., 564 N.Y.S.2d 308 (App. Div. 1990) (same); Dedely *ex rel.* Dedely v. Kings Highway Hosp. Ctr., Inc., 617 N.Y.S.2d 445 (Sup. Ct. 1994) (same); Olson v. Molzen, 558 S.W.2d 429 (Tenn. 1977) (same); *see also* Tatham v. Hoke, 469 F.Supp. 914 (W.D.N.C. 1979) (voiding on public policy grounds a \$15,000 damage limitation for substandard treatment that appeared in patient’s informed-consent form).

care” standard.<sup>85</sup> An agreement that allows a doctor to provide a patient substandard medical care without exposing himself to liability for malpractice contravenes public policy and is therefore invalid.<sup>86</sup>

Rules controlling medical malpractice cases differ from the general negligence and product-liability regimes in one important respect. Under these rules, a doctor’s compliance with the relevant custom, practice, or “school of thought” does not merely evidence the delivery of adequate care. Such compliance *is* adequate care as a matter of substantive law.<sup>87</sup> By proving her compliance with the relevant customary norm, the doctor therefore does more than simply increase her chances of winning the case; she guarantees herself this result.<sup>88</sup>

But the default “customary care” standard is not mandatory. If a patient wants to purchase an upscaled treatment and a doctor is willing to provide it, the parties are free to go ahead and substitute the custom default with the chosen “upscaled treatment” agreement.<sup>89</sup> Similarly, when a doctor offers an innovative treatment, she and her patient can enter into a special “experimental treatment” agreement that would override the custom default and enable the doctor to deliver the treatment to the patient.<sup>90</sup> Before making such an agreement, however, the doctor must inform the patient about the nature of the new treatment and its conventional alternatives.<sup>91</sup> The patient

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85. See cases cited *supra* note 84.

86. See cases cited *supra* note 84.

87. See *Jones v. Chidester*, 610 A.2d 964 (Pa. 1992) (articulating the “school of thought” rule as a complete defense against medical malpractice allegations); DOBBS, *supra* note 15, § 242, at 633; LAWRENCE O. GOSTIN & PETER D. JACOBSON, *LAW AND THE HEALTH SYSTEM* 430 n.1 (2006); HENDERSON & SILICIANO, *supra* note 16, at 1382. Note, however, that experimental treatments do not qualify as a “school of thought.” *Yates v. Univ. of W. Va. Bd. of Trs.*, 549 S.E.2d 681, 690 & n.14 (W. Va. 2001). Also note that courts may scrutinize doctors’ customs that determine the level of risk of injury or death to which a doctor may and may not expose her patient. See, e.g., *Helling v. Carey*, 519 P.2d 981 (Wash. 1974).

88. See DOBBS, *supra* note 15, § 242, at 633; GOSTIN & JACOBSON, *supra* note 87, at 430; James Gibson, *Doctrinal Feedback and (Un)Reasonable Care* (March 14, 2008) (unpublished manuscript, available at <http://ssrn.com/abstract=1109170>) (identifying the “doctrinal feedback” dynamic involving overcautious doctors whose excessive precautions against harm cyclically transform into legally binding customs); cf. Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH & LEE L. REV. 163, 172–79 (2000) (demonstrating that some courts treat doctors’ compliance with medical customs as strong but nondecisive evidence of due care).

89. See, e.g., *Sullivan v. O’Connor*, 296 N.E.2d 183 (Mass. 1973) (holding that such undertakings are valid and enforceable, subject to the “clear and convincing proof” requirement for oral agreements to upscale the treatment).

90. See *Baird v. Am. Med. Optics*, 713 A.2d 1019, 1028 (N.J. 1998) (holding an experimental-treatment agreement valid upon ascertainment of patient’s informed consent); *Estrada v. Jaques*, 321 S.E.2d 240, 254 (N.C. Ct. App. 1984) (same).

91. See Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 365–67, 375 (2002) (specifying, analyzing, and criticizing the “informed consent” requirements for experimental-treatment agreements). See generally Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899 (1994) (evaluating the existing requirements for “informed consent”). Note that providers of conventional medicine have no parallel obligation to inform patients about available experimental treatments. See *Moore v. Baker*, 989 F.2d 1129, 1133 (11th Cir. 1993) (“The law requires disclosure only of those alternatives

must then give her consent to the treatment, thereby sealing the formation of the parties' special agreement. After granting her informed consent, the patient can no longer sue the doctor for deviation from the custom.<sup>92</sup> The parties' agreement would trump the custom.

The rationale of these rules is two-fold. The doctor and the patient are not strangers to each other. Their relationship is formed by mutual contractual undertakings that can be—and often are—expressly negotiated.<sup>93</sup> Subject to the public-policy ban of substandard care, the doctor and the patient therefore can determine the treatment that best suits the patient's needs (and ability to pay for the treatment). The custom default here mirrors what doctors and patients typically agree to, considering the existing regulatory and self-regulatory requirements with which doctors must comply.<sup>94</sup> These requirements give patients a reliable quality assurance with respect to doctors' work. Based on this assurance, patients normally agree to receive the customary treatment without negotiating it expressly. This contracting mechanism economizes on transaction costs and spares patients from engaging in lengthy and nettlesome discussions about risks and harms.

A special "experimental treatment" agreement between the doctor and the patient not only overcomes the custom default but also precludes the applicability of the *res ipsa* rule in its custom-driven format. Once a valid agreement for receiving treatment that falls outside the ordinary has been entered, the patient can no longer base her lawsuit against the doctor on what does and does not happen "in the ordinary course of events"—the very foundation of *res ipsa*.

The evidentiary requirements that control the admission of expert testimony are similarly adjusted. The signing of an "experimental treatment" agreement bars the patient from complaining against the treatment's unconventional nature. She would only be able to make malpractice allegations about the way in which the doctor actually delivered the special treatment. Medical experts testifying for both sides consequently would have to focus on the new treatment's nature and benefits. The custom-driven doctrines of *Frye* and *Daubert* would not block their testimony.

In theory, then, in the context of medical malpractice, custom constitutes a default rule around which the parties can contract. As a result, custom's chilling effect on medical innovations is much smaller than in the other areas we discussed. All the doctor or a medical institution needs to do to get

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that are 'generally recognized and accepted by reasonably prudent physicians.' " (quoting GA. CODE ANN. § 31-9-6.1(a)(5) (1991))).

92. The experimental treatment still needs to be performed adequately, though. Failure to do so would expose the doctor to liability for malpractice. *See, e.g., Lenahan v. Univ. of Chi.*, 808 N.E.2d 1078, 1084–85 (Ill. App. 1 Dist. 2004) (holding that medical personnel must exercise reasonable care in administering experimental treatments and that a hospital can be held liable for its failure to supervise those who provide such treatments).

93. *See* RICHARD A. EPSTEIN, MORTAL PERIL: OUR INALIENABLE RIGHT TO HEALTH CARE? 6–8 (1997); Richard A. Epstein, *Medical Malpractice: The Case for Contract*, 1976 AM. B. FOUND. RES. J. 87.

94. *See* DOBBS, *supra* note 15, § 242, at 631–32.

around custom is to label innovative procedures (or devices) “experimental” and secure the informed consent of the patient to the treatment. The contractual “custom default” therefore only imposes on doctors and medical institutions the extra cost of obtaining informed consent from the patient. This extra cost seems quite minimal, given that virtually any medical treatment already requires informed consent.<sup>95</sup>

In practice, however, overcoming custom is a much more difficult and costly task than it initially appears. Attempts to contract around the default of customary care raise costs both *ex ante* and *ex post* for doctors and medical institutions—and the combined increase might, in fact, be quite substantial. *Ex ante*, the need to label the new treatment “experimental” is likely to frighten away some patients by undermining their confidence in the treatment. Securing the patient’s consent to an experimental treatment may therefore become challenging. *Ex post*, the “experimental” label makes the agreement more susceptible to judicial intervention and invalidation. The unusual character of the treatment is likely to induce courts to scrutinize the doctor-patient agreement more closely and expand the patient’s ability to sue the doctor.<sup>96</sup> Naturally, the willingness of the courts to review agreements concerning “experimental treatment” strengthens patients’ motivation to disregard their consent to the treatment and sue physicians in spite of the agreement.

## II. CUSTOM RULES AND INCENTIVE TO INNOVATE

As we showed in Part I, custom rules protect firms and individuals that rely on conventional knowledge and technologies from liability in torts. This Part carries out a detailed examination of the effect of these rules on the incentive to innovate. We first examine the *ex post* effects of custom rules on innovation and social welfare and then turn to the *ex ante* effects. By “ex

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95. Some jurisdictions base informed consent actions on the torts of assault and battery. There, informed consent needs to be obtained only with respect to invasive treatments, as opposed to treatments that are merely therapeutic. Noah, *supra* note 91, at 365; *e.g.*, *Morgan v. MacPhail*, 704 A.2d 617, 619–20 (Pa. 1997).

96. This expanded ability originates from the courts’ requirement that doctors tell patients that the treatment is experimental, that its risks and benefits are unknown, and that they have little or no experience with the treatment. *See Estrada v. Jaques*, 321 S.E.2d 240, 254–55 (N.C. Ct. App. 1984) (summarizing case law from several jurisdictions and interpreting patients’ right to informed consent to include the entitlement to a full “experimental treatment” warning). Apart from that, doctors need to inform the patient about the conventional alternatives to the proposed treatment, Noah, *supra* note 91, at 366, a requirement that sharply contrasts with the rule that expressly exempts conventional doctors from the duty to inform the patient about the *experimental* alternatives to their proposed treatment. *E.g.*, *Moore*, 989 F.2d at 1133. Courts also have underscored doctors’ financial and career benefits from delivering experimental treatments as a reason for subjecting the patient’s agreement to undergo such a treatment to heightened scrutiny. *Estrada*, 321 S.E.2d at 255; *Darke v. Estate of Isner*, 17 Mass. L. Rptr. 689 (Mass. Super. Ct. 2004). Some courts even require doctors to reveal to the patient their success rate with the experimental treatment. *See, e.g.*, *Gaston v. Hunter*, 588 P.2d 326, 351 n.26 (Ariz. Ct. App. 1978) (“In the case of a new or unusual procedure, the individual physician’s experience and ‘track record’ would seem even more important than when an established, common procedure is contemplated.”). These chilling effects will likely be exacerbated by the “doctrinal feedback” dynamic identified by Gibson, *supra* note 88.

post effects” we refer to the effects of custom rules on the market reception of innovations that have been produced. By “ex ante effects” we refer to the effects of custom rules on the production and design of innovations.

#### A. *Ex Post Effects*

We illustrate the ex post effects of the custom rules on innovation by discussing a simple example. Innovator *N* develops a new technology for maintaining electric hoists. The new technology is as safe as but more cost-effective than the dominant technology on the market. Absent liability for accidents, *N* can provide the new maintenance service at \$80 per hoist.

*N* is not the only provider on the market for hoist-maintenance services, however. Her competitor is *O*, who provides a similar service using the old and conventional technology. Absent liability for accidents, *O* can provide the maintenance service at a price of \$100 per hoist.

Under a no-liability assumption, over time *N* will drive *O* out of the market and the new technology will replace the old. This, of course, is the socially efficient outcome.

Under current negligence regime, the analysis changes dramatically. Tort liability for providers of hoist-maintenance services is determined by the general negligence doctrine. This doctrine holds that a provider must make a reasonable professional effort to avoid accidents and uses the existing industry custom as a benchmark. The doctrine also applies all other custom rules.

In this case, *O* is far less likely to be held negligent than *N*. The old and the new technology are equally prone to accidents. But the custom rules tax *N* and subsidize *O*. They help *O* defeat most lawsuits and expose *N* to an increased prospect of liability for accidents.

Realizing her heightened risk of liability, *N* adds \$50 to what she would otherwise charge per hoist; and so her final price is \$130. *O*, in contrast, knows that his expected liability for tort damages is minimal. *O* therefore adds only \$10 to his basic price and charges \$110 per hoist. As a result, *N* would either abandon her technology or undersupply the service. Both outcomes are inefficient and detrimental to society.

Importantly, the same result will obtain even in cases where the new technology is actually *safer* and is likely to reduce the rate of accidents. Imagine that *N*'s technology reduces the probability of accidents by 50%. Will it win over the conventional technology? Not necessarily. As long as the expected cost from the increased liability is greater than the expected cost-saving from the decline in the probability of accidents, the new technology will not be adopted. For simplicity's sake, assume that the conventional technology causes ten accidents per year and the new technology causes only five. Assume further that if the operator is held *negligent*, the average damage award is \$100,000 per accident. Finally, assume that due to the liability regime we discussed, adopters of the customary technology will prevail in 90% of the negligence suits against them, while adopters of the new technology will always lose. Under these assumptions, the new technology will be adopted only if it generates sufficiently large operational

cost-savings to offset the expected payouts to plaintiffs. In our case, the new technology will be adopted only if it reduces operation costs by \$400,000 per year. The resulting decrease of social welfare is apparent.

A similar anti-innovation bias exists in the area of product liability. To illustrate, let's revisit the elevator-accident example.<sup>97</sup> There, the plaintiffs could also sue the elevator's manufacturer on the ground that the elevator's design was defective. Under that scenario, if the manufacturer had installed conventional Z-brackets, it would have defeated the defective design claim because the technology would pass the prevalent doctrinal tests for "risk-utility" and "consumer expectation."<sup>98</sup> However, if the manufacturer had instead chosen to install a new control system in its elevators, the probability of losing the case under both "risk-utility" and "consumer expectation" standards would increase exponentially.

While the effect of medical malpractice rules on innovation is more nuanced, at the end of the day, they too discourage innovation. As we will show, the difference between negligence and product liability, on the one hand, and medical malpractice, on the other, is one of degree, not kind. To see this, imagine manufacturer *M* who develops a new intra-ocular lens for surgical implantation in the eyes of people suffering from cataracts. This device substantially reduces the risk of eye inflammation and infection relative to existing lenses. The project's profitability crucially depends on economies of scale. To make a profit, *M* needs to sell a very large number of new lenses, which means that the number of ophthalmologists willing to use the new lens must be very high. Accordingly, *M* contemplates organizing, at its expense, a special training course for ophthalmologists to induce them to adopt the new technology.

Will *M* succeed in introducing her innovative lenses to the market? The answer is unclear. The existing rules of "informed consent" impose special burdens on doctors who decide to adopt the new lens. These doctors must notify their patients about the lens's "experimental" status and tell each patient that the procedure's risks and benefits are as yet unknown. Moreover, the doctors are required to disclose to patients the benefit they received from *M* in the form of the free special training and reveal their motivation to use *M*'s lens. These disclosure requirements raise transaction costs for doctors who wish to implement the new technology. The higher transaction costs put the innovation-seeking doctors at a disadvantage vis-à-vis their more conservative peers, because the latter need not incur the cost of securing their patients' special consent to experimental treatment. The disclosure requirements the law places on the doctors will likely drive some patients away. Anticipating this, many doctors may decide not to order *M*'s innovative lenses. This means that *M*'s lenses will succeed in the market only if the medical benefits they generate are significant enough to compensate doctors for the increase in the negotiation and litigation costs they stand to incur if they offer them. Otherwise, *M*'s lenses, like many other innovative products,

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97. See *supra* text accompanying notes 54–56.

98. See *supra* notes 73–78 and accompanying text.

will be spurned by doctors. The effect of all this on social welfare is, of course, negative.

From an ex post perspective, the use of custom in the torts system increases the cost of commercializing innovations after their development. The distribution of the extra cost between producers and consumers will naturally depend on the elasticity of demand. When demand is highly inelastic, as is the case with life-saving innovations, the extra cost will be borne by consumers and the innovation will be produced. In cases where demand is elastic, however, producers will have to bear the extra cost of the increased legal liability. In such cases, innovators who will not be able to pass enough of the extra cost to consumers may simply choose to forego the innovation altogether. We now turn to discuss this possibility.

### B. *Ex Ante Effects*

The analysis so far has taken an ex post perspective. We examined the interactions that follow an innovation's development and identified their welfare-reducing effects. The ex ante effects of an innovator's heightened risk of liability are even more significant. In some cases, this risk may prevent development of new technologies ab initio. Realizing that the market may refuse to adopt new technologies for fear of the increased liability associated with them, firms may elect to forego the development of new technologies altogether.

Innovation involves three distinct stages:

(i) conception; (ii) development; and (iii) commercialization. The conception stage, representing the genesis of the inventive process, entails coming up with a viable idea for a new invention. The development stage encompasses the research and labor necessary to transform the idea into a patentable application (i.e., to operationalize it). Finally, the commercialization stage requires marketing the invention to the public.<sup>99</sup>

While all three stages are important, the commercialization stage has the greatest effect on innovators. The success of new technologies determines the innovators' reward. Failure to win over consumers implies that investments in R&D will not be recuperated. Hence, it is not surprising that even patented inventions are of relatively little value before their successful commercialization. Yet, the pro-status-quo bias of tort law impedes the introduction and adoption of new technologies. Aware of this bias, some inventors may decide that it is not worth their while to pursue innovative technologies and will invest their resources elsewhere.

We do not argue, of course, that all innovation will come to a halt. The precise effect of tort liability on innovation depends on the relevant R&D costs innovators must incur to produce new technologies and the superiority

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99. Oren Bar-Gill & Gideon Parchomovsky, *A Marketplace for Ideas?*, 84 TEX. L. REV. 395, 398 (2005).

of the results over conventional alternatives.<sup>100</sup> An innovator will consider carrying out her idea when her expected profit is greater than the costs of R&D. The anticipated payout to tort plaintiffs, however, always adds to the innovator's costs, thereby eroding her incentive to innovate. In some cases, this erosion may forestall the innovation completely. In others, it induces the innovator to develop and patent the innovation but stop short of commercializing it because of increased tort liability. Patent scholars have noted that less than five percent of patented inventions are of any value; the remaining ninety-five percent lay fallow, failing to yield any return to the inventors.<sup>101</sup> While we clearly do not claim that the anti-innovation bias of our torts system is solely, or even mostly, responsible for the large number of inventions that are never put to commercial use,<sup>102</sup> it likely contributes to this phenomenon.

Kip Viscusi and Michael Moore's leading empirical study of the effects of product liability on technological innovations partially bears out our predictions.<sup>103</sup> The study's main finding is that product liability chills innovation only at very high levels of expected liability payouts.<sup>104</sup> The study identifies no negative correlation between low to moderate liability payouts and the firms' innovative activities.<sup>105</sup> For high liability payouts, however, it does find a strong negative correlation.<sup>106</sup> This finding proves that high levels of product liability depress innovation.<sup>107</sup>

100. Cf. Mark Geistfeld, *Products Liability*, in 3 ENCYCLOPEDIA OF LAW AND ECONOMICS 347, 363 (Boudewijn Bouckaert & Gerrit De Geest eds., 2000). Professor Geistfeld argues that product liability motivates the development of novel safety technologies, which makes it welfare-enhancing. *Id.* As we explain in the text, however, custom rules give manufacturers a more attractive alternative: replication of conventional technologies. This alternative is privately cheaper but socially costlier than investing in safety-focused R&D. Similarly, Professor Benjamin H. Barton claims that tort liability spurs innovation and uses anecdotal evidence of playground designs to substantiate this claim. Benjamin H. Barton, *Tort Reform, Innovation, and Playground Design*, 58 FLA. L. REV. 265 (2006). He too fails to acknowledge the perverse effects of the custom rules. As we explain in the text, those rules subsidize innovations falling within the accepted technological paradigm (as seems to be the case with Professor Barton's playgrounds) and tax paradigm-shifters.

101. See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1507 (2001) ("[T]he total [estimated] number of patents litigated or licensed for a royalty (as opposed to a cross-license) is on the order of five percent of issued patents.").

102. For discussion of the factors that account for this phenomenon, see Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1 (2005), which lays out a general economic account of strategic patenting, and Robert P. Merges, *One Hundred Years of Solitude: Intellectual Property Law, 1900–2000*, 88 CAL. L. REV. 2187, 2222 (2000), which discusses patenting aimed solely at blocking competition.

103. W. Kip Viscusi & Michael J. Moore, *Product Liability, Research and Development, and Innovation*, 101 J. POL. ECON. 161 (1993).

104. *Id.* at 164–66, 174, 182. The study associates those payouts with the premiums firms paid insurers to obtain product liability coverage. It measures the intensity of the firms' efforts to innovate by associating it with the firms' expenditures on R&D. *Id.* at 169–72.

105. See *id.* at 164.

106. *Id.* at 164–66, 174.

107. *Id.* For discussions of this study, see Susan Rose-Ackerman, *Product Safety Regulation and the Law of Torts*, in PRODUCT LIABILITY AND INNOVATION: MANAGING RISK IN AN UNCERTAIN ENVIRONMENT 151, 151 (1994); Barton, *supra* note 100, at 278–80.

Viscusi and Moore's study is most impressive in its scope, model, and methodology.<sup>108</sup> We believe, nonetheless, that the reported findings do not capture the full effect of tort liability—or even product liability alone—on innovation. By focusing exclusively on firms' liability payouts, the study does not account for custom rules' distortionary effect on innovation. A firm's expectation of high-liability payouts will not necessarily induce it simply to cut back on R&D. Instead, the firm may confine its R&D activities to conventional technological frameworks. Staying within the conventional framework will allow a firm not only to avoid the doctrinal tax imposed on non-conventional innovators but also to do better by accepting the law's subsidy for improvements of customary technologies. Alternatively, the firm may patent its novel technologies without transforming them into products, just in order to block competitors. For these reasons, a firm's investment in R&D is not a dependable criterion for measuring the effects of tort liability on innovation. The custom rules do not always chill a firm's innovative activities completely. They will, in some cases, divert the path of those activities, prompting firms to develop products with low liability prospects despite the feasibility of technologically superior and safer alternatives. Indeed, a firm may even increase its investment in R&D in order to develop "liability-proof" products that align with industrial customs. Under this scenario, the firm's R&D investment would not be indicative of any scientific or technological advancement whatsoever.

Finally, it should be noted that, since innovation in many technological areas is cumulative, with new inventions building on preexisting ones, the dynamic efficiency loss occasioned by the custom rules may be far greater than it seems. By preventing certain inventions from ever being produced, the custom rules deprive society not only of those particular inventions but also of many subsequent innovations.

### III. REMEDYING THE ANTI-INNOVATION BIAS

The discussion so far established the prevalence of custom rules in our torts system and demonstrated their adverse effect on innovation. In this Part, we explore ways to correct this distortion. Policymakers can reform tort law in one of two ways to make it more welcoming to innovation. The first way to level the playfield is to eliminate the privileged status of custom and switch to a pure cost-benefit system. We term this alternative "equalizing down." An alternative way would be to retain the current deference to industry custom but grant certain innovations, whose safety was confirmed by a special board of experts in each industry, the same privileged status as enjoyed by custom. We term this alternative "equalizing up." In the remainder of this Part, we discuss the two alternatives and assess their respective strengths and weaknesses.

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108. Additional studies can be found in *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION* (Peter W. Huber & Robert E. Litan eds., 1991), a collection of essays that examine empirically, but ultimately leave open, the question whether product liability chills innovation.

### A. *Equalizing Down: Doing Away with Custom Rules*

Firms' rewards ought to be based on the costs and benefits their activities produce rather than on the extent of their compliance with customs. Firms that produce the greatest benefits and least damage should prevail in the marketplace. To enable fair competition among firms, the legal system should not impose special burdens on innovators in the form of an increased prospect of liability in torts; nor should it subsidize replicators of conventional technologies by decreasing their prospect of liability. The most straightforward way of accomplishing this would be to shift to a pure cost-benefit system that gives no deference to custom. To this end, the legal system should eliminate the evidential association between innovations and an increased risk of harm as well as abolish the rules that link safety to compliance with custom. We now turn to explaining how this proposal can be implemented in each of the areas we discussed: medical malpractice, product liability, and negligence.

In the area of medical malpractice, we propose that liability should be left to contractual agreements between physicians and patients—as is the case today. We wholeheartedly believe that the legal system is right to rectify the informational disparity between patients and doctors by setting forth elaborate requirements for “informed consent.” But it went awry in developing two different standards of “informed consent,” instead of one uniform standard. In other words, the “informed consent” standards for conventional and innovative treatments should be the same across the board. If a patient needs to know her doctor’s rate of success in performing a particular procedure, this information should be given to the patient not only when the procedure is innovative and “experimental,” but also when it is conventional.<sup>109</sup> Likewise, if a doctor must disclose her personal interest in delivering the chosen treatment, the doctor’s duty should not depend on whether the treatment is conventional or “experimental.”<sup>110</sup> Similarly, if a potential recipient of an innovative treatment needs to be aware of the treatment’s conventional alternatives,<sup>111</sup> patients receiving conventional medicine should then be informed about alternative options.<sup>112</sup> Finally, all doctors must give the patient correct information about the treatment’s risks and benefits. They should not be required to indiscriminately attach the “unknown” label to all risks and benefits associated with innovative

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109. Cf. *Johnson ex rel. Adler v. Kokemoor*, 545 N.W.2d 495 (Wis. 1996) (holding that a doctor’s failure to disclose his success rates to patient violated “informed consent”); Aaron D. Twerski & Neil B. Cohen, *The Second Revolution in Informed Consent: Comparing Physicians to Each Other*, 94 Nw. U. L. REV. 1 (1999) (advocating general disclosure of doctors’ success rates).

110. See Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 487–97 (2002) (describing trust as a foundation of doctor-patient relationship); Paul B. Miller & Charles Weijer, *Fiduciary Obligation in Clinical Research*, 34 J.L. MED. & ETHICS 424 (2006) (outlining doctors’ general obligation to inform patients about conflicts of interest).

111. See Noah, *supra* note 91, at 366 (“[P]hysicians generally must disclose reasonable alternative courses of action to the patient.”).

112. Cf. *Moore v. Baker*, 989 F.2d 1129, 1133 (11th Cir. 1993) (noting that doctors need not inform patients about experimental treatments).

treatments.<sup>113</sup> This reform would place innovative treatments on an informational par with conventional ones. By doing so, it would enable physicians to administer innovative treatments without exposing themselves to an increased risk of liability.

In the areas of product liability and general liability for accidents, where contracting between potential injurers and victims is not practicable on account of high transaction costs, we propose to eliminate the anti-innovation bias by abolishing the rules that establish this bias. Courts should deem industry customs irrelevant. Accordingly, industry customs should neither be admitted as evidence in negligence cases, when courts determine whether the precautions undertaken by the plaintiff were adequate, nor in product liability suits, when courts decide the “risk-utility” of product designs and set “consumer expectation” criteria. Every tort suit would then involve a custom-free examination of the risk of harm of the defendant’s activities. The defendant would be held negligent and responsible for the damage caused when the risk to which he exposed the plaintiff required greater precautions than he actually took. In the product liability area, courts would hold a product’s design defective when the risk of harm for an average consumer exceeded the product’s benefits. The defendant’s compliance or failure to comply with custom would not go into evidence, and the fact finder would consequently ignore it.

The *res ipsa* rule should undergo a similar adjustment. The rule’s “ordinary course of events” criterion associates negligence with any case in which the defendant causes damage to the plaintiff, without taking conventional precautions against that damage. Defendants who take conventional or customary precautions sidestep this evidential association. Defendants who use novel technology to avoid damage remain subject to the *res ipsa* rule and are consequently treated similarly to defendants who took no precautions at all. We propose to eliminate this distortion with a new rule that would attach a presumption of negligence only to cases featuring no precautions against damage whatsoever. In cases where some precautions were taken, the defendant’s negligence ought to be proven, not presumed. In particular, no presumption of negligence should attach to innovative precautions that depart from custom. If a plaintiff claims that the novel technology is unsafe, she ought to produce evidence that substantiates this claim. And if she fails to produce such evidence, the judge should dismiss the lawsuit. The *res ipsa* rule should not allow such a plaintiff to move her suit to the jury—a prospect that presently exposes innovators to a risk of losing the case<sup>114</sup> and puts them under serious pressure to settle.

Finally, rules controlling the admission of expert testimony—both *Frye* and *Daubert*—should remove all their restrictions on novel science and technology. To allow innovators to rebut accusations of wrongdoing, the law should permit innovators’ experts to testify in their defense. No other expert

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113. See Noah, *supra* note 91, at 377–79 (questioning the wisdom of the heightened informed-consent requirements for experimental treatments).

114. See *supra* notes 51–56 and accompanying text.

can properly develop the innovator's claim that her novel technology is safe. Admissibility of the innovator's expert testimony, therefore, should not depend on whether it aligns with accepted wisdom.

Our reform proposal gives rise to two objections. The first objection is that our analysis underestimates the importance of experience, dubbed the "life of the law" by one great jurist.<sup>115</sup> The gist of this objection is that conventional knowledge and technologies have been tested by and received affirmation from experience, while new technologies and knowledge have not yet passed this test. For this reason, society would do well to deem the time-honored conventional knowledge and technologies less hazardous than the new ones. The legal system consequently should design rules that induce firms and individuals whose activities might cause harm to another person to use conventional knowledge and technologies and exercise caution with innovations. This is what the custom rules do.

The second objection focuses on the adjudicative efficiency of the custom rules. Specifically, it holds that those rules minimize the costs of adjudicative errors and error avoidance as a total sum.<sup>116</sup> The cost of adjudicative errors is defined by the value of liabilities and entitlements that adjudicators mistakenly fail to recognize (and the legal system consequently fails to enforce). The cost of error avoidance, on the other hand, aggregates the expenditures on procedures and decisions that enhance accuracy in adjudication. Custom rules minimize the sum of those costs in three distinct ways. They protect damage-producing but still faultless firms against adjudicators' biases and populist temptations.<sup>117</sup> They also set dependable shortcuts for determinations of negligence by adjudicators who might decide cases erroneously if left to their own devices.<sup>118</sup> Finally, the rules increase the probability of an out-of-court settlement by making adjudicative procedures and decisions more predictable.<sup>119</sup>

We consider these two objections in order. We believe that the experience-based objection is overstated. Conventional knowledge and technologies have indeed been validated by human experience, a factor that weighs in their favor. Human experience, however, provides no reasons for being indiscriminately suspicious of novel technologies and medical treatments. Some novel technologies and treatments are unsafe, but many others are both safer and more efficacious than conventional alternatives. Any novelty, therefore, needs to be accepted or rejected on the merits. If a piece of experience-based knowledge is sound, it should be able to defeat its rivals

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115. O.W. HOLMES, JR., *THE COMMON LAW* 1 (Boston: Little, Brown, & Co., 1881).

116. This is what many rules of evidence actually do. See ALEX STEIN, *FOUNDATIONS OF EVIDENCE LAW* 141–71 (2005).

117. See Morris, *supra* note 16, at 1147–49.

118. See Henderson, *supra* note 16, at 923–24.

119. See generally Lucian Arye Bebchuk, *Litigation and settlement under imperfect information*, 15 RAND J. ECON. 404 (1984) (observing that parties' symmetrical information about trial's outcome promotes settlement and analyzing the nature and probability of settlements under asymmetrical information).

by its own epistemic force; and if it is questionable, it should not be protected against innovators' challenges. Sound knowledge needs no special reinforcement from the law. Unsound knowledge does not deserve that reinforcement.

The incumbent incentive is another reason for removing the a priori suspicion from novel technologies and medical treatments. Lines separating the novel from the conventional are not always drawn by impartial scientists. They are frequently drawn by owners and producers of conventional technologies, who are motivated to obstruct innovations in order to maintain their superiority on the market. The state should not protect these incumbents' interests by setting up rules that disfavor innovators. Furthermore, the state should normally stay away from the marketplace for knowledge and technologies.<sup>120</sup>

The efficiency-based objection to our proposals is equally unconvincing. The saving in adjudicative costs stemming from custom rules has a limit. Consequently, the social loss resulting from the innovations depressed by the custom rules is likely to be much greater. The benefits that a *single* life-saving technology or medical treatment can produce over time may well be greater than the total saving of adjudicative costs generated by the custom rules. It is, therefore, hard to see how the custom rules' advantages can offset the value of depressed innovations.

Ultimately, of course, the question whether the benefits from abolishing the custom rules would outweigh the costs thereof is an empirical one. We are not aware of any empirical studies that analyze this question. It is possible, therefore, that some readers may be wary of our call to abolish custom rules and would prefer to retain them. To put the minds of such readers at ease, we next delineate an alternative reform proposal that would make tort law more innovation friendly without abandoning the custom baseline.

### B. *Equalizing Up: Elevating Innovations to the Status of Custom*

If policymakers deem the advantages stemming from the use of custom rules worth keeping, they can make tort law more innovation friendly by granting *certain* (not all) new technologies the same privileged status as custom. To do so, special private boards of industry experts will be set up to review the safety of scientific and technological innovations in their relevant areas of expertise. Courts, in turn, will recognize those boards' findings by treating them as equivalent to customs. Innovators will then be able to submit their innovations for review by the relevant board. Innovations that successfully pass the inspection process will be entitled to the same status as customary and conventional technologies and will receive the same deference from courts in tort suits. Innovations that fail to receive the relevant

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120. This point echoes Hayek's economic theory of information production. See Richard A. Posner, *Hayek, Law, and Cognition*, 1 N.Y.U. J. L. & LIBERTY 147 (2005) (expounding Hayek's theory of private and decentralized information production); see also *id.* at 149–50 (attesting that, under Hayek's theory, legal sanctions should be used to enforce only abstract customs that set general frameworks for people's interactions).

board's approval will be deemed unsafe in any subsequent tort litigation. If a board fails to reach a decision during a period of two years, the innovation, once again, will be deemed as safe as any technology or medical treatment approved by custom.<sup>121</sup>

The proposed mechanism will alleviate much of the anti-innovation bias that plagues the existing system of torts, but only by generating several new costs.<sup>122</sup> First, the review process will delay the introduction of new technologies to markets. The review process is likely to take months, and until it is completed consumers will not be able to enjoy the innovations. Even so, the proposal probably represents a significant improvement over the current regime, which likely causes much greater delays in the introduction of innovations and sometimes blocks them altogether. Also, since the review is not mandatory, innovators who are certain of the safety of their products and services may choose not to subject them to board review and take their chances with courts.

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121. A comparison with Federal Drug Administration ("FDA") review is instructive. Under the accelerated, fee-based review system, it takes about a year on average for the FDA to give a pre-market approval to a drug, both new and generic, while the average period for a pre-market approval of medical devices is five months. MICHELE SCHOONMAKER, CRS REPORT FOR CONGRESS, THE U.S. APPROVAL PROCESS FOR MEDICAL DEVICES: LEGISLATIVE ISSUES AND COMPARISON WITH THE DRUG MODEL 33 tbl. 2 (2005). In a not so distant past, the average period for a new drug's non-expedited approval by FDA was eight and a half years. CTR. FOR DRUG EVALUATION AND RES., DEP'T OF HEALTH AND HUMAN SERV., THE CDER HANDBOOK 5 (rev., 1998). For medical devices, the approval period ranged between "months or even several years." Theresa J. Pulley Radwan, *Meeting the Objectives of the MDA: Implied Preemption of State Tort Claims by the Medical Device Amendments*, 10 J.L. & HEALTH 343, 347 (1995-96). Our two-year limit proposal accounts for the modern tendency to shorten the approval period, but is also mindful of four additional factors. First, the proposed review system is private and optional rather than state-imposed and compulsory. Second, proper scientific review of a novel technology may require lengthy experiments. Third, the FDA system, unlike ours, has no approval-by-default provision in the event of unduly delayed review. Finally, our equalizing-up mechanism effectively shields the innovator from liability in torts, while an FDA approval of a drug or medical device does not always have such effect. *See* *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (holding in connection with medical devices that FDA approval pursuant to section 510 of the Food, Drug, and Cosmetic Act, as amended by the Medical Device Amendments of 1976, does not block tort actions in state courts for both negligence and product liability); DAVID G. OWEN, *PRODUCTS LIABILITY LAW* § 8.10 at 558 & n.56 (2005) (attesting that drug manufacturers are liable for defective drugs despite FDA's clearance and presenting relevant case-law). *But see* *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008) (holding that when a medical device satisfies the FDA requirements for its pre-market approval, the manufacturer will defeat the tort action). Following this decision, the FDA may equalize-up the status of innovative medical devices. Whether it will do so often enough is an open question.

122. Eradication of the anti-innovation bias also can be achieved by substituting the fault-based doctrines of negligence and product liability with a no-fault regime of strict liability. This reform would do away with the custom rules, but in a radical and intensely controversial way that we avoid recommending. *See* James A. Henderson, Jr., *Why Negligence Dominates Tort*, 50 UCLA L. REV. 377 (2002) (analyzing problems that a transition from negligence to strict liability would engender). The federal preemption mechanism is another far-reaching alternative. This mechanism blocks tort actions complaining against technologies that comply with the safety standards set by the appropriate federal agency. The agency consequently can "equalize up" new technologies that are yet to become state-of-the-art. *See, e.g., Riegel*, 128 S.Ct. 999 (holding that requirements for pre-market approval of medical devices, issued by FDA pursuant to section 510 of the Food, Drug, and Cosmetic Act, as amended by the Medical Device Amendments of 1976, preempt conflicting tort actions against manufacturers); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 864-86 (2000) (holding that the DOT's Federal Motor Vehicle Safety Standards, promulgated under the National Traffic and Motor Vehicle Safety Act of 1966, preempt conflicting tort actions against car manufacturers).

Second, implementation of the proposal will create new costs. The proposed review boards must be funded, and it will be the innovators who submit applications for review who will have to pick up the bill. The additional cost borne by innovators will increase the cost of commercializing innovations. On the margin, this cost increase may thwart commercialization of certain innovations and the production of others. To determine the social desirability of our proposal, it would be necessary to compare its chilling effect on innovation to the chilling effect of custom rules. Once again, we are not aware of empirical data that can aid policymakers in making this determination. Yet, for the reasons provided in Part II, we believe that the adverse effect of the current regime is greater. Furthermore, it must be borne in mind that our proposal does not force innovators to submit their innovations to board review; it only gives them an option to do so. Whether to use this option or live with the current custom-driven regime is the innovator's call. Hence, it is difficult to see how our proposal will make innovators worse off relative to the existing system.

Our proposal gives rise to still other costs: rent-seeking and favoritism. Board members can seek side payments from innovators as a condition for approving their technologies. Likewise, reviewers can play favorites with innovators and base their decisions on personal, rather than professional, reasons. The specter of these twin problems arises with respect to any administrative process, and our proposal is obviously no exception. Yet if board members are selected from firms within every industry, the problem may be more acute. Board members who review applications must be as independent as possible, preferably without prior affiliation to any of the firms whose innovations come under review.

At the end of the day, in deciding whether to retain the custom rules, policymakers ought to assess the net benefit from adopting our proposal and compare it to that of the custom rules. This assessment, of course, should include the value of innovations that the custom rules presently depress. One practical way to assess this tradeoff would be to implement our proposal in a single industry and measure the net effect. If the small scale experiment proves successful, it should be extended to other industries.

#### CONCLUSION

Innovation, like all other human behavior, is affected by legal rules. In this Essay, we analyzed the effect of tort liability on innovation. Tort law is commonly thought of as a mechanism of assigning liability to wrongdoers and thereby forcing them to internalize the costs they impose on others. This, indeed, is its primary effect. Yet, as we demonstrated in this Essay, tort law has a second, less salutary effect. By establishing safe harbors for industry customs and conventional technology, tort law taxes innovation and influences its course. Did policymakers intend to create this effect? For all we know, this hidden effect may well be inadvertent. It is quite possible that policymakers failed to appreciate the connection between tort liability and innovation. We were not able to find any historical records that address this

issue. What is more important, however, is that there is no a priori reason why tort law must impede innovation. There is no necessary connection between the deterrent effect and the anti-innovation effect of tort law; the two can be easily decoupled. It is possible to benefit from the deterrent effect of tort liability on wrongdoers without paying a significant price in the form of forgone or distorted innovation. As we explained, policymakers can accomplish this result either by eliminating courts' reliance on custom in making liability determinations or by instructing courts to give innovations whose safety was verified by independent industry experts the same deference they give custom. We openly admit that our solutions are not cost-free, but the costs to which they give rise are likely to be far outweighed by the benefits of unhindered innovation.

