

# WHEN THE “MACHINE THAT GOES ‘PING’” CAUSES HARM: DEFAULT TORTS RULES AND TECHNOLOGICALLY-MEDIATED HEALTH CARE INJURIES\*

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## I. INTRODUCTION

The publication of *To Err Is Human: Building a Safer Health System*<sup>1</sup> turned the reduction of medical error from a professional aspiration into a finite public and political issue. Despite the existence of newer and even contradictory studies,<sup>2</sup> for a generation of doctors, lawyers and policymakers medical error will irrevocably be associated with between 44,000<sup>3</sup> and 98,000<sup>4</sup> error-related deaths per year.<sup>5</sup> The reduction of those numbers has been established as an operational imperative.

The health care industry is still absorbing the implications of the information technology and e-commerce-led revolution of the last decade.<sup>6</sup> Business-to-consumer (hereinafter referred to as “B2C”) health advice sites and business-to-business (hereinafter referred to as “B2B”) models, such as continuing education, procurement and telemedicine, all seem to have traction in the marketplace. Penetration of technology into the health care delivery system is also being broadly driven by the electronic data interchange standards introduced by regulations made under the Health Insurance

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1. COMM. ON QUALITY OF HEALTH CARE IN AMERICA, INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Kohn et al. eds., 2000) [hereinafter *TO ERR IS HUMAN*].

2. See, e.g., Rodney A. Hayward & Timothy P. Hofer, *Estimating Hospital Deaths Due to Medical Errors: Preventability Is in the Eye of the Reviewer*, 286 JAMA 415 (2001).

3. *Id.*

4. *Id.*

5. See also Agency for Healthcare Research and Quality, *Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs* (2001) (estimating that 770,000 injuries and deaths each year are caused by adverse drug events, many of which are the result of medication errors), available at <http://www.ahrq.gov/qual/aderia/aderia.htm> (last visited Oct. 5, 2001).

6. See Nicolas P. Terry, *Structural and Legal Implications of E-Health*, 33 J. HEALTH L. 605 (2000).

Portability and Accountability Act of 1996 (HIPAA).<sup>7</sup> These standards will encourage electronic billing, insurance reimbursement and prescription fulfillment systems and also will promote infrastructure-related peripheral systems such as longitudinal patient records and computer surveillance systems.<sup>8</sup>

In general terms, however, the Institute of Medicine (IOM) was correct when it noted in the *Crossing the Quality Chasm* report that, “[h]ealth care delivery has been relatively untouched by the revolution in information technology that has been transforming nearly every other aspect of society.”<sup>9</sup> This will change rapidly because a massive infusion of technology is viewed as the key component in process-based reform of the health care delivery system.<sup>10</sup> While process and technology-based attacks on medical error may not represent a total solution for the medical error problem,<sup>11</sup> at a simple operational level this is where regulatory energies and investment dollars will be concentrated. As the IOM has recommended:

Congress, the executive branch, leaders of health care organizations, public and private purchasers, and health informatics associations and vendors should make a renewed national commitment to building an information infrastructure to support health care delivery, consumer health, quality measurement and improvement, public accountability, clinical and health services research, and clinical education. This commitment should lead to the elimination of most handwritten clinical data by the end of the decade.<sup>12</sup>

The growth of technologically-mediated care should directly reduce medical error. It will also have positive indirect effects such as improving the data sets that underlie peer review, state disciplinary oversight and medical malpractice litigation. A technologically-mediated health care delivery system also should deliver substantial reductions in information costs for consumers, improving choice as to both quality and safety. What seems less clear is the extent to which process re-engineering and conversion to technology-centered error reduction systems will create a new set of quality of care externalities. The United States health care industry may have been laggard in adopting

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7. See Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.).

8. See Nicolas P. Terry, *An eHealth Diptych: The Impact of Privacy Regulation on Medical Error and Malpractice Litigation*, 27 AM. J.L. & MED. 361 (2001).

9. COMM. ON QUALITY OF HEALTH CARE IN AMERICA, INST. OF MED., *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* 15 (2001) [hereinafter *CROSSING THE QUALITY CHASM*].

10. See James Reason, *Human Error: Models and Management*, 320 BRIT. MED. J. 768 (2000).

11. See Lucian L. Leape, *Foreword: Preventing Medical Accidents: Is “Systems Analysis” the Answer?*, 27 AM. J.L. & MED. 145 (2001).

12. *CROSSING THE QUALITY CHASM*, *supra* note 9, at 17.

information technologies, but it is no stranger to a broad range of other technologies and the failure rates that accompany them.<sup>13</sup>

This Article explores some of the liability questions posed by increasing the technology component in health care delivery. First, I take the position that the process and technology reforms triggered by *To Err Is Human* inevitably will confirm institutional liability as the default position for modern malpractice claims. I argue that process reform and technology-based quality control finally will fulfill the promise of corporate liability first outlined nearly forty years ago in *Darling v. Charleston Community Memorial Hospital*<sup>14</sup> and supersede a liability structure that relies on a species of *respondeat superior* doctrine that owes more to creative writing than hornbook law.

Second, I argue that the likely adverse event scenarios that will result from technologically-mediated diagnosis, treatment and care will severely test our current torts operational rules,<sup>15</sup> particularly those that lie at the intersection of malpractice and products liability.

## II. ERRORS, TECHNOLOGY AND AN INSTITUTIONAL DUTY DEFAULT

Re-reading *Darling* today, the opinion seems overly ambitious in tackling both the issue of institutional liability<sup>16</sup> and the use of accreditation standards and hospital bylaws as custom-surrogates.<sup>17</sup> It also seems somewhat underdeveloped at the doctrinal level, supplying neither analytical depth nor

13. See, e.g., Kenneth Chan, *When Implants Fail, Patients Suffer Twice*, N.Y. TIMES, Aug. 7, 2001, at F1.

14. 211 N.E.2d 253 (Ill. 1965). Cf. E. Haavi Morreim, *Playing Doctor: Corporate Medical Practice and Medical Malpractice*, 32 U. MICH. J.L. REFORM 939 (1999).

15. For a general discussion of allocation models and operational rules see Nicolas P. Terry, *Collapsing Torts*, 25 CONN. L. REV. 717 (1993).

16. *Darling*, 211 N.E.2d at 257 (citing *Bing v. Thunig*, 143 N.E.2d 3, 8 (N.Y. 1957)).

The conception that the hospital does not undertake to treat the patient, does not undertake to act through its doctors and nurses, but undertakes instead simply to procure them to act upon their own responsibility, no longer reflects the fact. Present-day hospitals, as their manner of operation plainly demonstrates, do far more than furnish facilities for treatment . . . . The Standards for Hospital Accreditation, the state licensing regulations and the defendant's bylaws demonstrate that the medical profession and other responsible authorities regard it as both desirable and feasible that a hospital assume certain responsibilities for the care of the patient.

*Id.*

17. *Id.* at 257.

In the present case the regulations, standards, and bylaws which the plaintiff introduced into evidence, performed much the same function as did evidence of custom. This evidence aided the jury in deciding what was feasible and what the defendant knew or should have known. It did not conclusively determine the standard of care and the jury was not instructed that it did.

*Id.*

operational detail.<sup>18</sup> Notwithstanding this fact, institutional<sup>19</sup> or corporate liability<sup>20</sup> as exemplified by *Darling*<sup>21</sup> has routinely been applied in cases involving facilities,<sup>22</sup> equipment,<sup>23</sup> staffing<sup>24</sup> and the maintenance of premises.<sup>25</sup> Some jurisdictions have been explicit in combining these strands into a comprehensive and cohesive declaration of institutional duty:

The hospital's duties have been classified into four general areas: (1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) a duty to select and retain only competent physicians; (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for the patients . . . .

. . . .

[W]e adopt as a theory of hospital liability the doctrine of corporate negligence or corporate liability under which the hospital is liable if it fails to uphold the proper standard of care owed its patient. In addition, we fully embrace the aforementioned four categories of the hospital's duties.<sup>26</sup>

In too many jurisdictions, however, the law has remained unsettled in cases involving diagnosis, treatment and care, which courts historically have viewed as the responsibility of individual care providers, rather than the institution. More specifically, questions have arisen as to whether institutions are directly

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18. See, for example, the comments of the court in *Gafner v. Down East Community Hospital*, 735 A.2d 969, 978 (Me. 1999) (addressing institutional liability more generally).

19. Institutional liability not only includes hospitals, but also managed care organizations, including health maintenance organizations (HMOs). See *Jones v. Chi. HMO*, 730 N.E.2d 1119, 1128 (Ill. 2000).

20. Defined by the Supreme Court of Pennsylvania as follows:

Corporate negligence is a doctrine under which the hospital is liable if it fails to uphold the proper standard of care owed the patient, which is to ensure the patient's safety and well-being while at the hospital. This theory of liability creates a nondelegable duty which the hospital owes directly to a patient. Therefore, an injured party does not have to rely on and establish the negligence of a third party.

*Thompson v. Nason Hosp.*, 591 A.2d 703, 707 (Pa. 1991) (footnote omitted).

21. See, e.g., *Darling v. Charleston Cmty. Hosp.*, 211 N.E.2d 253 (Ill. 1965).

22. See, e.g., *Hernandez v. Smith*, 552 F.2d 142 (5th Cir. 1977); *Chandler Gen. Hosp. Inc. v. Purvis*, 181 S.E.2d 77 (Ga. Ct. App. 1971).

23. *Emory Univ. v. Porter*, 120 S.E.2d 668 (Ga. Ct. App. 1961).

24. See, e.g., *Merritt v. Karcioğlu*, 668 So. 2d 469 (La. Ct. App. 1996); *Johnson v. Misericordia Cmty. Hosp.*, 301 N.W.2d 156 (Wis. 1981); *Wood v. Samaritan Inst.*, 161 P.2d 556 (Cal. Ct. App. 1945).

25. *Flowers v. Torrance Mem'l Hosp. Med. Ctr.*, 884 P.2d 142 (Cal. 1994) (involving a patient falling from a gurney).

26. *Thompson v. Nason Hosp.*, 591 A.2d 703, 707-08 (Pa. 1991).

liable in informed consent cases<sup>27</sup> and the extent to which the institutional duty is non-regressive, meaning whether it is limited to pre-adverse event credentialing or policymaking,<sup>28</sup> or continues forward to apply to occasions of individual treatment.<sup>29</sup> The indeterminacy surrounding the reach of *Darling*<sup>30</sup> has threatened to minimize its impact and characterize it as little more than an institutional version of administrative or ministerial liability.<sup>31</sup>

Only a few courts have shown outright hostility towards the doctrine of institutional liability.<sup>32</sup> Objections to the institutional default may, however, be

27. See, e.g., *Cross v. Trapp*, 294 S.E.2d 446, 472 (W. Va. 1982) (holding that absent agency relationship with physician, hospital had no duty to obtain patient's informed consent to surgery). See also *Wells v. Storey*, No. 1970450, 1999 Ala. LEXIS 361 (Ala. Nov. 24, 1999); *Bryant v. HCA Health Servs. of N. Tenn., Inc.*, 15 S.W.3d 804 (Tenn. 2000); *Cooper v. Curry*, 589 P.2d 201 (N.M. Ct. App. 1978). See also *Giese v. Stice*, 567 N.W.2d 156 (Neb. 1997) (reviewing authorities); Cf. *Clark v. Perry*, 442 S.E.2d 57 (N.C. Ct. App. 1994); *Butler v. S. Fulton Med. Ctr.*, 452 S.E.2d 768, 772 (Ga. Ct. App. 1994).

In obtaining a consent form, a nurse is not acting as a "borrowed servant" of the doctor, but as an employee of the hospital because the task of obtaining a properly executed form is administrative and does not involve professional medical skill or judgment . . . . The verification that a consent form has been properly executed and is part of the patient's records does not require application of medical judgment and the hospital may be liable under some circumstances for the nurses' failure to obtain the form in violation of its internal procedure.

*Butler*, 452 S.E.2d at 772.

28. For example, an institution may have a duty to use reasonable care in formulating the policies and procedures that govern its medical staff and nonphysician personnel. See *Denton Reg'l Med. Ctr. v. LaCroix*, 947 S.W.2d 941 (Tex. App. 1997); *Air Shields, Inc. v. Spears*, 590 S.W.2d 574 (Tex. Civ. App. 1979).

29. This is particularly the case where the patient's own relationship with the institution is tenuous. See, e.g., *Pedroza v. Bryant*, 677 P.2d 166, 172 (Wash. 1994) (holding that corporate liability should not be imputed to a hospital that granted hospital privileges to a non-employee physician who allegedly harmed a patient in his private office off the hospital premises). See also *Tripp v. Pate*, 271 S.E.2d 407 (N.C. Ct. App. 1980).

30. See generally David H. Rutchik, *The Emerging Trend of Corporate Liability: Courts' Uneven Treatment of Hospital Standards Leaves Hospitals Uncertain and Exposed*, 47 VAND. L. REV. 535 (1994).

31. See, e.g., *Advincula v. United Blood Servs.*, 678 N.E.2d 1009, 1023 (Ill. 1996).

32. See, for example, *Gafner v. Down East Community Hospital*, 735 A.2d 969, 979-80 (Me. 1999), where the allegation of institutional negligence was the hospital's failure to have in place a written policy requiring mandatory consultation with a specialist in the case of high risk births. The court stated:

There are a number of reasons for our refusal to accept the [plaintiffs'] theory of liability against the Hospital. Private hospitals in Maine are extensively regulated. The Legislature has created duties and guidelines for the actions of those hospitals in a number of areas. Before the expansion of tort liability into an area that has been significantly controlled by the Legislature, we should allow the Legislature to address the policy considerations and determine whether imposing such a duty constitutes wise public policy.

more deep-rooted and viewed as an endorsement of the deconstruction of individual professionalism, that itself may be an anathema to many judges. At a more superficial level, the very label, "institutional liability," may be problematic, suggesting to some judges a blanket rule re-allocating adverse event losses to hospitals. It is far more accurate to state the contended-for rule as one of institutional *duty*. Recognition of such a duty is but one element in a liability analysis. Indeed, "for a hospital to be charged with negligence, it is necessary to show that the hospital had actual or constructive knowledge of the defect or procedures which created the harm. Furthermore, the hospital's negligence must have been a substantial factor in bringing about the harm to the injured party."<sup>33</sup> Additionally, most allegations of diagnosis, treatment and care deficiencies will depend on expert testimony as to the national, customary standard of care of institutions.<sup>34</sup>

Conventional arguments in favor of adopting the default position of institutional duty need not be related in detail. These include improved deterrence because of the realities of modern credentialing and bylaws, more efficient compensation systems because of the market power of large institutions in planning and buying indemnity, and reduced system costs as plaintiffs are able to avoid the costs and uncertainties associated with individual liability models.<sup>35</sup> I take the position that these arguments are

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Moreover, creating a duty on the part of hospitals to control the actions of those physicians who have traditionally been considered independent contractors may shift the nature of the medical care provided by those physicians. In an area as replete with the possibility of unexpected or unintended consequences as this, we should exercise restraint in the use of our authority to create new causes of action . . . .

In sum, there exist serious and unanswered public policy questions regarding the wisdom of requiring hospitals to control the medical judgments and actions of independent physicians practicing within their facilities. Those questions implicate both quality of care and economic considerations. We will not lightly adopt a new theory of liability in an area of such significant concern for the public health. We decline to do so here.

*Id.* at 979-80.

33. *Thompson v. Nason Hosp.*, 591 A.2d 703, 708 (Pa. 1991).

34. *See, e.g., Washington v. Wash. Hosp. Ctr.*, 579 A.2d 177 (D.C. 1990) (holding that the alleged failure of the hospital to provide anesthesiologists with an end-tidal carbon dioxide monitor was sufficient to create an issue of fact for jury).

35. Underlying the tort of institutional negligence is a recognition of the comprehensive nature of hospital operations today. The hospital's expanded role in providing health care services to patients brings with it increased corporate responsibilities. As *Darling* explained:

Present-day hospitals, as their manner of operation plainly demonstrates, do far more than furnish facilities for treatment. They regularly employ on a salary basis a large staff of physicians, nurses and interns, as well as administrative and manual workers, and they charge patients for medical care and treatment, collecting for such services, if necessary, by legal action.

*Darling*, 211 N.E.2d at 257.

strongly reinforced by the phenomena of process reform and the emergence of technologically-mediated health care. Further, I argue that key technological and structural shifts facing our health care delivery system, adapted to reduce medical error, will confirm the final maturation of an institutional duty default. These phenomena I identify as institutional marketing, regulating technologically-mediated care, accrediting technology and the structural and organizational realities associated with technologically-mediated health care.

#### A. Institutional Marketing

In the absence of corporate or enterprise duty emerging as the default liability rule for quality of care or "technical care" litigation,<sup>36</sup> courts have continued to refine intellectually bankrupt vicarious liability rules to approximate institutional liability. These theories include case-by-case agency based on the right to control rather than actual control,<sup>37</sup> agency by estoppel,<sup>38</sup> and non-delegable duty.<sup>39</sup> It is, however, theories based on ostensible agency<sup>40</sup> or apparent agency<sup>41</sup> that have flourished in a health care industry environment re-organizing around consolidated entities, integrated delivery, institutional realities and holistic marketing. Furthermore, these are features that are both confirmed and reinforced by technological advancement, as hospitals both tout their process technologies and embrace new technological channels such as the web to market and provide their comprehensive services.

Of the agency theories that apply institutional duty to (arguably) individual errors, the current favorite is ostensible or apparent agency. More specifically, several courts are showing a preference for the version in the RESTATEMENT

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Expounding on the point, this court later stated: "[A] modern hospital . . . is an amalgam of many individuals not all of whom are licensed medical practitioners. Moreover, it is clear that at times a hospital functions far beyond the narrow sphere of medical practice." *Greenberg v. Michael Reese Hosp.*, 415 N.E.2d 390, 395 (Ill. 1980). "Thus, in recognizing hospital institutional negligence as a cause of action, *Darling* merely applied principles of common law negligence to hospitals in a manner that comports with the true scope of their operations." *Jones v. Chi. HMO*, 730 N.E.2d 1119, 1127 (Ill. 2000). See generally Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381 (1994); Arthur F. Southwick, *Hospital Liability—Two Theories Have Been Merged*, 4 J. LEGAL MED. 1, 49 (1983). Cf. *Rutchik*, *supra* note 30, at 548-50.

36. A distinction was advanced between interpersonal care and technical care. 1 AVEDIS DONABEDIAN, *EXPLORATIONS IN QUALITY ASSESSMENT AND MONITORING: THE DEFINITION OF QUALITY AND APPROACHES TO ITS ASSESSMENT* 4-6 (1980).

37. See *Berel v. HCA Health Serv. of Tex., Inc.*, 881 S.W.2d 21, 21 (Tex. App. 1994).

38. See *Sword v. NKC Hosp., Inc.*, 661 N.E.2d 10, 13 (Ind. Ct. App. 1996).

39. See *Jackson v. Power*, 743 P.2d 1376 (Alaska 1987); *Beeck v. Tucson Gen. Hosp.*, 500 P.2d 1153 (Ariz. 1972).

40. See *Schlotfeldt v. Charter Hosp.*, 910 P.2d 271 (Nev. 1996).

41. See *Jackson*, 743 P.2d at 1376.

OF TORTS<sup>42</sup> over that to be found in the RESTATEMENT OF AGENCY.<sup>43</sup> The former approach to apparent agency is preferred by malpractice plaintiffs because it lacks the more rigorous justifiable reliance provision found in the latter.<sup>44</sup> Building on this more generous representational standard, courts have pioneered a rule that essentially places the onus on the hospital or HMO to refute a patient's belief that the treating physician is an employee of the institution.<sup>45</sup> As framed by an Oregon court:

(1) the hospital must hold itself out as a provider of medical services, and (2) unless the patient has actual knowledge of the physician's actual status as an independent contractor, the patient can recover if it is objectively reasonable for the patient to believe that physician is an employee of the hospital.<sup>46</sup>

As a result robust examples of *de facto* institutional duty are to be found in cases where health care organizational reality and institutional marketing combine, leaving the hospital with little room to refute the patient's reasonable expectations of a health care provider's employment status. For instance, in *Kashishian v. Port*, involving the allegedly negligent acts of an independent contractor cardiologist, the Supreme Court of Wisconsin observed that "[m]odern hospitals have spent billions of dollars marketing themselves, nurturing the image with the consuming public that they are full-care modern health facilities."<sup>47</sup>

### *B. Regulating Technologically-mediated Care*

Measured against the modest goal of providing compensation for fault-caused adverse events, the law of medical malpractice operates at a reasonable level of efficiency. Arguably, it provides a needed role for patients or their representatives in assuring a forum for public accountability for substandard care. The malpractice system aimed at an individual care provider, however, is an incredibly clumsy tool for deterring medical error. Little better are our state

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42. RESTATEMENT (SECOND) OF TORTS § 429 (1965).

43. RESTATEMENT (SECOND) OF AGENCY § 267 (1958).

44. See *Jennison v. Providence St. Vincent Med. Ctr.*, 25 P.3d 358 (Or. 2001).

45. See, e.g., *Sword v. NKC Hosps. Inc.*, 714 N.E.2d 142 (Ind. 1999); *Butler v. Domin*, 15 P.3d 1189, 1198 (Mont. 2000) (finding § 429 decisions "particularly relevant"); *Jennison*, 25 P.3d at 366.

46. *Jennison*, 25 P.3d at 358. See also, the following statement by the court in *Butler*:

Butler's testimony that he did not receive notice of the employment relationship between Dr. Ehrlich and St. Patrick Hospital is sufficient to raise a genuine issue of material fact as to whether St. Patrick Hospital intentionally or negligently caused Butler to believe that Dr. Ehrlich was its agent. Furthermore, it is not apparent from the record that Butler had any knowledge which would indicate that he did not in fact believe that Dr. Ehrlich was St. Patrick Hospital's employee.

*Butler*, 15 P.3d at 1198.

47. *Kashishian v. Port*, 481 N.W.2d 277, 282 (Wis. 1992). See also *Simmons v. Tuomey Reg'l Med. Ctr.*, 533 S.E.2d 312 (S.C. 2000).



licensure-based disciplinary systems that, while arguably effective in egregious cases such as fraud, substance abuse and multiple instances of error, lack the resources to tackle closer cases or the legal competence to address systemic failures. Not surprisingly, therefore, the decades since *Darling* have witnessed a steady increase in regulatory activity that looks to improve quality by being compliance-based and institution-oriented.

For example, the Health Care Quality Improvement Act of 1986 requires (assumedly institutional) peer review entities that take adverse actions to report the same to state licensure boards.<sup>48</sup> It is the *institution* that subsequently enjoys a correlated immunity from damages.<sup>49</sup> Health care institutions that desire drug and device research funding must appoint *Institutional* Research Boards (IRBs). It is the IRB that then must determine that "[i]nformed consent will be sought from each prospective subject or the subject's legally authorized representative . . . ."<sup>50</sup> Indeed, even courts that have been less than enthusiastic about imposing institutional liability in diagnosis, care and treatment cases have done so where the institution has assumed the consent duty in this context of regulated clinical investigation.<sup>51</sup>

These trends, demonstrating the assumption of an institutional role followed by its regulation, will be solidified by the most rigorous regulation of technologically-mediated health care that we have yet seen: the HIPAA privacy regulations (PIHI).<sup>52</sup> The PIHI regulations apply to health care entities that utilize Electronic Data Interchange (EDI) for their transactions. The likelihood of any health care institution not doing so is minimal. PIHI requires consented-to disclosure<sup>53</sup> for treatment, payment or health care operations purposes and authorized disclosures for other purposes.<sup>54</sup> Theoretically, these consents and authorizations could be kept separate from the informed consents required for treatment; in practice it seems unlikely that they will be. As a result, these *institutional* duties will occupy the same operational space as

48. 42 U.S.C. § 11133 (1995).

49. 42 U.S.C. § 11111(a)(1) (1995).

If a professional review action . . . of a professional review body meets all the standards specified in section 11112(a) of this title . . . the professional review body . . . shall not be liable in damages under any law of the United States or of any State (or political subdivision thereof) with respect to the action.

*Id.*

50. 45 C.F.R. § 46.111(4) (2000).

51. *See, e.g.,* *Fritter v. Iolab Corp.*, 607 A.2d 1111 (Pa. Super. Ct. 1992); *Kus v. Sherman Hosp.*, 644 N.E.2d 1214 (Ill. App. Ct. 1995), *appeal denied*, 652 N.E.2d 343 (Ill. 1995).

52. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462 (Dec. 28, 2000) (to be codified at 45 C.F.R. pt. 160 and 164).

53. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,810-11.

54. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,811.

treatment-related informed consent, vaporizing any institutional arguments that the latter remain individual duties.

### C. Accrediting Technology

*Darling* established a link between institutional duty and accreditation standards by suggesting that the latter operates as a surrogate for traditional expert testimony as to the standard of care.<sup>55</sup> The 2001 revisions<sup>56</sup> to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards mandate increased proactive reporting and risk reduction systems in order to reduce medical error.<sup>57</sup> Specifically, there are new requirements promoting database driven risk management and error reduction systems<sup>58</sup> and mandating improvements in institutional knowledge-base systems.<sup>59</sup> It is beyond a doubt that accreditation agencies view technologically-mediated care as an institutional responsibility, making it more likely than ever that a court examining a malpractice claim resulting from a technology induced error would hold the institution accountable by default.<sup>60</sup>

### D. Infrastructure and Organizational Realities

The Supreme Court of New Jersey recently ruled that “[o]ur medical-legal jurisprudence is based on images of health care that no longer exist.”<sup>61</sup> Of course, *Darling*<sup>62</sup> and the more faithful of its followers<sup>63</sup> have long urged that the business realities of health care delivery are the most potent arguments in favor of institutional duty. Such arguments are premised on the shift in the center of gravity of health care from individuals to institutions from the perspective of both the business relationships and the expectations of consumers. The new reality of technologically-mediated health care is that it can *only* exist at the institutional level.

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55. *Darling*, 211 N.E.2d at 257.

56. Joint Commission on Accreditation of Healthcare Organizations, Revisions to Joint Commission Standards in Support of Patient Safety and Medical/Health Care Error Reduction (July 1, 2001), available at [http://www.jcaho.org/standard/fr\\_ptsafety.html](http://www.jcaho.org/standard/fr_ptsafety.html) (last visited Sept. 29, 2001).

57. *Id.* See Standard LD.5.2 of the Leadership Chapter for a discussion of this standard.

58. *Id.* See Standard IM.8 of the Management of Information Chapter for a discussion of these new requirements.

59. *Id.* See Standard IM.9 of the Management of Information Chapter regarding knowledge-based information systems, resources and services.

60. See generally *id.*

61. *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1246 (N.J. 1999). *Perez* was concerned with the continued validity of the learned intermediary rule in an environment dominated by direct-to-consumer advertising of prescription drugs. *Id.* at 1254-55, 1263. See also *infra* note 102 and accompanying text.

62. See *supra* notes 16-17 and accompanying text.

63. See *supra* note 35.

Technologically-mediated medicine will comprise a vast array of services that will range from information systems and knowledge bases to physician order entry (POE) systems.<sup>64</sup> For example, Automated Medication Dispensing Devices will eliminate indecipherable or confusing handwritten orders, flag drug interactions, and positively identify the patient and drug prior to administration.<sup>65</sup> Other expert systems that check patient diagnoses and treatment regimes against clinical practice guidelines will also enter the market.<sup>66</sup> As the IOM has recognized, "these 'smart' systems are expected to lead to a redefinition of the physician's role, as they begin to perform functions that formerly only a physician could perform."<sup>67</sup>

Indeed, institutions, and institutions alone, will design, build, control and operate this new health information infrastructure upon which the new applications and processes will be built. The legal rules must reflect this changing reality. Consider, for example, just one court's rationale that is given for denying an institutional duty to obtain informed consent: "[T]he hospital does not know the patient's medical history, nor the details of the particular surgery to be performed."<sup>68</sup> Such a statement is facially and irretrievably at odds with the new technologically-mediated health systems.

### III. TECHNOLOGICAL CARE AND OPERATIONAL LIABILITY RULES

In 1991, the IOM recognized that "the interaction of . . . 'smart' systems with computer-based patient records will . . . raise a host of legal and policy issues . . . ."<sup>69</sup> Specifically, the IOM report queried the "allocation of responsibility (and liability) for errors in the artificial intelligence system, whether caused by faulty hardware, faulty software or error in the system's

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64. See, e.g., Michael D. Murray, *Automated Medication Dispensing Devices*, in MAKING HEALTH CARE SAFER: A CRITICAL ANALYSIS OF PATIENT SAFETY PRACTICE 111-17 (Shojania et al. eds., 2001) (prepared by the University of California at San Francisco – Stanford University Evidence-based Practice Center under Contract No. 290-97-0013 for the Agency for Healthcare Research and Quality), at <http://www.ahrq.gov/clinic/ptsafety/pdf/ptsafety.pdf> [hereinafter MAKING HEALTH CARE SAFER].

65. For example, MEDSTATION System 2000/Rx System 2000 "[a]llows controlled access to 95% of all medications, [d]isplays only pharmacy approved orders for a selected patient [and] [i]nterfaces to automated med charting system." See <http://www.pyxis.com/products/medstation2000.asp> (last visited Sept. 29, 2001) for additional information.

66. See generally COMM. ON IMPROVING THE PATIENT RECORD, DIV. OF HEALTH CARE SERVS., INST. OF MED., THE COMPUTER-BASED PATIENT RECORD: AN ESSENTIAL TECHNOLOGY FOR HEALTH CARE (Richard S. Dick et al. eds., 1991) [hereinafter COMPUTER-BASED PATIENT RECORD].

67. *Id.* at 179. For a discussion about the impact of technology on the physician-patient relationship, see Frances H. Miller, *Health Care Information Technology and Informed Consent: Computers and the Doctor-Patient Relationship*, 31 IND. L. REV. 1019 (1998).

68. *Krane v. Saint Anthony Hosp. Sys.*, 738 P.2d 75, 77 (Colo. Ct. App. 1987).

69. COMPUTER-BASED PATIENT RECORD, *supra* note 66, at 179.

medical rules.”<sup>70</sup> Providers’ most immediate legal vulnerabilities, discussed first below, will be faced in the transition from traditional services to more technologically-enabled care. Hospitals which have re-engineered their facilities and built technologically sophisticated infrastructures on which to run longitudinal patient records and POE systems could experience system-wide failures related either to component failures or widespread system design issues. Similarly, individual devices, such as B2B handheld computers used by physicians to access records or B2B monitoring appliances used in patients’ homes,<sup>71</sup> are likely to involve some level of patient risk that the torts, malpractice and products liability systems must process.

#### A. Failure to Upgrade Technology

While there seems to be abstract agreement as to the need for process reform and increased use of technology, institutions will face considerable difficulties in setting their priorities for the reforms that lie ahead. For example, a recent University of California at San Francisco (UCSF) report prepared for the Agency for Healthcare Research and Quality (AHRQ) used evidence-based medicine practices to rate patient safety practices that had shown potential for reducing adverse events.<sup>72</sup> The eleven most highly rated of the seventy-nine potential patient safety practices generally impacted clinical rather than organizational matters.<sup>73</sup> This suggests that the hypothetical “reasonable” hospital may still face more traditional challenges before it can allocate resources to system re-engineering.

Clearly a health care institution is under a duty to provide its patients with appropriate and usable medical equipment.<sup>74</sup> Proving negligent breach of that duty, however, can be quite complex. Some courts subscribe to the view that “the standard of nonmedical, administrative, ministerial, or routine care at a hospital need not be established by expert testimony because the jury is competent from its own experience to determine and apply such a reasonable-care standard.”<sup>75</sup> This, however, represents confusion between ministerial or administrative care and common knowledge, and between “the manner of

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70. *Id.*

71. *See, e.g.,* Panasonic, Welcome to Panasonic’s Telecare Solutions, at <http://www.panasonic.com/telecare/> (last visited Sept. 29, 2001); HomMed, How it Works, The HomMed Monitor and the HomMed Central Station, at [http://www.hommed.com/patients\\_families/how\\_it\\_works\\_print.html](http://www.hommed.com/patients_families/how_it_works_print.html) (last visited Oct. 8, 2001); Vitaphone, at [http://login.vitaphone.de/new\\_content\\_start.htm](http://login.vitaphone.de/new_content_start.htm) (last visited Oct. 8, 2001).

72. *See generally* MAKING HEALTH CARE SAFER, *supra* note 64.

73. *Id.* at 16.

74. *See, e.g.,* Hernandez v. Smith, 552 F.2d 142, 144 (5th Cir. 1977). *See also* Suttle v. Lake Forest Hosp., 733 N.E.2d 726, 731 (Ill. App. Ct. 2000) (discussing hospital’s failure to have equipment on hand for measuring the blood pressure of newborns).

75. St. Paul Med. Ctr. v. Cecil, 842 S.W.2d 808, 812 (Tex. App. 1992).

proof by which negligence can or must be established and the character of the negligence itself. . . ."<sup>76</sup> An adverse event may be caused by ordinary negligence (for instance, a defect in premises), administrative negligence (for instance, a hiring error or system failure), ministerial negligence (for instance, a nonphysician care provider's mistake) or professional negligence (a medical error by an individual physician or an institution). In each case, the question of whether expert testimony is required will depend on factors such as the intricacies of the equipment and procedure or the complexity of the particular adverse event.<sup>77</sup> It is more likely that common knowledge will substitute for expert testimony in a "simple" fact pattern, such as a facilities error.<sup>78</sup> Thereafter, a court that requires expert testimony will have to decide what type of expert would be required. Thus, an allegation of negligent maintenance of equipment seldom will require professional expert testimony,<sup>79</sup> unlike cases involving how the equipment was used on the patient.<sup>80</sup>

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76. *Flowers v. Torrance Mem'l Hosp. Med. Ctr.*, 884 P.2d 142, 147 (Cal. 1994).

77. See, e.g., *Pliffner v. Correa*, 643 So. 2d 1228, 1233 (La. 1994) ("Expert testimony is not required where the physician does an obviously careless act, such as fracturing a leg during examination, amputating the wrong arm, dropping a knife, scalpel, or acid on a patient, or leaving a sponge in a patient's body, from which a lay person can infer negligence."). See also *Rehabilitative Care Systems of America v. Davis*, in which the court stated:

[T]he sole claim in the present case is that RCSA negligently supervised Davis in carrying out his exercise program by failing to be present or at least nearby to prevent his being injured if the Total Gym malfunctioned . . . the standard of care in this type of situation is not beyond the understanding of an average juror, i.e., something that would require expert testimony.

43 S.W.3d 649, 657 (Tex. App. 2001).

78. See generally *In re Waters v. Jarman*, 547 S.E.2d 142 (N.C. Ct. App. 2001) (discussing applicability of procedural rule regarding expert testimony). In *Waters*, the court stated "[o]ur courts have applied the medical malpractice statutory standard of care and required expert testimony where the corporate negligence claims arose out of clinical care provided by the hospital to the patient." *Id.* at 144-45. The *Waters* court further stated:

However, where the corporate negligence claims allege negligence on the part of the hospital for administrative or management deficiencies, the courts have instead applied the reasonably prudent person standard of care . . . . Collectively, we believe these cases stand for the proposition that corporate negligence actions brought against a hospital which pertain to clinical patient care constitute medical malpractice actions; however, where the corporate negligence claim arises out of policy, management or administrative decisions, such as granting or continuing hospital privileges, failing to monitor or oversee performance of the physicians, credentialing, and failing to follow hospital policies, the claim is instead derived from ordinary negligence principles. This distinction is consistent with the statutory definition of medical malpractice actions, which requires that the claim arise out of services "in the performance of medical, dental or other health care."

*Id.* at 145.

79. See, e.g., *Broadway v. Bay Hosp., Inc.*, 638 So. 2d 176, 177 (Fla. Dist. Ct. App. 1994).

80. See, e.g., *Dean v. Ochsner Med. Found. Hosp. & Clinic*, 749 So. 2d 36, 39 (La. Ct. App. 1999).

The recent case of *Smith v. United States*<sup>81</sup> illustrates issues that may arise during the transitional period. *Smith* dealt with a six-month delay between performing a mammogram and notifying the patient and her physician of a discovered abnormality.<sup>82</sup> Traditionally, the defendant's hospital had used a form-based system for requesting a radiological test and transmitting results to the originating physician.<sup>83</sup> In addition, it was the hospital's policy that abnormal results were reported to the originating physician by phone.<sup>84</sup> The mammogram in question had been performed while the hospital was transitioning to a computer-based system under which the test results would be entered into the computer system such that the originating physician would be notified when he next logged on.<sup>85</sup> A coding of "abnormal" also would result in a specific e-mail notification being automatically generated and sent to the originating physician.<sup>86</sup> In addition, during the transitional phase, a hard copy of the results would be printed at the originating physician's clinic.<sup>87</sup> In the case at hand, the originating physician had not been trained on the computer system, and there was no record of a phone call being made to him or a copy of the abnormal test result being printed at the clinic where he worked.<sup>88</sup> Trying the case without a jury, the district court judge held that "the hospital had a duty to implement a reasonable procedure during the transition phase to computers which would timely deliver radiology test results to requesting physicians, and that it did not breach that duty."<sup>89</sup>

*Smith* is not a clean case. The court believed that the physicians were the responsible parties and so viewed this as an occasion of individual professional malpractice more than institutional negligence.<sup>90</sup> Furthermore, evaluation of its holding is clouded by issues such as the Federal Tort Claims Act's<sup>91</sup> impact on the alleged negligence of the independent computer contractors; the court's somewhat confused approach to the standard of care (whether ministerial or professional); whether and what expert evidence was required and the unsatisfactory nature of much of the expert testimony.

Nevertheless, the case does point to the future of litigation over such issues. First, fulfilling some unspoken contrarian destiny, complex systems

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81. 119 F. Supp. 2d 561 (D. S.C. 2000).

82. *Smith*, 119 F. Supp. 2d at 563.

83. *Id.* at 575.

84. *Id.*

85. *Id.* at 566-67.

86. *Id.* at 567.

87. *Smith*, 119 F. Supp. 2d at 568.

88. *Id.*

89. *Id.* at 575.

90. Discussing the testimony of the originating physician and the radiologist, the court commented "[both] had a motive to blame the hospital procedures for the error that occurred to distract from their own likely negligent acts." *Id.* at 576.

91. *See generally* 28 U.S.C. § 1346 (1994).

designed to reduce medical mistakes will themselves be error prone. Second, particularly thorny problems are likely to arise during the transition from paper to electronic records and procedures. Third, we likely will see considerable litigation regarding the designs of health care technology systems, with particular emphasis placed on user interfaces; the incorporation of multiple systems; error-checking and other sub-systems designed to either reduce human error or flag possible system errors. Fourth, the nature of expert testimony will change in what would have been considered ministerial or even professional cases where we would have required either administrator or physician expert testimony. In contrast, we will now see an increased use of information technology (IT) and Health Information Management (HIM) experts. Fifth (taking *Smith* at face value), it is likely that in the early stages of IT deployment in health care environments, the standard of care based on health care technology custom is going to be quite low. Defendants, however, should take little comfort from this as their peer institutions demonstrate an increasingly voracious appetite for technology and rapidly upgrade their infrastructure and service.

### *B. System and Appliance Failures*

Once complex new systems are in place, some adverse events inevitably will be traced to system-wide failures or defects in the software or hardware applicable to discrete components within the hospital (for instance, a POE cart). Individual appliance failure may also occur in a Web-enabled monitoring appliance installed in a patient's home. These technologies will prove highly troubling to currently established torts liability categories. Specifically, an attempt to process such an adverse event using a products liability categorization will mobilize the resistance historically shown by courts to applying strict liability in fact-patterns involving health care providers.<sup>92</sup> Equally, even if the courts adopt a negligence allocation model, the substitution of these new appliances for ministerial, and in some cases even professional human interactions, will raise questions about the types of expert testimony that may be required.

Before addressing the health care delivery nature of these implicated products, a more fundamental issue might be raised (though relatively swiftly dismissed) as to whether products liability type theories could be available

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92. This issue is antecedent to questions that likely will arise in such litigation over the admissibility of FDA approval or even the preemption of common law claims. *See, e.g.,* Weiland v. Teletronics Pacing Sys., Inc., 721 N.E.2d 1149 (Ill. 1999). *Cf. Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998). It also involves litigation, more generally with the effect of FDA approval of the device. *See, e.g.,* Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827 (Neb. 2000). *See generally* Arnold J. Rosoff, *On Being a Physician in the Electronic Age: Peering into the Mists at Point-&-Click Medicine*, 46 ST. LOUIS U. L.J. 111 (2002) (discussing FDA regulation of e-health devices).

against an upstream defendant such as a system supplier or an appliance seller. This argument suggests that products liability is not applicable because the injury is not so much caused by the physical product itself as by its output, its intangible diagnosis or data. This type of argument has surfaced elsewhere in e-health,<sup>93</sup> suggesting obstacles to constructing actions against health advice Web sites.<sup>94</sup> Courts confronted with similar issues have refused to immunize the manufacturers of aeronautical charts<sup>95</sup> and arguably pulled computer software into the liability net.<sup>96</sup> The few reported cases directly on point<sup>97</sup> suggest that computerized systems that cause injury will fall within the ambit of products liability<sup>98</sup> and may even benefit from a wellspring of judicial skepticism about the integrity of complex computer-based systems.<sup>99</sup>

More specifically, adverse health care events have had a complex and generally unsatisfactory relationship with strict liability. It is not without a sense of irony that an important clue as to how our courts have wished to process such cases may be gleaned from one of the most complex (and now suspect) intersections, the learned intermediary doctrine. A sub-rule of strict products liability that is applied in warning cases brought against prescription drug and medical device manufacturers, the learned intermediary deems the prescribing physician to be the “consumer” of the injury-producing drug or

93. See Nicolas P. Terry, *Cyber-Malpractice: Legal Exposure for Cybermedicine*, 25 AM. J.L. & MED. 327, 351-58 (1999).

94. See, e.g., *Birmingham v. Fodor's Travel Publ'ns. Inc.*, 833 P.2d 70, 77 (Haw. 1992) (holding that publisher of travel book did not have a duty to warn tourist of dangerous condition of beach).

95. See, e.g., *Brocklesby v. United States*, 767 F.2d 1288, 1296 (9th Cir. 1985); *Saloomy v. Jeppesen & Co.*, 707 F.2d 671, 676-77 (2d Cir. 1983); *Fluor Corp. v. Jeppesen & Co.*, 216 Cal. Rptr. 68, 74 (Cal. Ct. App. 1985).

96. See *Winter v. G.P. Putnam's Sons*, which stated:

[A]eronautical charts are highly technical tools. They are graphic depictions of technical, mechanical data. The best analogy to an aeronautical chart is a compass. Both may be used to guide an individual who is engaged in an activity requiring certain knowledge of natural features. Computer software that fails to yield the result for which it was designed may be another . . . . The chart itself is like a physical “product” while the “How to Use” book is pure thought and expression.

938 F.2d 1033, 1036 (9th Cir. 1991) (footnote omitted).

97. In contrast to the voluminous case law dealing with low quality software and hardware that causes pure economic loss. See, e.g., *Black, Jackson & Simmons Ins. Brokerage, Inc. v. Int'l Bus. Machs. Corp.*, 440 N.E.2d 282, 283 (Ill. App. Ct. 1982); *Prent Corp. v. Martek Holdings, Inc.*, 618 N.W.2d 201, 205 (Wis. Ct. App. 2000).

98. See, e.g., *Sparacino v. Andover Controls Corp.*, 592 N.E.2d 431, 436 (Ill. App. Ct. 1992) (holding that a manufacturer of a programmable energy management system was not liable but only because this particular risk was not foreseeable).

99. See, e.g., *Perez-Trujillo v. Volvo Car Corp.*, 137 F.3d 50, 54 (1st Cir. 1998) (“We find particularly troubling Volvo’s counterintuitive assumption that an electrical component *cannot* malfunction and that its unfailing performance can be predicted with absolute certainty in any and all circumstances.”).



device. As a result, the manufacturer owes a duty to warn of risks associated with the drug or device to the treating physician and not the end-user patient.<sup>100</sup>

The effect of the learned intermediary doctrine is that the patient is limited to a failure to warn, or failure to obtain informed consent, action against the physician. The allocational effects are more far-reaching. First (and obviously), the courts are shifting product-related risks from manufacturers to health care providers. Second, the courts are allowing more of those product-related risks to be externalized to consumer-patients by processing them through a negligence-based rather than strict liability system.<sup>101</sup>

Today, it is arguable that the learned intermediary doctrine is in something of a retreat,<sup>102</sup> and may even have been fatally undercut,<sup>103</sup> by the growth of direct-to-consumer pharmaceutical advertising.<sup>104</sup> However, the courts still seem to subscribe to the second of the allocational positions described above—that those who provide health care services may externalize more risks to patients than those who supply products to them. This approach resonates in the varied intersections between strict liability (and hence products liability levels of risk re-allocation) and health care services that we have observed in modern tort law. It is an approach that the realities of technologically-mediated health care will severely test and may finally force us to reject.

### C. Strict Liability for Adverse Events

The first intersection of note is the suggestion that strict liability be imposed in cases of adverse error. The Washington case of *Helling v. Carey*<sup>105</sup> is justly famous for attempting to correct an error made fifty years earlier when *The T.J. Hooper*<sup>106</sup> failed to include professional malpractice in its retreat from exculpatory custom.<sup>107</sup> *Helling*, however, also contained a concurrence that

100. See, e.g., *Tracy v. Merrell Dow Pharm., Inc.*, 569 N.E.2d 875, 878 (Ohio 1991).

101. An additional variable is the informed consent standard used in a particular jurisdiction. See generally *Ketchup v. Howard*, 543 S.E.2d 371, 381-86 (Ga. Ct. App. 2000). Thus, a professional custom jurisdiction will externalize more risks to consumers than a jurisdiction applying a patient expectation standard of care.

102. See, e.g., *Friedl v. Airsource, Inc.*, 753 N.E.2d 1085, 1089 (Ill. App. Ct. 2001) (holding that the doctrine was not applicable in case of failure to provide adequate instructions for use). But cf., *Vitanza v. Upjohn Co.*, 778 A.2d 829 (Conn. 2001) (refusing to fashion exception to learned intermediary doctrine where manufacturer distributed promotional free samples).

103. *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1264 (N.J. 1999).

104. See Direct-to-Consumer Promotion, 61 Fed. Reg. 24,314 (May 14, 1996); Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 Fed. Reg. 43,171 (Aug. 12, 1997); Guidance for Industry on Consumer-Directed Advertisements; Availability, 64 Fed. Reg. 43,197 (May 9, 1999).

105. 519 P.2d 981 (Wash. 1974).

106. 60 F.2d 737 (2d Cir. 1932).

107. The *Helling* court stated:

argued “[i]f the standard of a reasonably prudent specialist is, in fact, inadequate to offer reasonable protection to the plaintiff, then liability can be imposed without fault.”<sup>108</sup> In spite of *Helling*’s presence in most torts<sup>109</sup> and health law<sup>110</sup> texts, this approach has failed to engender any judicial interest, although it has been the subject of limited statutory experiments.<sup>111</sup>

A year prior to *Helling*, a federal district court in Wisconsin suggested that strict liability could apply to health care delivery that was ministerial in nature rather than professional.<sup>112</sup> With words that resonate strongly today in the context of institution-delivered technology services, the court argued:

[T]he mechanical and administrative services provided by hospitals should necessarily be exempt from strict liability. Several considerations lead me to this conclusion. They are: first, the serious consequences which can result when a patient receives defective hospital services; second, the near total inability of laymen to recognize or control such defective service; and, finally, since doctors already are hampered by an inexact science, it is essential that they receive all pertinent information accurately to determine if a particular course of treatment is appropriate. In short, it is in the public interest that those services which hospitals perform for both doctors and patients be performed properly.<sup>113</sup>

Other courts, however, have ignored this siren call to apply strict liability for ministerial adverse events.<sup>114</sup> One criticism voiced about such liability is the difficulty in distinguishing between ministerial and professional care.<sup>115</sup> A similar argument may be made about the goods-services dichotomy discussed in detail below.<sup>116</sup> In such cases courts seem concerned with the system or administrative costs of parsing the contended for rule. One “solution” is to impose such costs on defendants. As a particularly lonely voice for this

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Under the facts of this case reasonable prudence required the timely giving of the pressure test to this plaintiff. The precaution of giving this test to detect the incidence of glaucoma to patients under 40 years of age is so imperative that irrespective of its disregard by the standards of the ophthalmology profession, it is the duty of the courts to say what is required to protect patients under 40 from the damaging results of glaucoma.

*Helling*, 519 P.2d at 983.

108. *Id.* at 985 (Utter, J., concurring). See also *Clark v. Gibbons*, 426 P.2d 525, 539 (Cal. 1967) (Tobriner, J., concurring in part, dissenting in part).

109. See, e.g., JERRY J. PHILLIPS ET AL., *TORT LAW, CASES, MATERIALS, PROBLEMS* 192 (2d ed. 1997).

110. See, e.g., BARRY R. FURROW ET AL., *HEALTH LAW* 196 (4th ed. 2001).

111. See, e.g., The Virginia Birth-Related Neurological Injury Compensation Act, VA. CODE ANN. § 38.2-5009 (1950).

112. *Johnson v. Sears, Roebuck & Co.*, 355 F. Supp. 1065, 1067 (D. Wis. 1973).

113. *Id.*

114. See, e.g., *Hector v. Cedars-Sinai Med. Ctr.*, 225 Cal. Rptr. 595, 601 (Cal. Ct. App. 1986); *Femrite v. Abbott Northwestern Hosp.*, 568 N.W.2d 535, 543 (Minn. Ct. App. 1997).

115. See, e.g., *Hector*, 225 Cal. Rptr. at 601.

116. See *infra* notes 123-125.

position argued in a case involving a hypodermic needle that broke in plaintiff's gum:

The injured patient should have the option of suing the dentist directly. It is the dentist with whom plaintiff has dealt and in whose hands and confidence the patient has put herself. It may be more difficult to sue a manufacturer or supplier located in a distant state or a foreign country. The dentist chose the instrument. The dentist is in a better position to know and prove the identity of the manufacturer or distributor. If he cannot, the patient should not be denied recovery on that account. The dentist should also know the quality of the instrument and the reliability of his source of supply. This rule may encourage greater caution in purchasing equipment and examining for defects.<sup>117</sup>

This type of malpractice-strict liability intersection case essentially seeks to apply strict liability to product-related adverse events. This was essentially the position of the New Jersey Supreme Court in *Anderson v. Somborg*,<sup>118</sup> where the plaintiff alleged negligence against health care providers and strict product liability against suppliers of an angulated pituitary rongeur. The court took the view that in such a mixed fact-pattern the burden was on the defendants to disprove culpability and "since at least one of the defendants could not sustain his burden of proof, at least one would be liable."<sup>119</sup> While somewhat flawed because of the court's misunderstanding of the concept of product "defectiveness,"<sup>120</sup> *Anderson* nevertheless points to one method of dealing with system or administrative costs—shifting them to the defendants.

#### *D. Strict Liability for Supply of a Product Involved in Adverse Events*

The most successful strict liability argument made by patients who suffered adverse events has been that of strict products liability.<sup>121</sup> Even these claims have been limited in their success. In contrast to the strict liability arguments discussed above, these are not allegations that the health care provider should be strictly liable on a theory analogous to products liability. Rather, the provider is characterized as the *supplier* of the defective product;

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117. *Magrine v. Spector*, 241 A.2d 637, 642 (N.J. Super. Ct. App. Div. 1968), *aff'd*, 250 A.2d 129 (N.J. 1969) (Botter, J., dissenting); *cf.* *Tanuz v. Carlberg*, 921 P.2d 309, 310 (N.M. Ct. App. 1996).

118. 338 A.2d 1 (N.J. 1975).

119. *Id.* at 4.

120. The court treated the claim more like one brought in absolute liability. *See* Nicolas P. Terry, *Collapsing Torts*, 25 CONN. L. REV. 717, 724 n.41 (1993).

121. *See, e.g.*, *Eby v. Milton S. Hershey Med. Ctr.*, 21 Pa. D. & C.4th 281 (C.P. Dauphin Co. 1993) (allowing strict liability claim for injection of "inherently unsafe" solution); *Bell v. Poplar Bluff Physicians Group*, 879 S.W.2d 618 (Mo. Ct. App. 1994) (interpreting malpractice statute of limitations); *Providence Hosp. v. Truly*, 611 S.W.2d 127 (Tex. Civ. App. 1980) (finding hospital liable for breach of warranty for "contaminated drug").

meaning, the claim is a straightforward products liability action. As framed by a Pennsylvania court:

In adopting the strict liability as set forth we are making a reasonable extrapolation from the already expanding interpretation of 402A, and clear policy considerations. The surgical patient is without control over the procedures and instruments used upon him. His health and future safety are at the mercy and skill of the treating physicians and the instruments he employs. It is elementary that if a hospital supplies equipment to an operating physician the hospital must appraise themselves of the risks involved and adopt every effort to insure the safety of the equipment chosen. Furthermore, there was testimony in this case to indicate that the defect could have been discovered by a preliminary test on animal bone. To require this minimal technique is not unreasonable and may very well have avoided the injuries to the plaintiff.<sup>122</sup>

The overwhelming majority of courts have been skeptical of imposing strict liability on health care institutions. Several defense arguments have had traction with courts.<sup>123</sup> First, much is made of a declared service-product dichotomy. As one court explained it:

Physicians, like hospitals, are providers of medical services. The physician's expertise lies in the diagnosis, treatment and cure of illness, not in the research or development of prosthetics or devices used to aid medical diagnosis or treatment. A physician is not in the business of selling products, but rather is in the profession of providing medical services. Products such as the prosthetic device in this case are supplied and utilized only as needed to deliver the professional medical service. They are incidental, or integral, to a physician's service, but they are not the focus of the physician's delivery of health care.<sup>124</sup>

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122. *Grubb v. Albert Einstein Med. Ctr.*, 387 A.2d 480, 490 (Pa. Super. Ct. 1978).

123. Frequently these defenses are successfully combined. *See, e.g., Hoven v. Kelble*, 256 N.W.2d 379 (Wis. 1977).

There are differences between the rendition of medical services and transactions in goods (or perhaps other types of services as well). Medical and many other professional services tend often to be experimental in nature, dependent on factors beyond the control of the professional, and devoid of certainty or assurance of results. Medical services are an absolute necessity to society, and they must be readily available to the people. It is said that strict liability will inevitably increase the cost for medical services, which might make them beyond the means of many consumers, and that imposition of strict liability might hamper progress in developing new medicines and medical techniques.  
*Id.* at 391 (footnotes omitted).

124. *Cafazzo v. Central Med. Health Servs., Inc.*, 635 A.2d 151, 154 (Pa. Super. Ct. 1993); *see also In re Breast Implant Prod. Liab.*, 503 S.E.2d 445, 448-51 (S.C. 1998); *Royer v. Catholic Med. Ctr.*, 741 A.2d 74 (N.H. 1999); *McKenna v. Harrison Mem'l Hosp.*, 960 P.2d 486 (Wash. Ct. App. 1998); *Weissman v. Dow Corning Corp.*, 892 F. Supp. 510 (S.D.N.Y. 1995); *St. Mary Med. Ctr., Inc. v. Casko*, 639 N.E.2d 312 (Ind. Ct. App. 1994); *Cobb v. Dallas Fort Worth Med. Ctr.-Grand Prairie*, 48 S.W.3d 820 (Tex. Civ. App. 2001); *Podrat v. Codman-Shurtleff, Inc.* 558 A.2d 895 (Pa. Super. Ct. 1989); *Hoff v. Zimmer*, 746 F. Supp. 872 (W.D. Wis. 1990) (hip

A few courts, cognizant of the dichotomy, nevertheless have applied strict products liability in cases where a product, such as a surgical gown, is clearly incidental to any professional services.<sup>125</sup> Overall, however, far too much seems to be made of this distinction. Indeed, at least one court otherwise hostile to the imposition of strict liability on health care providers has dismissed the service-product distinction as a legal fiction noting:

To be sure, the chief function of hospitals is to provide a service. But when a product is provided as part of the service, and the service provider bills separately for the product, the rule that has emerged outside of the hospital context is that the provision of the product is a distribution for purposes of strict products liability. To depart from this characterization of such a transaction for the special case of hospitals would, in our view, generate unnecessary confusion. If there are sound policy reasons for not imposing strict products liability on hospitals, those policy reasons should be addressed directly, not obscured by artificial semantic distinctions.<sup>126</sup>

Other theories antithetical to the application of products liability to health care delivery scenarios seem to be on no stronger ground. For example, some courts have viewed the supply of the product as merely incidental to the provision of the professional services.<sup>127</sup> Others have characterized the health care provider as the actual consumer of the product.<sup>128</sup> Perhaps the most interesting recent development and, from the plaintiff's perspective, ominous development has been a series of cases that reject strict products liability on the explicit basis that the defendant was a health care provider.<sup>129</sup>

If the imposition of strict liability on health care providers that work with or implant products has not been well received, some upstream liability remains, shifting costs from patients to drug and device makers. But here, too, judicial conservatism in compensating patient-consumers is evident.

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prosthesis); *Goldfarb v. Teitelbaum*, 540 N.Y.S.2d 263 (N.Y. App. Div. 1989) (mandibular prosthesis); *Hector v. Cedars-Sinai Med. Ctr.*, 225 Cal. Rptr. 595 (Cal. Ct. App. 1986) (pacemaker); *Probst v. Albert Einstein Med. Ctr.*, 440 N.Y.S.2d 2 (N.Y. App. Div. 1981) (metal spinal rod); *Vergott v. Deseret Pharm. Co.*, 463 F.2d 12 (5th Cir. 1972) (intracath needle); *San Diego Hosp. Assn. v. Superior Court*, 35 Cal. Rptr. 2d 489 (Cal. Ct. App. 1994); *Pierson v. Sharp Mem'l Hosp., Inc.*, 264 Cal. Rptr. 673 (Cal. Ct. App. 1989).

125. See, e.g., *Thomas v. St. Joseph Hosp.*, 618 S.W.2d 791 (Tex. Civ. App. 1981); *Porter v. Rosenberg*, 650 So. 2d 79 (Fla. Dist. Ct. App. 1995); *Karibjanian v. Thomas Jefferson Univ. Hosp.*, 717 F. Supp. 1081 (E.D. Pa. 1989).

126. *Parker v. St. Vincent Hosp.*, 919 P.2d 1104, 1107 (N.M. Ct. App. 1996) (citations omitted).

127. See *Easterly v. HSP of Tex., Inc.*, 772 S.W.2d 211, 213 (Tex. Ct. App. 1989).

128. See *N. Miami Gen. Hosp. v. Goldberg*, 520 So. 2d 650, 652 (Fla. Dist. Ct. App. 1988); *Cafazzo*, 635 A.2d 151 at 154-55.

129. See *Rogers v. Synthes, Ltd.*, 626 So. 2d 775, 777 (La. Ct. App. 1993); *Budding v. SSM Healthcare Sys.*, 19 S.W.3d 678, 681 (Mo. 2000); *Tanuz v. Carlberg*, 921 P.2d 309, 312 (N.M. Ct. App. 1996); *Parker*, 919 P.2d at 1110.

Jurisdictions that have shifted pharmaceutical drug cases out of strict liability and back into negligence<sup>130</sup> likely will do the same with medical devices.<sup>131</sup> Equally, the learned intermediary doctrine, wounded though it is,<sup>132</sup> will block some strict liability failure to warn cases.<sup>133</sup> Manufacturing or design defect cases are not susceptible to the learned intermediary rule, but likely will face preemption issues in many implant cases.<sup>134</sup>

#### IV. CONCLUSION

In a February 2001 report, the President's Information Technology Advisory Committee (PITAC) commented:

New information technologies have the potential to dramatically improve our health care system as it exists today. Information technology can help ensure that health-related information and services are available anytime and anywhere, permit health care practitioners to access patient information wherever it may be located, and help researchers better understand the human body, share information, and ultimately develop more beneficial treatments to keep Americans healthy.<sup>135</sup>

Yet, as discussed in this Article, our courts will experience some difficult questions as technologically-mediated quality control proliferates. While it seems arguable that the health care industry must not face too many disincentives as it explores the role of technology in reducing medical error, there seems to be scant justification for continuing to allow the health care industry to externalize more costs than other industries. The tort system has been a willing conspirator in this process, preferring an individual professional liability model to a more realistic institutional one, thus insulating health care providers from the true costs associated with using and distributing products. It would be a mistake to recognize the imperative of reducing medical error and the attendant institutional responsibility, only to permit health care entities

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130. See, e.g., *Freeman v. Hoffman-La Roche, Inc.* 618 N.W.2d 827 (Neb. 2000).

131. See *Artiglio v. Superior Court*, 27 Cal. Rptr. 2d 589 (Cal. Ct. App. 1994) (breast implant).

132. See *supra* note 95 and accompanying text.

133. See, e.g., *Miller v. Bristol-Myers Squibb Co.*, 121 F. Supp. 2d 831 (D. Md. 2000); *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732 (N.D. Tex. 2000); *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87 (Tex. App. 2000); *Alexander v. Smith & Nephew, P.L.C.*, 98 F. Supp. 2d 1310 (N.D. Okla. 2000); *In re Norplant Contraceptive Prod. Litig.*, 165 F.3d 374 (5th Cir. 1999); *Brown v. Drake-Willock Int'l, Ltd.*, 530 N.W.2d 510 (Mich. Ct. App. 1995).

134. See, e.g., *Richardson v. Advanced Cardiovascular Sys., Inc.*, 865 F. Supp. 1210 (E.D. La. 1994); *Dunlap v. Medtronic, Inc.*, 47 F. Supp. 2d 888 (N.D. Ohio 1999).

135. President's Information Technology Advisory Committee, Panel on Transforming Health Care, Report to the President on Transforming Health Care Through Information Technology 17 (Feb. 2001), available at <http://www.itrd.gov/pubs/pitac/pitac-hc-9feb01.pdf> (last visited Nov. 12, 2001); see also *CROSSING THE QUALITY CHASM*, *supra* note 9, at 175-76. ("IT has enormous potential to improve the quality of health care.").

to shift costs associated with ameliorating technologies to the very patients who were threatened by the original errors.

The realities of technologically-mediated health care delivery expose the arguments and fictions that have underpinned the generosity shown to the health care industry by the courts. The fundamental error of those clustered around "the machine that goes 'ping'" was that they almost forgot about the patient.<sup>136</sup> Applying institutional liability and mainstream products liability principles to technologically-mediated care would be a sign that the tort system will not make the same mistake.

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136. *The Miracle of Birth*, in MONTY PYTHON'S THE MEANING OF LIFE (1983), *script available at* <http://www.montypython.net/meaningmm.php3#Miracle%20of%20Birth> (last visited Nov. 12, 2001).

OBSTETRICIAN: Eehhh. Still something missing, though.

DOCTOR SPENSER: Hm?

OBSTETRICIAN: Hmmm. Mmmmm. [snap]

OBSTETRICIAN and DOCTOR SPENSER: Patient!

OBSTETRICIAN: Yes.

*Id.*

