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# MANUFACTURER AND PROFESSIONAL USER'S LIABILITY FOR DEFECTIVE MEDICAL EQUIPMENT

ROSEMARY RUBIN\*

## INTRODUCTION

**I**N THE FIELD of products liability the modern trend seems to be moving toward complete consumer protection. This usually means extending the liability to reach the ultimate manufacturer with whom the defective product originated. This trend has led to the erosion of privity requirements to a great degree. Under the theory of strict liability, the seller<sup>1</sup> is held strictly liable for any unreasonably dangerous products which he places on the market in that dangerous condition.<sup>2</sup> Strict liability affords extra protection for innocent consumers whether in privity or not and without the burden of showing an actual negligent act.

One particular area of product liability, however, has been slow to accept strict liability. In the field of medical devices and equipment the courts seem reluctant to find liability without a clear showing of negligence, whether the defendant is the doctor, the hospital, or the manufacturer of the product. In this paper the focus will be on the emerging law in this area regarding medical equipment made only for use by experts, including nurses, doctors, dentists, anesthesiologists, emergency personnel and hospitals. The discussion will exclude blood and drug cases for these lead to conclusions of their own. The concentration will instead be on needles, scalpels, intermedullary pins, pacemakers, X-ray equipment, and other hospital machines used for the care of patients. Such equipment, by its very nature, is complex and beyond the scope of the layman's ability to use. This creates problems of privity since the injured party is almost never the buyer of the product in any sense. The warnings and warranties involved with such products, since they extend only to the experts who are often expected to know how to use these products, also create problems in interpretation for the courts.

The special need for these products, too, arouses the cautious attitude of the courts.<sup>3</sup> Their use is required in life saving and healing operations,

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<sup>1</sup> Case law has defined *seller* broadly to include anyone who places an article in the stream of commerce. *See, e.g., Greenman v. Yuba Power*, 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1962).

<sup>2</sup> RESTATEMENT (SECOND) OF TORTS § 402A (1965).

<sup>3</sup> Swartz, *Product Liability: Manufacturer's Responsibility for Defective or Negligently Designed Medical and Surgical Instruments*, 18 DEPAUL L. REV. 348 (1969) [hereinafter cited as Swartz].

often in emergency situations. The great healing potential lies in sharp contrast to the immeasurable harm done when machines such as these fail. These products come into intimate contact with the human body and its vital functions. The injury caused by a defective surgical needle, which breaks, is indeed great; but the patient usually survives in such a situation, so it is minor compared to the destruction caused by a defective surgical drill or artificial pacemaker.<sup>4</sup>

Doctors likewise stress the need for such equipment and point out that often they too are unaware of possible defects. The medical profession looks to the manufacturers to provide safe equipment for them to use. Louis Orkin, M.D., in an address to the Session on Anesthesiologists at the 117th annual convention of the American Medical Association, illustrated the need for strict standards imposed on doctors and manufacturers.<sup>5</sup> He claims that manufacturers have been resistant in the past to attempts to make this type of equipment safer, and doctors have been lax because of their dependence on the manufacturers to supply this equipment.<sup>6</sup> But human life must come first.

### PROFESSIONAL'S USER'S LIABILITY

Doctors should be concerned about the problem for indeed recovery for the injured patient is often sought against them. When a patient is injured during a medical procedure, he does not stop to think what caused the injury. He looks to the doctor, whom he sought for healing, and lays the blame there. Even if he does think to look to the manufacturer for recovery, the manufacturer is often hard to locate<sup>7</sup> or insulated from suit by jurisdictional or procedural barriers.<sup>8</sup> The actions against the doctor, however, at least in the past, had to be based on malpractice which is a negligence action. Mere showing of an accident or injury was not enough.<sup>9</sup> The standard of care for malpractice is usually very difficult to prove, whether a defective product is involved or not. A doctor is only

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<sup>4</sup> *Id.* at 349. Swartz points out that the great potential for healing often overshadows the equally great potential for harm. He warns that in this line of rapidly evolving product liability law, attorneys must be aware that there is nothing sacrosanct about the specialized tools called medical or surgical instruments.

<sup>5</sup> Orkin, *Responsibility of Manufacturers and Consumers*, 206 J. AMER. MED. ASSN. 2888 (1968).

<sup>6</sup> *Id.* at 2889. Dr. Orkin draws an analogy between medical equipment and automobiles. He states that the public will not accept a faulty car or driver. He questions why standards are apparently lower for medical equipment.

<sup>7</sup> See *Magrine v. Spector*, 100 N.J. Super. 223, 241 A.2d 637 (1968), *aff'd*, 53 N.J. Super. 259, 250 A.2d 129 (1969); *Magrine v. Krasnica*, 94 N.J. Super. 228, 227 A.2d 539 (1967). There was nothing to indicate who manufactured the product anywhere in the doctor's records. Tracing the origin of the needle proved to be impossible.

<sup>8</sup> See *Repass v. Kileket X-Ray Corp.*, 212 F. Supp. 402 (N.J. 1962) (statute of limitations had run); *Gill v. Surgitool, Inc.*, 256 Cal. App. 2d 583, 64 Cal. Rptr. 207 (1967) (manufacturer not doing business in the state).

<sup>9</sup> *E.g.*, *Hine v. Fox*, 89 So. 2d 13 (Fla. 1956).

held to the reasonable standard of professional skill and care in his locale and at the present state of the art.<sup>10</sup> While this is fairly broad in scope today, still negligence of a professional cannot be proven without expert testimony offered by comparable professionals.<sup>11</sup> This is often impossible to procure for trial since doctors are reluctant to testify against each other. Often, too, these "errors" are not bad medical practice, but merely human failings for which a doctor is not liable unless he was negligent. Without this proof, the mere showing that an accident happened will not carry the burden for a malpractice action, either against a doctor or a hospital.<sup>12</sup> And as yet the courts have not seen fit to impose strict liability on a doctor for failure of or defect in his equipment.<sup>13</sup>

Under a negligence theory there are cases where recovery was obtained against hospitals and doctors using defective equipment. It goes almost without saying that where there is misuse of the product, the hospital or doctor is liable. Also, where there is actual knowledge of the defect, liability is imposed for the continued use. In *Shepherd v. McGinnis*,<sup>14</sup> the plaintiff developed an infection due to contaminated sutures furnished by the hospital and used by the doctor. The doctor used this product many times before and had experienced similar problems with it. Evidence at trial showed that the doctor and the hospital had even informed the manufacturer of the product of the problems, and thereafter the sutures were removed from use. However, similar sutures, made by the same manufacturer and packaged in the same way, which according to the doctor was the cause of the trouble, were used again with the same type of infection developing. Therefore, since actual knowledge of the defect was shown on the part of the doctor and the hospital, their continued use constituted malpractice; and the plaintiff recovered.<sup>15</sup>

A somewhat related area of duty resting on the doctor and the hospital is the duty of care in the selection of materials and products. In *Phillips v. Powell*,<sup>16</sup> a very old products liability case, the injury resulted

<sup>10</sup> *Wharton v. Warner*, 15 Wash. 470, 135 P. 235 (1913).

<sup>11</sup> For discussion of malpractice of doctors and hospitals relating to medical equipment see 35 A.L.R.3d 1068 (1971).

<sup>12</sup> In *Hine v. Fox*, 89 So. 2d 13 (Fla. 1956), the court held that in cases involving charges of malpractice against professionals, negligence will not be presumed, but must be proved. The court also stated that the doctrine of *res ipsa loquitur* did not apply in malpractice cases. 89 So. 2d at 16. *Accord*, *Magrine v. Krasnica*, 94 N.J. Super. 228, 227 A.2d 539 (1967); *Payne v. Garvey*, 264 N.C. 593, 142 S.E.2d 159 (1965).

<sup>13</sup> See *Magrine v. Krasnica*, 94 N.J. Super. 228, 227 A.2d 539 (1967).

<sup>14</sup> 257 Iowa 35, 131 N.W.2d 475 (1964).

<sup>15</sup> The rationale behind this decision is no doubt sound. No professional user should be held liable without fault for a product he has no control over at the manufacturing stage. This risk rightly falls to the manufacturer who has the ability to control the production process.

<sup>16</sup> 210 Cal. 39, 290 P. 441 (1930).

from the breakage of a scalpel during a tracheotomy. The doctor admitted that the type he used was not the proper one for this particular operation. His failure to select and use what he knew or should have known was the right instrument was held to be negligent malpractice. Today, however, with such complex instruments the doctors may not be able to determine a good or a defective product; and, thus, their duty in selection is somewhat more limited. As long as reasonable standards of the profession are met, the doctor is not negligent.<sup>17</sup>

Doctors and hospitals do have a duty to inspect the equipment they use and provide for the care of patients. For the doctor, this duty generally extends only to patent or discoverable defects.<sup>18</sup> For the hospital, however, the rule is stricter; the hospital is often held liable for less obvious defects, particularly where there is a duty to inspect and maintain the equipment.<sup>19</sup> Two cases, *South Highlands Infirmary v. Camp*<sup>20</sup> and *Nelson v. Swedish Hospital*,<sup>21</sup> serve excellently to illustrate this distinction.

In *South Highlands* the surgical instrument was not furnished directly to the patient, but to another employed by the patient, to be used in the treatment of the patient. The defect in the equipment was latent, and the evidence adduced from a surgeon who testified on behalf of the infirmary revealed that it was not standard practice for a surgeon, before performing an operation with a surgical instrument, to dismantle the instrument or machine to look for defects.<sup>22</sup> Thus, it would appear that where the defect is latent, the doctor can rely on the hospital to furnish safe equipment.

In *Nelson* the breach of duty likewise was in the failure to inspect and provide safe equipment. There, however, the defect was not hidden. The defect was a loose bolt which caused the head of an X-ray machine to fall on the plaintiff. Had any care been exercised, the defect would have been noticed; the manufacturer's representative could then have been called in to repair it as the contract called for. In finding both the hospital and doctor negligent, the court pointed out that the machine's constant usage over a three-year period, sometimes involving as many as six

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<sup>17</sup> *Ball v. Mallinkrodt Chem. Works*, 53 Tenn. App. 218, 381 S.W.2d 563 (1964). Plaintiff alleged that the doctor used a product that he knew might cause bad side effects without warning her. However, the particular product, a contrast agent, was well regarded in the profession and did have a "low toxicity" relative to other similar products as the warnings stated. Thus the doctor was exonerated; his selection of the product was reasonable by professional standards and not deemed to be negligent.

<sup>18</sup> *South Highlands Infirmary v. Camp*, 279 Ala. 1, 180 So. 2d 904 (1965). Early cases had held doctors liable for latent defects as well. *E.g.*, *Tennant v. Barton*, 164 Wash. 279, 2 P.2d 735 (1931).

<sup>19</sup> See *Nelson v. Swedish Hospital*, 241 Minn. 551, 64 N.W.2d 38 (1954).

<sup>20</sup> 279 Ala. 1, 180 So. 2d 904 (1965).

<sup>21</sup> 241 Minn. 551, 64 N.W.2d 38 (1954).

<sup>22</sup> 279 Ala. 1, 6, 180 So. 2d 904, 907-08 (1965).

treatments daily, would, of itself, give cause to a reasonable person for inspecting the machine at periodic intervals.<sup>23</sup>

In *Rose v. Hakim*<sup>24</sup> the hospital was held liable for the permanent brain damage of an infant which resulted from the negligence of the hospital employees and the defective equipment used. The infant suffered a cardiac arrest during a tonsillectomy which, because of a defect in the monitoring device, went partially undetected and resulted in the permanent brain damage. The court's opinion does not specify exactly what type of defect was involved, nor does it specify the hospital's duty with respect to the equipment which the hospital used.<sup>25</sup> There is no mention in the case whether or not the defect was discoverable, nor whether proper inspection had been done. But it appears from the discussion of the facts that the mere use of defective equipment in this instance caused the hospital to be liable for the resulting injury. This case is indeed extreme, perhaps because of the additional negligence of the nurses and the nature of the injury. Whether mere use of defective equipment without some other negligence or breach of duty as well would result in holding a hospital liable in another circumstance is still doubtful. This case comes as close to holding a hospital strictly liable for its use of defective machinery as any could without specifically saying so.<sup>26</sup>

Other courts, however, have specifically refused to extend the concept of strict liability to a hospital as a supplier of defective equipment. In *Silverhart v. Mount Zion Hospital*,<sup>27</sup> a needle which was furnished for the doctor's use by the defendant hospital broke in the patient during a hysterectomy and became lodged in her pelvic region. Applying the *Greenman v. Yuba Power*<sup>28</sup> definition of "seller," plaintiff sought to extend strict liability not only to the one who actually sold the product, but also to the one who brought it in contact with the injured party. Even though the hospital was really a buyer of the product, in its relation to the patient, it was also a supplier. This theory had earlier been unsuccessful against a dentist in *Magrine v. Krasnica*.<sup>29</sup> The *Silverhart* court again

<sup>23</sup> 241 Minn. 551, 558, 64 N.W.2d 38, 43 (1954).

<sup>24</sup> *Rose v. Hakim*, 335 F. Supp. 1221 (D.D.C. 1971).

<sup>25</sup> The general rule seems to be that the equipment furnished by a private hospital for a patient's use should be reasonably fit for the uses and purposes intended under the circumstances, and where a hospital furnishes defective equipment to a patient who, because of such defective equipment suffers injury proximately resulting therefrom, liability can be imposed as for negligence.

*South Highlands Infirmary v. Camp*, 279 Ala. 1, 5, 180 So. 2d 904, 907 (1965).

<sup>26</sup> Note that the negligence in *Rose v. Hakim* was *not* related to the product at all, yet the court does not dismiss the allegation that the defective equipment was at least a partial cause of the injury. Note also that the holding was *not* based on the theory that the hospital was a "supplier," and hence a seller under the doctrine of *Greenman v. Yuba Power*, 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1962).

<sup>27</sup> 20 Cal. App. 3d 1022, 98 Cal. Rptr. 187 (1971).

<sup>28</sup> 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1962).

<sup>29</sup> 94 N.J. Super. 228, 227 A.2d 539 (1967).

declined to impose strict liability on one who was not in some way related to the process of production. Like the dentist in *Magrine*, the court held that the hospital was merely a user, not a seller as that term was broadly defined in *Greenman v. Yuba Power*.

One commentator has criticized the *Silverhart* decision, claiming that the California court based its decision on the outdated sales-service distinction.<sup>30</sup> This distinction refers to the difference in treatment given warranties accompanying a sale of goods vis-à-vis the treatment given to warranties accompanying a sale of services.<sup>31</sup> Although early product liability cases stressed this distinction, erosion came quickly, first in the preparation and sale of food cases, thence in other service transaction cases.<sup>32</sup> The courts, however, still seem to draw the line prior to holding professionals—doctors, dentists, etc.—strictly liable for services rendered.<sup>33</sup> Perhaps this is logical in light of the great need for their services. But Russell argues that the sales-service distinction is potentially arbitrary.<sup>34</sup> Comparing *Newmark v. Gimbel's*<sup>35</sup> with *Magrine v. Krasnica*<sup>36</sup> and *Silverhart v. Mt. Zion Hospital*,<sup>37</sup> he criticizes what he calls the special protection given to the medical profession.<sup>38</sup> In *Newmark* the plaintiff recovered for injuries resulting from defective hair dye provided by defendant as a part of the services. Whereas in *Magrine* the plaintiff failed to recover from a dentist for injuries resulting when a needle broke in the plaintiff's mouth. Likewise, in *Silverhart*, the plaintiff failed to recover from a doctor for injuries resulting when a needle broke in the patient during a hysterectomy and became lodged in her pelvic region. If a plaintiff can recover against a beautician for a service-related injury,

<sup>30</sup> See Russell, *Product and the Professional: Strict Liability in the Sales-Service Hybrid Transaction*, 24 HASTINGS L.J. 111, 123-25 (1972) [hereinafter cited as Russell].

<sup>31</sup> *Id.* at 111-12. For a discussion of this concept and its application to product liability law see Farnsworth, *Implied Warranties of Quality in Non Sale Cases*, 57 COLUM. L. REV. 653 (1957).

<sup>32</sup> Russell, *supra* note 30, at 116-18.

<sup>33</sup> See, e.g., *Cutler v. General Electric*, 4 UCC REP. SERV. 300 (N.Y. Sup. Ct. 1967) (case against the doctor and hospital summarily dismissed because of the sales-service distinction).

<sup>34</sup> In *Silverhart v. Mt. Zion Hospital*, a 1971 California appellate case, the court demonstrated the potential arbitrary qualities of the sales-service distinction, stating that the hospital would be subject to strict liability if the product supplied was "not integrally related to its primary function of providing medical services..." To illustrate, the court noted that had the patient been injured by a product purchased from the hospital gift shop, recovery based on strict tort liability would not be possible. This distinction ignores the fact that reliance on gifts from the hospital's shops is far less and the opportunity to inspect for defects far greater than the reliance and opportunity for inspection afforded a party injured by defective surgical instruments used in the course of the hospital's normal operation. Russell, *supra* note 30, at 127.

<sup>35</sup> 54 N.J. 585, 258 A.2d 697 (1969).

<sup>36</sup> 94 N.J. Super. 228, 227 A.2d 539 (1967).

<sup>37</sup> 20 Cal. App. 3d 1022, 98 Cal. Rptr. 187 (1971).

<sup>38</sup> Russell, *supra* note 30, at 131-32.

cannot the same reasoning be used to impose liability on a doctor or dentist for similar service-related injuries?

The dissenting judge in *Magrine v. Spector*<sup>39</sup> also argued that strict liability should fall on the professional, who, in turn, is able to spread the cost of the risk out with adequate insurance. Malpractice insurance, however, has already reached exorbitant proportions and the exorbitance is reflected in equally high medical fees; but if the trend continues in the direction of imposing strict liability on doctors, insurance may become the only answer.

On the other hand, while the *Silverhart* court's reasoning may be arbitrary and a thinly veiled attempt to insulate medical professionals from strict liability, this may be most favorable. It is also well founded in principles of malpractice, which insulate the doctor from liability without a clear showing of negligence. And it leaves at least one path open for the injured patient. He can look to the manufacturer of the defective product, rather than toward the professional user. Until recently, however, there have been very few cases holding the manufacturer strictly liable for defective medical equipment.

### MANUFACTURER'S LIABILITY

Recovery against manufacturers of medical equipment thus far has been successful on two theories, negligence and breach of warranty. As of 1969, the majority of reported cases had prevailed in negligence.<sup>40</sup>

#### *Negligence*

The first type of negligence is negligent production or manufacture. In *Clark v. Zimmer Mfg. Co.*<sup>41</sup> an intermedullary nail used to repair a broken leg was so weak that normal stress caused it to break. The plaintiff based his action on the negligent manufacture and breach of the implied warranty of fitness for the particular purpose. Negligent manufacture was also one cause of action in *Orthopedic Equipment Co. v. Eutsler*.<sup>42</sup> There the pin was too small for the hole specified by its label, and the pin exacerbated the injury rather than repaired it.

Closely allied with negligence in manufacture or production is the

<sup>39</sup> The benefit that a patient receives in damages is not offset by an unfair burden placed on the dentist. The dentist does have a claim over against the supplier and manufacturer of the defective needle. He should know who they are in most cases. If strict liability would create higher insurance costs, these costs may be mitigated through the claim over. Even without the claim over, the loss may be distributed through fees for dental services or by insurance, the cost of which may be reflected in such fees.

100 N.J. Super. 223, 233, 241 A.2d 637, 643 (1968). *But see* *Magrine v. Krasnica*, 94 N.J. Super. 228, 238-240, 227 A.2d 539, 545-46 (1967).

<sup>40</sup> Swartz, *supra* note 3, at 362.

<sup>41</sup> 290 F.2d 849 (1st Cir. 1961).

<sup>42</sup> 276 F.2d 455 (4th Cir. 1960).

failure to inspect for defects. Whereas hospitals and doctors have a duty to inspect for patent defects,<sup>43</sup> the manufacturer has an even greater duty which extends to latent defects.<sup>44</sup> Often this duty can be allocated by contract as it was in *Nelson v. Swedish Hospital*.<sup>45</sup> The equipment involved in that case was an X-ray machine, which, unlike an intermedullary pin, the hospital could have easily inspected. In *Nelson*, the manufacturer, by contract, had limited its responsibility to repair and replacement only. The warranty included defects in workmanship, but required the hospital to inspect the machine periodically and report to the manufacturer if any part needed attention. In the suit against the hospital, the plaintiff tried to bring in General Electric, the manufacturer, as a third-party defendant; but the jury found no negligence on the part of the manufacturer. The contract specifically spelled out the manufacturer's duties, as well as the hospital's, in regard to the equipment. Of course, a manufacturer cannot contract away liability for its own negligence, but the right to allocate certain duties, including inspection, is quite acceptable in regard to machinery, medical equipment being no exception.

Negligent design, which is usually a viable basis for an action involving many defective products, has very often been overlooked in actions involving medical products.<sup>46</sup> In several cases involving intermedullary pins,<sup>47</sup> the defect was related not only to the production, but also to the design of the pin or nail. The material used and the design of the product were inadequate for the type of stress the product was meant to withstand. The court decisions, however, make little mention of allegations of design defects. Nevertheless, where other negligence is hard to prove, a faulty design is often, because of the presence of inferior material or faulty workmanship, quite obvious in every product of a particular "batch."<sup>48</sup> In the intermedullary pin cases the defect was detectable in the metal, thus breach of warranty of fitness and negligent construction were successful arguments; but in *Chadwick v. Air Reduction Co.*<sup>49</sup> the defect involved the construction of the whole product. The injured party was an infant whose foot became lodged in the heating unit of an incubator. The defect was clearly a design problem, for the manufacturer has a duty

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<sup>43</sup> Hospitals may have a duty to inspect for certain less obvious defects. See notes 20-23 and accompanying text.

<sup>44</sup> *Hine v. Fox*, 89 So. 2d 13 (Fla. 1956).

<sup>45</sup> 241 Minn. 551, 64 N.W.2d 38 (1954).

<sup>46</sup> Swartz, *supra* note 3, at 368-69.

<sup>47</sup> See, e.g., *Clark v. Zimmer Mfg. Co.*, 290 F.2d 849 (1st Cir. 1961); *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960); *Bowles v. Zimmer Mfg. Co.*, 277 F.2d 868 (7th Cir. 1960); *McKasson v. Zimmer Mfg. Co.*, 12 Ill. App. 3d 429, 299 N.E.2d 38 (1973).

<sup>48</sup> See Swartz, *supra* note 3; *McKasson v. Zimmer Mfg. Co.*, 12 Ill. App. 3d at 435, 299 N.E.2d at 42, where testimony of two metallurgists supported the negligent design theory.

<sup>49</sup> 239 F. Supp. 247 (N.D. Ohio 1965).

to create a product which is safe for its intended use. The very fact that the baby could get his foot caught shows that the design was not safe.<sup>50</sup>

Another much overlooked type of design defect—lack of durability in a medical machine—has not been discussed in any case found thus far.<sup>51</sup> Durability is especially important when the product will be implanted in the human body, as with an intermedullary pin or an artificial pacemaker. In *Friedman v. Medtronic*<sup>52</sup> a pacemaker failed and caused the death of the patient. The action against the manufacturer of the pacemaker was based on express and implied warranties.<sup>53</sup> These facts might also provide a good vehicle for advancing a negligent design argument based on the lack of durability of the pacemaker. Perhaps because of the “exotic” nature of the equipment, the proper lifespan is not determinable. Still, some sort of reasonable expectation seems possible. Doctors, too, call for better durability in such products as well as better warning devices and standardization of designs to speed repairs. Because of the constant threat to the patient of pacemaker failure, great steps need to be taken to increase their reliability.<sup>54</sup>

The manufacturer has still another duty, which, if breached, is deemed negligence. While he is not the insurer of his product, he does have a duty to warn of any potential dangers involved with the use of the product.<sup>55</sup> These warnings, however, in the case of medical equipment, are intended for professional people who are deemed to be aware of the dangers. In *O'Connell v. Westinghouse X-Ray Co.*,<sup>56</sup> the doctor himself was injured, because he worked too close to an X-ray machine. He alleged that the manufacturer was negligent in not providing a guard rail and a better warning of the dangers of overexposure. The court reasoned, however, that the doctor himself was contributorily negligent for he knew of the danger and still did not keep the proper distance. While the manufacturer does have a duty to warn of potential dangers, it does not have a duty to insure against negligent misuse. Doctors often do know of the dangers inherent in some medical equipment, especially X-ray machines, but with some more complex types of equipment and with new products their knowledge may be just as limited as the lay public's.

One frustrating case involving the duty to warn is *McLaughlin v.*

<sup>50</sup> The reported case dealt only with a procedural point—whether or not suit could be brought against a dissolved corporation for a claim arising prior to dissolution.

<sup>51</sup> See Swartz, *supra* note 3, at 368-69.

<sup>52</sup> 345 N.Y.S.2d 637 (Sup. Ct., App. Div. 1973).

<sup>53</sup> A new trial was granted after a verdict for the plaintiff because there was inadequate expert testimony and improper jury instructions.

<sup>54</sup> For a discussion of the problems in this area see Hellerstein, M.D., Hornster, M.D., and Ankeney, M.D., *The Runaway Artificial Pacemaker: Report of a Case*, 62 OHIO MED. J. 907 (1966).

<sup>55</sup> *Friedman v. Medtronic*, 345 N.Y.S.2d 637 (Sup. Ct., App. Div. 1973).

<sup>56</sup> 288 N.Y. 486, 41 N.E.2d 177 (1942).

*Mine Safety Appliances Company*.<sup>57</sup> Although it is squarely in line with the duty to warn theories, it makes recovery for the innocent plaintiff impossible. The facts of the case are very unique. A child was rescued at a drowning scene by a firemen rescue squad. A nurse volunteered her services, and she used chemical heat blocks sold and supplied to the firemen to warm the child. The manufacturer had fully warned, demonstrated and instructed the firemen in the use of the equipment, which included proper insulation of the heat blocks. There was also a warning on the box which contained the equipment. However, in the emergency situation, the firemen removed the heat blocks from the box and failed to tell the volunteer nurse to wrap the blocks before placing them on the child. The words written on the blocks themselves said "Entirely Self Contained." Therefore, the nurse, not being aware of the dangers, applied the apparatus; as a result the child suffered terrible burns. The child's father sued the manufacturer on the theory of failure to warn adequately of the dangers inherent in the product. The appellate court held, however, that the firemen's intervening negligence in failing to convey the warnings to the nurse superseded any possible negligence on the part of the manufacturer. The manufacturer's warnings were deemed extensive and sufficient; thus, the duty then fell to the purchaser to reconvey the message.<sup>58</sup>

The dissent in the case advances the argument that the manufacturer should have foreseen use in an emergency situation and put the warning directly on the heat blocks themselves. Without such a warning, the blocks may be called inherently dangerous. The equipment was meant precisely for the type of use which the facts in the *McLaughlin* case suggest, and failure to convey the warnings to helpers was indeed quite foreseeable. The dissent's suggestion would not have eliminated the need for the extensive demonstration warnings given to the purchasers; but, in addition, would have required that the warning be printed on the product as well.<sup>59</sup> The dissent's argument seems more in line with the trend toward consumer protection, and with holding the one who creates the hazard liable. Because of the huge potential of these products for both healing and harm, extraordinary precautions must fall to the manufacturer to insure the proper use of the equipment. Ordinary standard cannot suffice where medical products are involved. But, as yet, the courts continue to adhere to the concept of "reasonable" standards of performance.

### *Breach of Warranty*

Turning now from negligence theories to breach of warranty, it is not unusual to find many of the same cases. This is to be expected, for if a product is negligently designed or manufactured it certainly will not meet

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<sup>57</sup> 11 N.Y.2d 62, 181 N.E.2d 430, 226 N.Y.S.2d 407 (1962).

<sup>58</sup> *Id.* at 71-72, 181 N.E.2d at 435, 226 N.Y.S.2d at 414.

<sup>59</sup> *Id.* at 72, 181 N.E.2d at 436, 226 N.Y.S.2d at 415.

merchantability requirements. Furthermore, because the manufacturer knows exactly the type of use these products are intended for, the warranty of fitness for a particular purpose is usually applicable as well.

Very few cases deal with express warranties, because express warranties are usually intended for the buyer, in these cases the doctor or the hospital, not the injured patient.<sup>60</sup> Therefore, an express warranty action is not a very viable avenue of recovery for the injured plaintiff. In *Friedman v. Medtronic, Inc.*, the courts discussed the problem faced in suits based on express warranties this way:

In order for an express warranty to exist, there must be an affirmation of fact or promise by the seller, the natural tendency of which is to induce the buyer to purchase. Thus, for a buyer to recover for breach of express warranty, he must show that the warranty was relied on.<sup>61</sup>

Most of the successful suits based on warranty assert a breach of the implied warranty of fitness for a particular purpose. In addition, there is usually present an allegation of negligence on the part of the manufacturer, for when medical equipment is negligently constructed it cannot possibly be suitable for its intended purpose. The manufacturer clearly is aware of the intended use and even may have designed the product to meet some special need.<sup>62</sup>

Basing an action upon breach of the implied warranty of merchantability is also a viable alternative, but is relied upon less often than the fitness warranty. The plaintiff in *Orthopedic Equipment Co. v. Eutsler*<sup>63</sup> relied on this warranty, as well as the negligence discussed above. The case involved mislabeling. An intermedullary pin was marked with the wrong dimensions, so that when the doctors drilled the hole for it to be inserted into, the hole was too small. When the nail was inserted, it caused further injury and eventually the loss of the leg. Since the mislabeling of a medical device is a violation of the Federal Food, Drug and Cosmetic Act,<sup>64</sup> this was deemed negligence per se. In addition, the product did not comply

<sup>60</sup> The privity problem has been alleviated somewhat by UNIFORM COMMERCIAL CODE § 2-318 (1966 version). Courts have extended the intended user theory of section 2-318 to include patients injured by faulty medical equipment. While it is only dicta, the court in *Ribando v. American Cyanamid Co.*, 37 Misc. 2d 603, 235 N.Y.S.2d 110 (Sup. Ct. 1962), put it quite succinctly:

The court is mindful of the limitations imposed by the rule of privity in breach of warranty actions, but was of the opinion that patients, for whose use hypodermic needles are purchased by their doctors, belong in the same category as members of the family or employees of purchasers, for whose benefit as direct intended users of the product the privity rule has in recent cases been relaxed.

*Ribando*, *supra* at 604, 235 N.Y.S.2d at 111.

<sup>61</sup> 345 N.Y.S.2d 637, 643 (Sup. Ct., App. Div. 1973).

<sup>62</sup> See *Bowles v. Zimmer Mfg. Co.*, 277 F.2d 868 (7th Cir. 1960), holding the manufacturer of a defective intermedullary pin liable for negligence in manufacture and breach of warranty for fitness.

<sup>63</sup> 276 F.2d 455 (4th Cir. 1960).

<sup>64</sup> 21 U.S.C.A. §§ 301-392 (1972).

with the merchantability warranty in that it was not adequately labeled.<sup>65</sup> Recovery, therefore, was based on both negligence and breach of warranty.

While suits based on breach of warranty and negligence have been successful against the manufacturers of medical equipment, seeking to hold the manufacturer to strict liability for its defective medical equipment could prove to be a much better path for an injured plaintiff to follow. Under general principles of strict liability, no fault need be proven, only that the injury resulted from an unreasonably dangerous condition in the product which existed at the time the product left the manufacturer's control.<sup>66</sup> In *McKasson v. Zimmer Manufacturing Co.*<sup>67</sup> the court relied on strict liability because the defect in the intermedullary pin made the product inherently dangerous, and as such caused the plaintiff's further injury. The evidence of the defendant's testing method was irrelevant and hence inadmissible in the strict liability action. The manufacturer had marketed a pin not adequate to withstand the pressure necessary for its primary function of aiding in the repair of a broken bone. In this condition, the product caused more injury to the patient rather than advancing his healing. This was enough to call the product unreasonably dangerous to plaintiff's health. Thus, the manufacturer was held strictly liable for the injuries resulting from such a product.

#### SUMMARY

Thus far under the *Magrine* decision strict liability is not applicable to a doctor, nor under *Silverhart* is it applicable to a hospital. But under *McKasson* it is applicable to a manufacturer. Here is where the liability should fall. Manufacturers must be held accountable when products such as these fail for, indeed, human life is in their hands. A defective medical machine or surgical tool clearly becomes an inherently dangerous product, and hence its producer should be held strictly liable.

Extending the theory of strict liability to the manufacturer, while, of course, not eliminating possible recovery based on negligence or breach of warranty, is well in line with the trend to protect the innocent consumer in need of medical attention. Strict liability will serve to make recovery against manufacturers possible where a defective product exists, but where no negligence can be shown. This effective means of recovery against manufacturers whose products actually cause the injury will not eliminate malpractice actions against doctors or hospitals. It will, however, limit actions against non-negligent parties merely because they are the most accessible. Thus, when a medical machine fails, as with other products consumers come into contact with, the injured plaintiff will have an easier line of access to the party actually responsible for the defective product.

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<sup>65</sup> UNIFORM COMMERCIAL CODE § 2-314(2) (e) (1966 version).

<sup>66</sup> RESTATEMENT (SECOND) OF TORTS § 402A (1965).

<sup>67</sup> 12 Ill. App. 3d 429, 299 N.E.2d 38 (1973).