

# MEDICAL EXPERT SYSTEMS: GRAPPLING WITH ISSUES OF LIABILITY

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## INTRODUCTION

The British mathematician Alan Turing once addressed the question of whether machines would ever "think."<sup>1</sup> Mr. Turing proposed a simple exercise which has since become known as "Turing's Test."<sup>2</sup> The test is a type of imitation game in which a computer, a human being, and an impartial human observer are put in separate sealed rooms. Turing opined that the machine would have achieved thought when the human observer asking questions could not identify which room contained the machine and which contained the human by the answers coming from each room.<sup>3</sup>

Some years after Mr. Turing proffered his perceptive observation, the rapid advance of computer technology has produced human-like "thought" in machines through the use of expert system programming. Such capabilities are not new. Twenty years ago, Dr. Joseph Weizenbaum of MIT developed a computer program called ELIZA that responds in a startlingly human manner to statements made by an observer. While operating ELIZA initially required one of the largest computers then available, it currently can be run on virtually any personal computer and costs approximately twenty dollars.<sup>4</sup>

Although ELIZA is little more than illusion, a great number of computer systems presently provide valuable assistance in clinical decision-

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1. Turing, *Computing Machinery and Intelligence*, in *COMPUTERS AND THOUGHT* 11 (E. Feigenbaum & J. Feldman eds. 1981).

2. *Id.* at 9.

3. *Id.* at 11-13.

4. I. Moskatel, *Looking at Intelligence in Law Practice*, *NETWORK*, Vol. 4, No. 1, p. 14 (Aug. 1986).

making, mathematics, circuit design, and oil exploration. These so-called "expert" systems can ask questions, discard irrelevant information, and produce both a reasoned conclusion and a credible explanation of how that conclusion was obtained. For example, the MIT Laboratory for Computer Science has developed a program that recommends an appropriate dose of the drug digitalis based on a patient's history and symptoms.<sup>5</sup>

The use of expert computer systems in medicine has increased dramatically over the past ten years and several systems now perform health care functions, such as printing results of laboratory tests.<sup>6</sup> Indeed, a Computer Axial Tomography ("CAT") scan provides diagnoses of neural disorders and injuries. Looming on the horizon are computer programs for in-home use that will help lay people roughly to categorize or diagnose their own illnesses as well as those of their children.<sup>7</sup>

Such medical expert systems will present courts with unique and difficult liability questions regarding personal injuries resulting from the use of these programs by either untrained physicians or lay users. This Comment will focus on two types of medical expert systems: those designed for in-home use and those restricted to operation by a physician.

There are significant differences in the marketing of the two types of programs; hence, liability cannot be determined according to a single, universal rule. When an expert system is intended for home use, a program user who relies on a computer generated diagnosis may seek to hold the physician who developed the program, the software manufacturer, the seller, or others in the commercial stream strictly liable for distributing a defective product. On the other hand, use of a professional expert system may expose the attending physician, as well as the manufacturer, developer, and seller to liability.

This Comment suggests that strict products liability is the more effective method of assigning liability for personal injuries connected to unrestricted use of a home expert system. However, an analysis of the liability spawned by the use of a professional system must account for the service component in the relationship between an injured patient and a physician. This Comment proposes that liability for professional

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5. Gorry, Pauker & Silverman, *Computing Clinical Expertise That Considers Clinical Responses to Digitalis*, 64 AM. J. MED. 452 (1978).

6. Several expert systems programs are now commercially available for use in accounting and law. These programs include "Expert Edge," which is priced at \$800, produced by Human Edge Software, and "Personal Consultant" from Texas Instruments, which is in the \$900 to \$3,000 price range depending upon the sophistication desired.

7. See, e.g., J. Rose, *Thinkalong Software: First Opinion Pediatrics* (unpublished software, copyright 1985).

expert systems should be contingent upon proof of professional negligence when a claim is brought against a user-physician and proof of unreasonable danger when a defective product claim is brought against a manufacturer.

## I. SYNOPSIS OF MEDICAL EXPERT SYSTEMS TECHNOLOGY AND LIMITATIONS

An expert system is a computer program intended to embody the knowledge of an expert in a particular intellectual domain. The goal of an expert system project "is to write a program that achieves a high level of performance on problems that are difficult enough to require significant expertise for their solution."<sup>8</sup> These programs are usually long, normally upwards of 500,000 characters. Although these systems cannot perfectly mimic human reasoning, they can match human queries to machine explanations. Thus, as an indexing and reference system, medical expert systems are unsurpassed.

An expert program performs deductive reasoning using a compiled knowledge base, an inference procedure, and specific user-supplied data. The knowledge base is a collection of carefully selected logical rules reflecting the expertise of individuals working in the field. The inference procedure acts upon the specific data and the knowledge base to analyze, form hypotheses, and arrive at solutions to problems. In theory, the knowledge base is separable from the inference procedure. The knowledge base of an expert system is the portion of the program that enables a computer to simulate the reasoning function which makes these systems so potentially valuable.<sup>9</sup>

In the case of a medical expert system, the developer physician (or other medical authority) would enter principles into the knowledge base. These principles will be used to deduce answers to users' questions. Each rule used in such a system must take the form of an "IF-THEN" conditional. For example, a developer might construct the following principle: IF "swollen, red throat" is entered, THEN ask if donut-shaped pustules are also present. The "IF" clause defines a set of conditions such that if each is true, the statement contained in the "THEN" clause is executed.

The user-supplied data is simply information entered into the computer by the user. The computer selects relevant principles based on the

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8. Feigenbaum, *Knowledge Engineering: The Applied Side of Artificial Intelligence*, 426 ANNALS N.Y. ACAD. SCI. 91, 91-92 (1984).

9. *Id.*

input, asks questions to find out any additional pertinent facts, and generates an answer.

For example, a medical expert system for use in the home might be designed to perform a triage screening of basic health problems based on a user's specific complaints. This software would place an ailment in one of three categories: (1) life-threatening emergency situations; (2) problems requiring professional evaluation; and (3) situations likely to self-resolve. The program might then present the user with a prognosis, an explanation of the categorization and suggestions as to appropriate reactions. For example, the following prognosis might appear in a nonemergency case:

URETHRITIS- MALE, GONORRHEA  
ROUTINE PROFESSIONAL CARE  
URETHRITIS, PENIS INFECTION, CHLAMYDIA,  
GONORRHEA

Medical evaluation needed in next day or so.

\* Lab work indicated.

\* Antibiotic probably required to eradicate infection.

Burning on urination or a discharge from the penis are suspicious signs of an infection in the urethra (the tube leading from the bladder). This is especially true in a sexually active male. These symptoms need laboratory evaluation with cultures and urinalysis. See your physician in the next day or so for appropriate studies.<sup>10</sup>

A more extreme situation might prompt the system to offer advice such as:

EMERGENCY SITUATION  
POSSIBLE SHOCK OR SUSTAINED LOW BLOOD  
PRESSURE

Professional help must be obtained immediately.

\* Keep victim lying down; elevate feet above head.

\* Do not give anything to eat or drink.

\* Apply pressure to any bleeding area and cover all burns.

Shock is a decrease in blood pressure below the level necessary to pump the blood to the vital organs. It can be produced by a number of situations such as blood loss,

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10. J. Rose, *supra* note 7.

heart failure, infection, or allergic reaction. True shock is NOT caused by unpleasant emotional experiences.

Contact your doctor or emergency facility immediately.<sup>11</sup>

An excellent example of a professional system, designed to augment a physician's own personal skill and reasoning, is MYCIN, which produces diagnoses of infectious diseases, particularly blood and meningitis infections, and advises physicians on antibiotic therapies for treating those disorders.<sup>12</sup> When "consulting" MYCIN, a physician is asked only for patient history and laboratory test results. The program then generates a probable diagnosis based on the existence or non-existence of specified conditions and a possible plan of treatment. MYCIN's knowledge base consists of approximately 500 rules; approximately one-half deal with blood infections and one-half with meningitis infections.

MYCIN's reasoning consists of a chain of rules that concludes the presence of an infecting organism from test data and patient history. A sample piece of knowledge embodied in MYCIN is the following:

IF:

- 1) the infection that requires therapy is meningitis, and
- 2) the type of the infection is fungal, and
- 3) organisms were not seen on the stain of the culture,  
and
- 4) the patient is not a compromised host, and
- 5) the patient has been to an area that is endemic for  
coccidioidomycosis, and
- 6) the race of the patient is one of: black asian indian, and
- 7) the cryptococcal antigen in the csf was not positive

THEN: there is suggestive evidence that cryptococcus is not one of the organisms that might be causing the infection.<sup>13</sup>

The program can answer a variety of questions during or after a consultation session, including "Why are you asking for this information?" and "How was a conclusion reached?" In MYCIN, a conclusion is ordinarily stated as a measure of uncertainty based on a continuum

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11. *Id.*

12. MYCIN was originally developed as the Ph.D. thesis of E. H. Shortliffe, Computer Science Department, Stanford University. It was further perfected by the Heuristic Programming Project at Stanford University. See generally E. SHORTLIFFE, *COMPUTER-BASED MEDICAL CONSULTATIONS: MYCIN* (1976).

13. Feigenbaum, *supra* note 8, at 94.

from 0.1 to 1.0, where 1.0 is a definite certainty, 0.9 is "very strong evidence," 0.6 is "suggestive evidence," and so on.

While expert systems such as MYCIN can be useful, both home and professional systems have limitations and cannot entirely supplant physicians in the identification and treatment of health problems. For example, if a patient has tested positive for cholera bacteria, MYCIN will recommend a two-week course of tetracycline. This treatment is accurate, but not complete:<sup>14</sup> while the antibiotic will destroy the bacteria, it will not save the patient from the fatal ravages of untreated diarrhea and other symptoms.<sup>15</sup> Furthermore, a program like MYCIN cannot render a prognosis concerning the effect of a treatment, nor can it answer a question about the results of a hypothetical course of treatment. Finally, to maintain its worth, a medical expert system would have to be constantly updated to reflect changes in the state of the medical arts.<sup>16</sup>

In short, the efficacy of medical expert systems for prescribing a course of treatment is bounded by the individual vagaries of medical cases. An expert system can only implement those principles incorporated into the system by the program developer. If a specific disorder is not correlated to the knowledge base rules, or if an individual's combination of symptoms is unique and therefore unforeseen at the time the program is created, the expert system will not respond adequately to the user's query.

Nevertheless, a properly designed medical expert system can still play a valuable role in an individual's total health care regime. Professional systems serve to cut down upon the number of physician mistakes.<sup>17</sup> Furthermore, an expert system developed for in-home operation should also produce tangible benefits. These programs can successfully classify routine ailments and help eliminate unnecessary trips to the family physician, especially when a disorder is minor and self-resolving. Thus, as a supplement to a regular health care program, an in-home

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14. McCarthy, *Some Expert Systems Need Common Sense*, 42 ANNALS N.Y. ACAD. SCI. 19, 131 (1984).

15. Professor Edward Feigenbaum of Stanford University hinted at these constraints when he stated that heuristic knowledge "can be extracted by a careful, painstaking analysis by . . . a knowledge engineer, operating in the context of a large number of highly specific performance problems." Thus, these systems lack the ability to function in situations which, although very similar to those envisioned by the developer, are different from the program model in subtle, often crucial ways. Feigenbaum, *supra* note 8, at 101.

16. McCarthy, *supra* note 14, at 130.

17. "When MYCIN is used in its intended manner, it scores better than medical students or interns or practicing physicians and on a par with experts in bacterial diseases. . . ." *Id.*

medical expert system can help to control skyrocketing medical costs,<sup>18</sup> avoid unnecessary complications by identifying afflictions at an early stage, and ease uncertainty about health problems, thereby engendering significant psychological benefits.

## II. COMPUTER EXPERT SYSTEMS: A PRODUCT OR A SERVICE?

In evaluating the potential liability associated with use of a medical expert system, courts must decide whether the system is a product or a service. Classification as a product means that the developer, manufacturer, and sellers may all be subject to strict liability; by contrast, characterization as a service implies a negligence standard. Since the elements necessary to establish a claim under the two standards differ dramatically,<sup>19</sup> resolution of this issue will have a tremendous impact upon the potential success of a user's personal injury claim.

### A. Expert Systems as Products

A judicial decision to characterize the system as a product rather than a service can stem from the corporeal nature of the article itself or from overriding policy considerations. Due to their nature, "multifaceted medical computer programs do not fall neatly into either category . . . ."<sup>20</sup> Two general factors may be useful in reaching a rough

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18. Health insurance for the elderly is just one example of the skyrocketing cost of health care in America. Government spending for Medicare has increased from \$16.6 billion in 1970 to a projected \$63.8 billion in 1986. Total U.S. expenditures on health care have increased from \$180.4 billion in 1970 to an estimated \$400.6 billion in 1986. The trend toward increasing medical costs has greatly accelerated over the years. During the decade 1970 to 1980, total U.S. outlays on health care rose by \$108.4 billion. In the six years since 1980, health care expenditures have already increased by \$111.8 billion (all figures are in 1982 dollars). Brooks, *Health Insurance for the Elderly*, San Francisco Chron., Nov. 3, 1986, at 15, col. 1. Another indication of the severity of the inflationary spiral in medical costs is that over the past five years, hospital room charges have increased by 70 percent. *Hospital Costs Most Expensive in California*, San Francisco Chron., Nov. 5, 1986, at 17, col. 2.

19. W. PROSSER & P. KEETON, *HANDBOOK OF THE LAW OF TORTS* § 103, at 712-13 (5th ed. 1985) (distinguishing negligence from products liability where a plaintiff must show a breach of warranty or an unreasonably dangerous condition).

20. Brannigan & Dayhoff, *Liability for Personal Injuries Caused by Defective Medical Computer Programs*, 7 AM. J. L. & MED., 123, 130 (1981). Classifying a medical expert system as either a product or a service is seldom simple or straightforward. Computer software is sometimes classified as a "good." *RRX Indus. v. Lab-Con Inc.*, 772 F.2d 543, 546 (9th Cir. 1985) (computer software a "good" within Cal. Com. Code § 2-105, a label normally reserved for tangible personal property-like products; Note, *Computer Programs as Goods Under the U.C.C.*, 77 MICH. L. REV. 1149 (1978) (stating that while it is logical to consider a computer program as a "good" under U.C.C. § 2-105(1), the sale of the program must be primarily a transaction in goods). In contrast, California specifically classifies custom computer software as a service for purposes of the state

determination about whether an article is a product or service: (1) the tangible form of a product; and (2) the ownership potential of a product.<sup>21</sup> Even though these factors may be useful to some extent, in the final analysis, policy considerations will dictate whether a court applies strict products liability doctrine to either type of medical expert system.<sup>22</sup>

### 1. *The Tangible Form of a Product*

As a general observation, most products, such as automobiles or bicycles, are visible items subject to sensory perception. In contrast, services usually have no corporeal existence apart from their visible effects upon other objects.<sup>23</sup> Nonetheless, many services produce a tangible end-product, as where an attorney prepares a legal brief or a writer composes a manuscript. At this level, the distinction between products and services blurs; classification must hinge upon more than simple physical characteristics.<sup>24</sup> A medical expert system is tangible in nature, yet it is also the end result of the developer's services; it lies in that gray area where product and service merge.

Accordingly, the importance of the tangible form of an expert system varies according to the type of system and the circumstances. Although a program developed for professional use is clearly tangible, its corporeal qualities are only apparent to the physician who uses the program and are not perceived or encountered by the patient. In other

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sales and use taxes. CAL. REV. & TAX. CODE § 6010.9 (West Supp. 1987); *General Business Sys. v. State Bd. of Equalization*, 162 Cal. App. 3d 50, 208 Cal. Rptr. 374 (1984) (affirming refund of sales tax charged taxpayer on the transfer of custom computer programs delivered on punch cards).

21. *Brannigan & Dayhoff*, *supra* note 20, at 130-31.

22. *Id.* at 130, 132.

23. *Id.*

24. Furthermore, there is no legal rule or precedent which restricts the definition of products to articles of physical substance. A number of recent decisions have addressed the issue of whether a public utility should be held strictly liable for injury caused by "defective" electrical current. *E.g.* *Ransome v. Wisconsin Elec. Power Co.*, 87 Wis. 2d 605, 620, 275 N.W.2d 641, 648 (1979) (reversed dismissal of complaint stating there can be recovery in a strict liability action for defective electricity). Because electricity is a form of energy, it possesses no concrete aspect beyond its effects. Nevertheless, when confronted with strict liability claims connected to the provision of electrical power, courts have treated electricity as a product. Even courts which have refused recovery have not questioned the status of electricity as a product. *E.g.*, *Genaust v. Illinois Power Co.*, 62 Ill. 2d 456, 463, 343 N.E.2d 465, 469 (1976) (assumed *arguendo* that electricity was a product); *Petroski v. Northern Ind. Pub. Serv. Co.*, 171 Ind. App. 14, 30-31, 354 N.E.2d 736, 747 (1976) (no transfer to would-be consumer); *Erwin v. Guadalupe Valley Elec. Co-op*, 505 S.W.2d 353, 355 (Tex. Civ. App. 1974) (placement of transmission line was not design or assembly or manufacture of product, but placement of product). Thus, while tangibility may be useful as a rough description of a product, it is not necessary for the application of a rule of strict liability.

words, the intended use of a professional system is slightly different from that of in-home programs in a way that makes the tangibility factor less pertinent. This distinction may make a court less willing to classify an expert system employed by a medical practitioner as a tangible product.

## 2. *Ownership Potential of a Product*

Ownership is a second criterion by which to distinguish a product from a service: one of the hallmarks of a product is its capacity to be possessed. The ability to purchase and own a medical expert system indicates that this software resembles a product more than a service.<sup>25</sup> Once such a program becomes an article of commerce, its ownership potential is indistinguishable from that of items normally conceived of as products, such as automobiles or bicycles.<sup>26</sup>

Like tangibility, the ownership factor is much less relevant in the case of medical expert systems which are designed for use by medical practitioners and not the general public. These medical expert systems are undoubtedly subject to ownership, but not by the injured claimant. Injuries resulting from a physician's use of an expert system will not flow from the plaintiff's own direct manipulation of the software, as in the instance of a program intended for in-home use. Thus, professional expert systems are less likely to be classified as products for purposes of strict liability.

## B. **Expert Systems as Providers of Professional Health Services**

In light of the two factors discussed above, medical expert systems might be described as products; however, the functions performed by such programs are normally characterized as the provision of services.

### 1. *The Practice of Medicine By a Medical Expert System*

Medical expert system programs are designed and constructed to augment traditional physician services. Thus, one of the more persuasive arguments in favor of categorizing an expert system as a service is that these programs practice medicine. Although the phrase "the practice of medicine" is not explicitly defined by statute, states have enacted statutes that regulate the practice of medicine within the state. For example, the California Business & Professions Code provides an adequate definition<sup>27</sup> of the practice of medicine:

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25. *Id.* at 132.

26. Brannigan & Dayhoff, *supra* note 20, at 132.

27. *Stevenson v. State Bd. of Medical Examiners*, 10 Cal. App. 3d 433, 438, 88 Cal.

[t]he physician and surgeon's certificate authorizes the holder to use drugs or devices in or upon human beings and to sever or penetrate the tissues of human beings and to use any and all other methods in the treatment of diseases, injuries, deformities, and other physical and mental conditions.<sup>28</sup>

California courts have further refined this description by enumerating the constituent parts of the practice of medicine: diagnosing, prescribing, and treating ailments.<sup>29</sup>

A medical expert system that categorizes a user's symptoms approximates the diagnostic element of the practice of medicine under California law. "Diagnosis" is defined to "include any undertaking by any method, device or procedure whatsoever, and whether gratuitous or not, to ascertain or establish whether a person is suffering from any physical or mental disorder."<sup>30</sup> Diagnosis extends to the taking of a person's blood pressure and the use of any mechanical devices or machines for the purpose of representing to any person a conclusion with respect to a physical, mental, or nervous condition.<sup>31</sup> Thus the established legal meaning of the term "diagnosis"—the recognition of disease from symptoms—extends to the function of a detailed medical expert system.<sup>32</sup>

However, several considerations may place medical expert software outside the realm of practicing medicine. First, the California Business and Professions Code plainly contemplates diagnosis with the aid of mechanical devices, rather than diagnosis by the device itself.<sup>33</sup> Second, in-home medical expert systems do not prescribe for and treat illnesses. A home medical program merely categorizes complaints into general determinations. A program would not prescribe any specific steps to alleviate the problem, nor would it suggest any particular steps to effect a cure. Rather, prescription and treatment would clearly be left to the physician or surgeon to whom the user is directed. The category of self-resolving advice is arguably a form of treatment and prescription;

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Rptr. 815, 816 (1970).

28. CAL. BUS. & PROF. CODE § 2051 (West Supp. 1986).

29. See *People v. Cantor*, 198 Cal. App. 2d Supp. 843, 848, 18 Cal. Rptr. 363, 366 (1961) (use of hypnosis to lose weight constituted practice without license where cure was promised); see also 66 Ops. Cal. Atty. Gen. 427, 433 (1983) (registered nurse can inject or infuse a patient with "contrast/opaque" materials used for diagnostic studies so long as physician is within proximity of patient so physician can respond should adverse effects occur).

30. CAL. BUS. & PROF. CODE § 2038 (West Supp. 1987).

31. *Id.*

32. *Cantor*, 198 Cal. App. 2d Supp. at 847, 18 Cal. Rptr. at 365.

33. CAL. BUS. & PROF. CODE § 2038 (West Supp. 1987) (defining "diagnose" or "diagnosis" to include the "use of mechanical devices or machines for the purpose of making a diagnosis").

however, because the program would warn a user of the system's limitations and advise seeking professional help if a problem persists, any course of treatment would ultimately be decided upon by the user.

Conversely, a program designed to be used by a physician attempts a more precise identification of a patient's condition and suggests the exact procedures or drugs that will eliminate an affliction; thus, the use of such a program is much more likely to constitute the practice of medicine under appropriate statutes. Indeed, a system like MYCIN is designed to aid a physician in the identification and possible treatment of disease. While the program itself does not physically examine and treat a patient, it is intended to be an integral part of the using physician's examination of the patient. In the hands of a physician, the expert system is but another tool of the physician's practice; the system itself does not practice medicine.

On the other hand, an in-home medical expert system that attempts to achieve the sophistication of MYCIN may be incorrectly viewed by a non-physician as a replacement for traditional medical services. As a matter of policy, a court may well wish to discourage the proliferation of these technical systems for use in the homes of untrained, unsophisticated purchasers. By holding the developers of this latter type of system liable under a medical malpractice theory, the evolution of such expert systems for private applications could be discouraged. Thus, courts may be more willing to classify technically sophisticated in-home systems which attempt specific diagnosis and prescription as services.

## 2. *Computer Programs as "Processes" Instead of Products*

Another argument that a computer program should be classified as a service, and hence governed by a negligence standard, is founded upon the nature of computer programming. Although software can be produced on a mass scale, the fabrication of individualized programs is also perfectly feasible. The capacity to program each computer system individually, when added to the intangible quality of internal program impulses, prompted one noted author to conclude that a computer program should not be considered a product.<sup>34</sup> According to this theory, computer software constitutes a process that is no more a product than is an industrial manufacturing process.<sup>35</sup>

This reasoning has little relevance in the case of computer software which is sold on a mass scale and which is not individually tailored for the particular needs and equipment of each user. The electrical nature

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34. Freed, *Products Liability in the Computer Age*, 12 FORUM 461, 478 (1977).

35. *Id.* at 473-76.

of internal computer operation is not a sufficient reason to classify the program itself as a service or process. Software directs a computer hardware system to respond in a particular manner — the internal electrical impulses are the language by which this guidance is accomplished. Many other products have value largely as a result of an intangible effect that they produce. Medical expert systems cannot be classified neatly as either products or services. Rather, an analysis of these systems requires looking at how they combine features of both classifications.

### C. "Hybrid" Cases: Transactions Involving Both a Product and a Service

In a number of instances, particularly in the medical field, a transaction encompasses more than the mere provision of a service or the transmittal of a product. Many situations involve the rendering of a service which in some manner includes the use or transfer of a product — a hybrid transaction. These situations can produce one of two injury-causing events: the use of a defective product during the provision of a service; or the improper use of an otherwise safe article. Medical expert systems involve hybrid transactions.<sup>36</sup>

The distinction between the service element and the product element of a hybrid transaction is often troublesome.<sup>37</sup> A medical expert system that is intended for general use in the home does not suffer from this complexity. Professional services are clearly rendered at an early stage in the compilation and programming of the system knowledge base; however, once the program is reproduced for mass distribution, the service element of the production process is no longer an integral part of a purchaser's manipulation of the software. The manufacturing of this type of product is identical to the production of a variety of products wherein a service generates the final commercial article, such as the designing of an automobile or the writing of a book. Although much work goes into manufacturing a given material good, once a good is complete it becomes a "product" in the legal sense.

By contrast, when a physician uses a medical expert system the product is inseparable from the service transaction. Because the

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36. Not surprisingly, many courts have applied strict liability in tort to hybrid situations. *See, e.g.*, *O'Laughlin v. Minnesota Natural Gas Co.*, 253 N.W.2d 826 (Minn. 1977) (strict liability adopted for installation defects). *But see*, *Hoover v. Montgomery Ward & Co.*, 270 Or. 498, 528 P.2d 76 (1974) (refused to apply strict liability to installation situation).

37. *See* W. PROSSER & P. KEETON, *supra* note 19, §104 at 720. The contrary positions adopted by Minnesota and Oregon with respect to strict liability for installation services illustrates these difficulties. *See supra* note 36.

physician is using a product to provide a service, the hybrid situation cannot be analyzed readily under either strict liability or negligence principles. Some courts have applied strict liability standards, while others have applied negligence standards. Thus, categorizing a transaction as a hybrid, rather than as a simple product or service, leaves the standard of liability undetermined.

Courts have generally examined three elements in determining whether to hold an individual who uses a defective product in the provision of a service strictly liable. These considerations are: (1) the nature of the activity; (2) whether the defective product was actually conveyed or merely used in providing a service; and (3) whether the service or the product was the primary focus of the bargain.<sup>38</sup> Judicial interpretations of these factors, combined with certain policy aims, outline a workable framework in which to apportion liability for the professional use of a medical expert system.

A physician's use of a medical expert system can give rise to two possible sources of injury and two potential theories of recovery. A patient injured by a medical expert system can claim that the physician used a defective computer program during the course of treatment. The crux of this claim is that the product was flawed. However, this type of claim is less likely to result in the imposition of strict liability. For example, in *Magrine v. Krasnica*,<sup>39</sup> a court refused to apply strict liability where injuries were caused by a dentist's use of a defective hypodermic needle which broke during treatment. In that case, both parties conceded that the breakage was due to a latent defect in the needle itself, and not to the dentist's negligence.<sup>40</sup>

The court stressed that the dentist was in no better position than the plaintiff to control, inspect, and discover the hidden defect in the hypodermic needle that was purchased from a manufacturer,<sup>41</sup> and that the transaction was essentially one for professional services predicated on the relationship between the dentist and his patient.<sup>42</sup> The dentist's job was not to sell the needle, but to treat patients.

An alternative cause of action for a patient injured by a physician's use of a professional expert system would be that, even though the

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38. *Id.*

39. 94 N.J. Super. 228, 227 A.2d 539 (1967), *aff'd sub nom.*, *Magrine v. Spector*, 100 N.J. Super. 223, 241 A.2d 637 (1968), *aff'd* 53 N.J. 259, 250 A.2d 129 (1969).

40. *Magrine*, 94 N.J. Super. at 230, 227 A.2d at 540.

41. 94 N.J. Super. at 234, 227 A.2d at 543. The court did not rule on the strict liability of the needle manufacturer because plaintiff had not pursued such a claim. 94 N.J. Super. at 240, 227 A.2d at 546.

42. *Id.* at 235-38, 227 A.2d at 543-45; *see also*, *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 978-79, 95 Cal. Rptr. 381, 392-93 (1971).

program itself was not defective, the physician used it improperly or negligently. The focus of this second cause of action would be that the professional service itself, and not the product used, was somehow inadequate. For example, in *Barbee v. Rogers*,<sup>43</sup> the petitioner sought damages for eye injuries caused by the improper fitting of contact lenses. The defendants were two optometrists who operated eighty-four offices throughout the state of Texas.<sup>44</sup> The court recognized that the defendants' activities fell between those ordinarily associated with the practice of a profession and those characteristic of a merchandising concern.<sup>45</sup> In spite of the retail facet present in defendants' enterprise, the court held the rule of strict liability inappropriate because the injury was not attributable to the product itself, but instead was connected to the improper fitting of the lenses — a professional service.<sup>46</sup>

The focal point of the court's decision in *Barbee* was that the plaintiff did not prove that the contact lenses themselves were somehow flawed.<sup>47</sup> Rather, the thrust of the plaintiff's complaint was that the contact lenses he purchased from the defendants were incorrectly fitted to his eyes.<sup>48</sup> Consequently, the plaintiff did not demonstrate that the defendants had manufactured or sold a defective product.<sup>49</sup> Thus, courts faced with the problem of assigning liability for negligence in the provision of professional services have applied ordinary malpractice standards and not the standard of strict liability. A claim that an expert medical system was improperly used or relied upon by a physician in diagnosing a patient should also be governed by negligence standards.

One could argue that strict liability is appropriate in expert system cases because a physician who uses an expert system will probably be in a better position than his or her patient to detect and compensate for any flaws in the program.<sup>50</sup> These defects may be latent in the sense that they are not discoverable until the physician guides the computer into the specific area in which the "bug" is located; however, once the doctor inputs the information necessary to enter the flawed part of the program, the physician should be able to discern a program response that does not coincide with the physician's own medical knowledge and

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43. 425 S.W.2d 342 (Tex. 1968).

44. *Id.* at 344-45.

45. *Id.* at 345-46.

46. *Id.* at 346.

47. "The miscarriage, as such there was, rests in the professional acts of respondents and not in the commodity they prescribed, fitted and sold." *Id.*

48. *Id.* at 343-44.

49. Plaintiff incorrectly assumed that the defendants were also the manufacturers of the lenses. *Id.* at 344.

50. *But cf., Magrine*, 94 N.J. Super. 228, 227 A.2d 539 (court determined that dentist was not in a better position). *See supra* note 39.

expertise. This distinction seems to support the imposition of strict liability upon a physician who uses an expert system because a defect may be detected before an injury occurs.

Nevertheless, the best standard of liability for a physician's use of a defective expert system is professional negligence. A defect in a medical expert system will not immediately produce an injury. The harm in such a case will result only when the physician fails to realize that the program's diagnosis or suggested treatment is inaccurate and proceeds to implement the system's plan of action. Such behavior can be deemed negligent since a physician who reaches an incorrect diagnosis or prescribes an improper course of treatment is normally liable for medical malpractice if such conduct falls below the customary standard of care in the profession.<sup>51</sup> The bare fact that the physician relies upon a medical expert system in arriving at the wrong conclusions—rather than making an error based on personal knowledge—should not convert what would be liability for negligence into strict liability.

Other policy considerations indicate that holding a physician strictly liable for the use of a medical expert system may not be warranted. A physician who uses a medical expert system does not inject the program into the commercial marketplace.<sup>52</sup> Furthermore, the essence of the bargain for which a medical patient contracts is the physician's professional services, and not the use of an expert system. A physician who employs expert system software will not normally possess sufficient assets, nor will he or she be able to spread the costs of a risk over a large enough group, to support a policy of risk distribution.<sup>53</sup> Finally, forcing a physician to internalize higher costs under a strict liability standard will contribute to an increase in medical expenses that may be unwarranted, especially in light of the existing incentives to discover and correct defects provided by a negligence standard.

Several courts have summarized the reasons why strict liability should not be extended to cover the rendering of defective health care services. In *Carmichael v. Reitz*,<sup>54</sup> a patient initiated a strict liability action for injuries sustained as the result of ingesting a drug prescribed by the defendant physician. As in *Barbee*, the claimant did not argue that the drug was flawed, but contended that the doctor had prescribed an inappropriate medication under the circumstances. In rejecting the

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51. See generally D. LOUISELL & H. WILLIAMS, *MEDICAL MALPRACTICE* § 4.02 (poor results in practice), § 8.04 (requirement of reasonable skill and care) (1986).

52. *Magrine*, 94 N.J. Super. at 235-38, 227 A.2d at 543-45. See also, *supra* note 42 and accompanying text.

53. See, e.g., *Greenberg v. Michael Reese Hosp.*, 83 Ill.2d 282, 415 N.E.2d 390 (1980) (discusses economics of risk distribution in context of physician's use of X-rays).

54. 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971).

plaintiffs' claim of strict liability, the court relied on the continuing validity of a distinction between a transaction in which the primary objective is the provision of a service, and one in which the principal purpose is to acquire ownership of a product.<sup>55</sup>

Moreover, the *Carmichael* court emphasized that the provision of a defective medical service did not comply with the requirements of strict liability as enunciated in section 402A of the Second Restatement.<sup>56</sup> The court noted that the Restatement formulation only applies to a seller of an injury-causing product who is regularly engaged in the business of selling that item.<sup>57</sup> The court concluded that a physician treating or diagnosing a patient is selling his or her services as a healer of illness, and uses a product such as a drug only as an aid in achieving a cure.<sup>58</sup> Thus, liability was contingent upon proof of professional negligence.

Likewise, the Wisconsin Supreme Court ruled, in *Hoven v. Kelble*,<sup>59</sup> that the doctrine of strict liability does not apply to the rendition of professional health care services. There, a husband and wife sought damages for injuries incurred while the husband underwent a lung biopsy. One of the theories upon which the plaintiffs sought to hold the hospital, surgeon, and anesthesiologist liable was strict liability for the provision of defective medical services. The court rejected plaintiffs' contention that recovery should be allowed if a hypothetical and perfectly informed physician working in a perfect environment could have avoided the injurious result.<sup>60</sup>

The court observed that adoption of strict liability with respect to professional medical services would establish a standard of performance at the zenith of the profession's achievement, a level virtually impossible to sustain.<sup>61</sup> Moreover, a variety of policy concerns created substantial differences between the sale of a good and the rendition of health care services. These circumstances include the concern that medical services

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55. *Id.* at 978, 95 Cal. Rptr. at 392.

56.

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold. (2) The rule stated in Subsection (1) applies although (a) the seller has exercised all possible care in the preparation and sale of his product, and (b) the user or consumer has not bought the product from or entered into any contractual relationship with the seller.

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

57. 17 Cal. App. 3d at 979, 95 Cal. Rptr. at 393.

58. *Id.*

59. 79 Wis. 2d 444, 256 N.W.2d 379 (1977).

60. *Id.* at 460, 472, 256 N.W.2d at 387, 393.

61. *Id.* at 460, 256 N.W.2d at 387.

are often experimental and uncertain, the fact that medical services are absolutely indispensable to society, the potential that medical costs would dramatically increase with the imposition of strict liability, and the fear that strict liability would hamper the development of new medicines and medical techniques.<sup>62</sup>

The foregoing decisions indicate that a physician should not be held strictly liable either for the proper use of a defective program or the improper use of a program. When a patient visits a physician the basis of the relationship is the skill of the doctor in treating afflictions; the crux of the transaction is the performance of a service. A physician who uses a medical device is not a merchant engaged primarily in the sale of that item. This undermines the requirement that the seller be engaged in the business of marketing these products for strict liability to apply.

Even though a physician who uses a medical expert system should not be held strictly liable at any stage, a health care practitioner is still subject to liability for negligence. Furthermore, the rejection of strict liability with respect to a physician who uses a medical expert system does not necessarily mean that strict liability is wholly inappropriate in the professional use of such a program. If a claimant asserts that a program is defective, the manufacturer and others in the chain of distribution can still be held strictly liable for the sale of an unreasonably dangerous product.

### III. STRICT PRODUCTS LIABILITY FOR MEDICAL EXPERT SYSTEMS

Based on the analysis of whether medical expert systems are products or services, this Comment has argued that the manufacturer of either an in-home or a professional medical expert system should be subject to strict product liability for personal injuries caused by a defective program. However, it is inappropriate to hold a professional health care provider strictly liable for the use of a defective medical expert system. The proper vehicle for assigning physician liability for the improper or negligent use of a medical implement is ordinary professional negligence doctrine.<sup>63</sup>

In a strict liability action, the injured plaintiff does not directly attack a manufacturer's conduct, but instead impugns the quality of the product itself.<sup>64</sup> According to the Restatement, a manufacturer or seller is strictly liable for any injuries caused by a product that is flawed in a

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62. *Id.* at 469-70, 256 N.W.2d at 391.

63. *See infra*, notes 132-41 and accompanying text.

64. W. PROSSER & P. KEETON, *supra* note 19, § 99 at 695.

manner that makes it unreasonably dangerous.<sup>65</sup> Thus, the crux of a strict product liability claim is whether a particular characteristic or feature of a product creates undue consumer peril. In the next section, this Comment will examine the proper application of these standards.

While the Restatement formulation remains the authoritative definition of strict liability, jurisdictions disagree about the burden of proof that it imposes upon a plaintiff. For example, in *Dippel v. Sciano*<sup>66</sup> the Wisconsin Supreme Court required the plaintiff to prove the existence of both a product defect and unreasonable danger: "[f]rom a reading of the plain language of the rule, the plaintiff must prove 1) that the product was in defective condition when it left the possession or control of the seller,[and] 2) that it was unreasonably dangerous to the user or consumer . . . ."<sup>67</sup> Not surprisingly, those jurisdictions that require proof of both a defect and unreasonable danger have done so to limit the liability of manufacturers and others in the chain of distribution.<sup>68</sup>

By contrast, in *Cronin v. J.B.E. Olsen Corp.*,<sup>69</sup> the California Supreme Court rejected a literal reading of the Restatement because it would "require the finder of fact to conclude that the product is, first, defective, and, second, unreasonably dangerous."<sup>70</sup> The court believed that such a reading was contrary to the aim of compensating injured consumers because it placed a heavy burden upon plaintiffs and was therefore inimical to the spirit of strict liability doctrine.<sup>71</sup> As a result, the court required proof of a product defect only.

Product defects fall into three major categories: (1) a flaw in the product that was present at the time of sale (i.e., manufacturing defect); (2) an error in product conceptualization or design; and (3) a failure by the producer or assembler of a product to adequately warn of a hazard related to a product's design.<sup>72</sup>

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65. RESTATEMENT (SECOND) OF TORTS § 402A comment i (1965).

66. 37 Wis.2d 443, 155 N.W.2d 55 (1967).

67. *Id.* at 460, 155 N.W.2d at 63.

68. *See, Dippel*, 37 Wis. 2d at 460, 155 N.W.2d at 63-64; *Byrns v. Riddell, Inc.*, 113 Ariz. 264, 267, 550 P.2d 1065, 1068 (1976).

69. 8 Cal.3d 121, 501 P.2d 1153, 104 Cal. Rptr. 433 (1972).

70. *Id.* at 133, 501 P.2d at 1162, 104 Cal. Rptr. at 442.

71. *Id.* *See also* CAL. JURY INSTRUCTIONS: CIVIL § 9.00, at 288-89 (1977 Revision). Numerous other jurisdictions that have faced the question of both defective condition and unreasonable danger have followed the California lead and have opted for a single element approach. *See Butaud v. Suburban Marine & Sporting Goods, Inc.*, 543 P.2d 209 (Alaska 1975); *Seattle-First Nat'l Bank v. Tabert*, 86 Wash. 2d 145, 542 P.2d 774 (1975); *Suter v. San Angelo Foundry & Mach. Co.*, 81 N.J. 150, 406 A.2d 140 (1979); *Morningstar v. Black & Decker Mfg. Co.*, 162 W. Va. 857, 253 S.E.2d 666 (1979); N.Y. PATTERN JURY INSTRUCTIONS SUPP. 2:141, at 109 (1979).

72. W. PROSSER & P. KEETON, *supra* note 19, § 99 at 695.

### A. Stages of Development: Manufacturing versus Design Defects

Classification of a product flaw as either a manufacturing or a design defect may have a significant impact upon the quantum of proof demanded of a plaintiff. If a defect is introduced during the purely mechanical task of reproducing the finished product for commercial distribution, the defect is one of manufacture and an injured user need only prove that the defect exists.<sup>73</sup> On the other hand, if a manufacturer committed an error in conceptualizing or designing the article, a plaintiff will have to prove both the existence of the alleged defect *and* that the manufacturer had a viable alternative to the chosen design.<sup>74</sup> This additional burden is often factually complicated and can determine a plaintiff's chances for success.

Thus, the initial problem is distinguishing design defects from manufacturing defects. The creation of a computer program design or concept is theoretically distinguishable from the coding of the program in an appropriate programming language and the implementation of the program in an appropriate medium. As a practical matter, however, the processes involved in most software development are not so neatly distinguishable.

Software development involves a lengthy period of "debugging," which is the location and elimination of operational flaws. The removal of all syntax errors from a computer program is a difficult, if not impossible, endeavor. Original program mistakes may become apparent only under a unique set of circumstances. Adjustments may introduce new flaws or reveal previously existing errors, especially if these modifications are not performed by the developer.<sup>75</sup> In other words, the debugging process may alter the ultimate program design, and is therefore not solely a manufacturing process.

This blending of activities "create[s] a continuum that begins with the abstract conceptualization of a program and moves to the mechanical task of reproducing the program for distribution."<sup>76</sup> The mechanical stage of coding and reproducing a medical expert program is clearly manufacturing and therefore warrants application of a stricter standard of liability; the abstract conceptualization phase is design work and

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73. See *infra* notes 103-14 and accompanying text.

74. See *infra* notes 86-102 and accompanying text; see also *Volkswagen of Am., Inc. v. Young*, 2722 Md. 201, 321 A.2d 737 (1974).

75. See generally R. NIMMER, *THE LAW OF COMPUTER TECHNOLOGY* § 7.05[2] at 7-20 (1985).

76. *Id.* § 7.06(2)(b) at 7-28 (1985).

requires a weighing of alternative designs. The status of the intermediate stages, particularly the debugging process, is much less certain.

For policy reasons, debugging should be considered a part of the design phase of software development. Debugging is closely analogous to the safety and efficiency testing performed by automobile manufacturers before their products reach the market. As in the case of automobile testing, the ultimate design of a computer program is not determined until the software has been tested under a variety of conditions and environments. Consequently, the design of a computer program is subject to alteration through the debugging process up until the time of actual sale to a consumer. Thus, liability for manufacturing defects should be limited to the final, packaged product sold to users.<sup>77</sup>

## B. Product Liability for Design Defects

Liability for design defects mandates some inquiry into the choices made by the manufacturer developing the product. Consequently, in the instance of a defective design, the determination often becomes extremely complex. The courts have generally taken two approaches in defining design flaws: a consumer-expectation test and a risk-utility model.<sup>78</sup> Most jurisdictions that retain the consumer-expectation test use it in conjunction with the risk-utility model.<sup>79</sup>

### 1. The Consumer Expectation Test

Under the consumer-expectation test, a product is flawed in design if it fails to live up to reasonable consumer expectations with respect to safety, based on the knowledge common to the community as to the product's features.<sup>80</sup> For a host of reasons this test alone is inadequate for evaluating the dangerousness of a particular design.<sup>81</sup> An injured

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77. Brannigan & Dayhoff, *supra* note 20 at 137 (1981); R. NIMMER, *supra* note 75, at § 7.06(2)(b).

78. W. PROSSER & P. KEETON, *supra* note 19, § 99 at 698-99.

79. *See, e.g.,* Barker v. Lull Eng'g Co., 20 Cal. 3d 413, 432, 573 P.2d 443, 455-56, 143 Cal. Rptr. 225, 237-38 (1978); Suter v. San Angelo Foundry & Mach. Co., 81 N.J. 150, 170-72, 406 A.2d 140, 150-51 (1979); Cremeans v. International Harvester Co., 6 Ohio St. 3d 232, 234, 452 N.E.2d 1281, 1284 (1983).

80. RESTATEMENT (SECOND) OF TORTS § 402A comment i; *see, e.g.,* Greenman v. Yuba Power Prods., 59 Cal. 2d 57, 64, 377 P.2d 897, 901, 27 Cal. Rptr. 697, 701 (1963) (Traynor, J.).

81. The consumer expectation test has been roundly criticized as too uncertain to regulate manufacturer conduct because, among other things, a manufacturer can manipulate consumer attitudes about safety through a media campaign that describes, limits, or modifies a product's purposes or capabilities. The California Supreme Court expressed this concern in *Barker v. Lull Eng. Co.*, 20 Cal. 3d 413, 430, 573 P.2d 443, 454, 143 Cal. Rptr. 225, 236 (1978); *see also* Keeton, *Product Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 37-38 (1973).

user can never recover for harm inflicted by an open or obvious hazard or risk of which the user was, or should have been, fully aware.

In addition, and more importantly for technological advances such as medical expert systems, the consumer expectation test can compel classification of a product as unreasonably dangerous even though it may not be so in actual fact.<sup>82</sup> For example, the development of a new drug that would be a "great boon to humanity" may be crushed under a landslide of liability due to a side effect or adverse reaction which amounts to an unforeseeable risk.<sup>83</sup> It is probable that the consumer-expectation test will produce just such an effect upon medical expert systems since the technology is new and has not been tested by the marketplace. Consumer hopes in regard to a new computer technology cannot be grounded upon concrete experience and therefore should not be incorporated into the legal standard for strict liability.

Another shortcoming of the consumer-expectation test is the difficulty of developing a more specific definition of reasonable consumer expectations.<sup>84</sup> "In a sense the ordinary purchaser cannot reasonably expect anything more than that reasonable care in the exercise of the skill and knowledge available to design engineers has been exercised."<sup>85</sup> In other words, consumer expectations are not sufficiently refined to identify specific product strengths and weaknesses. This problem is exacerbated in the technologically innovative computer industry because the average consumer has little familiarity with computer programming and therefore cannot identify precisely which step caused an injury. Thus, in demonstrating that a particular product feature or characteristic produced an injury, the consumer-expectation test may often be of little practical import.

## 2. *The Risk-Utility Model*

The pitfalls of indiscriminate use of the consumer expectation test prompted numerous courts to supplement that test with the risk-utility model.<sup>86</sup> According to the risk-utility model, a product is defective as

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82. See *General Motors Corp. v. Simmons*, 545 S.W.2d 502 (Tex. Civ. App.), *rev'd on other grounds*, 558 S.W.2d 855 (Tex. 1977).

83. W. PROSSER & P. KEETON, *supra* note 19, § 99.

84. See Hubbard, *Reasonable Human Expectations: A Normative Model for Imposing Strict Liability for Defective Products*, 29 MERCER L. REV. 465, 478 (1978); Montgomery & Owen, *Reflections on the Theory and Administration of Strict Tort Liability for Defective Products*, 27 S.C. L. REV. 803, 823 (1976).

85. W. PROSSER & P. KEETON, *supra* note 19, § 99 at 699.

86. See, e.g., *Barker Eng'g Co. v. Lull*, 20 Cal. 3d 413, 432, 573 P.2d 443, 456, 143 Cal. Rptr. 225, 238 (1978). In the wake of this California Supreme Court decision, the jury instruction committee in California composed a definition of defective design that encompasses both a consumer expectation and risk-utility analysis. The definition provides that a product is defective in design "unless the benefits of the design of the pro-

designed if the magnitude of this risk of danger outweighs the utility of the product.<sup>87</sup> Therefore, in its widely accepted form, the risk-utility model asks whether "on balance, the benefits of the challenged design outweigh the risk of danger inherent in such design."<sup>88</sup> Despite the apparent simplicity of the model, the process of balancing a product's risks against its utility can become very complicated.<sup>89</sup>

Application of this standard requires a consideration of the current state of the pertinent technology, the comparative costs and feasibility of alternative designs,<sup>90</sup> and the extent to which the questioned design choice pertains to the characteristics that made the product a commercial success.<sup>91</sup> Some additional common elements in the risk-utility balancing include the usefulness of the product, the availability of substitutes, and the consumer's ability to guard against a product's hazards.<sup>92</sup>

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duct as a whole outweigh the risk of danger inherent in the design" or "if the product failed to perform as safely as an ordinary consumer of the product would expect when used in a manner reasonably foreseeable by the defendant(s)." In determining whether the benefits outweigh the risks under the definition, one may consider, among other things, "the gravity of the danger posed by the design and the likelihood that such danger would cause damage, the mechanical feasibility of a safer alternate design at the time of manufacture, the financial cost of an improved design, and the adverse consequences to the product and the consumer that would result from an alternate design." CAL. JURY INSTRUCTIONS: CIVIL § 9.00.5 (West Supp. 1981).

87. *Raney v. Honeywell, Inc.*, 540 F.2d 932, 935 (8th Cir. 1976); *Turner v. General Motors Corp.*, 584 S.W.2d 844, 847 (Tex. 1979).

88. *Barker*, at 432, 573 P.2d at 456, 143 Cal. Rptr. at 238.

89. The risk-utility calculation encompasses a number of additional elements that are summarized in the Model Uniform Product Liability Act. "In order to determine that the product was unreasonably unsafe in design, the trier of fact must find that . . . the likelihood that the product would cause the claimant's harm . . . and the seriousness of those harms outweighed the burden on the manufacturer to design a product that would have prevented those harms [as well as] the adverse effect that alternative design would have on the usefulness of the product." UNIF. PRODUCT LIABILITY ACT § 104(b)(1), 44 Fed. Reg. 62,714, 62,721 (1979). See also *Caterpillar Tractor Co. v. Beck*, 624 P.2d 790, 791 (Alaska 1981).

90. The New Jersey Supreme Court, in the case of *O'Brien v. Muskin Corp.*, 94 N.J. 169, 184-85, 463, A.2d 298, 306 (1983), has apparently abandoned the requirement that the availability of alternative designs must be considered when weighing the risks and utility of a given product. The claim in *O'Brien* was that a swimming pool lining was too slippery for safe use. This extension of the goal of compensating injured victims has been persuasively criticized. See Note, *Strict Products Liability and the Risk-Utility Test for Design Defect: An Economic Analysis*, 84 COLUM. L. REV. 2045 (1984). Indeed most jurisdictions still require a plaintiff to prove the viability of alternative designs. See *Wilson v. Piper Aircraft Corp.*, 282 Or. 61, 66-71, 577 P.2d 1322, 1326-27 (1978); *Kerns v. Engelke*, 76 Ill. 2d 154, 161-64, 390 N.E.2d 859, 863-64 (1979).

91. See *Dreisonstok v. Volkswagenwerk, A.G.*, 489 F.2d 1066 (4th Cir. 1974).

92. A number of factors employed in risk-utility analysis were identified by Dean Wade. Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 837-38 (1973).

The case of *Wilson v. Piper Aircraft Corp.*<sup>93</sup> illuminates two principal considerations which influence the risk-utility calculation. In *Piper*, a light-aircraft manufacturer's decision to use a carburetor instead of a fuel injector was challenged by the plaintiffs, who contended that a fuel injector would decrease the possibility of fuel system freezing.<sup>94</sup> The court held the evidence insufficient to establish a design defect<sup>95</sup> and observed that use of a fuel injector could significantly compromise the safety of the airplane by reducing the aircraft's responsiveness and performance. Thus, while a fuel injector system might decrease risk in one area it would also reduce overall utility and contribute to an increase in the airplane's price.<sup>96</sup> *Piper* thus reveals two vital considerations: whether a manufacturer can technologically improve its product's safety design without increasing the item's cost to the point that a consumer would no longer purchase it;<sup>97</sup> and whether the suggested alternative, while solving a particular problem, would create new or additional risks that outweigh the benefits of a different design.<sup>98</sup>

At least in theory, a carefully constructed medical expert system would embody the most widely accepted and effective methods of diagnosing an illness. If a system designer failed to include some well-established medical principles in the knowledge base, or inputted erroneous information, proof of a design defect would be relatively simple; a properly designed program would avoid the risk of injury at little or no additional cost. Because a safe and useful program would not attempt to treat illnesses as a physician does, potential differences in courses of treatment would be of little significance. Thus, a viable medical expert system could be technologically impervious to alteration until advances are made in the healing arts, at which point the knowledge base could be updated.

Furthermore, even if some disagreement did exist in the medical community over what signals indicate a particular ailment, choosing one set of rules over another would likely produce a mere trade-off in

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93. 282 Or. 61, 577 P.2d 1322, *reh'g denied*, 282 Or. 411, 579 P.2d 1287 (1978). For the history of products liability in Oregon see generally, Vetri, *Legislative Codification of Strict Products Liability Law in Oregon*, 59 OR. L. REV. 363 (1981).

94. *Piper*, 282 Or. at 69-71, 577 P.2d at 1327.

95. The court held that a party challenging a product design must present "evidence from which the jury could find the suggested alternatives [were] not only technically feasible but also practicable in terms of cost and the over-all design and operation of the product." *Id.* at 69, 577 P.2d at 1327.

96. *See id.* at 70, 577 P.2d at 1327.

97. This aspect of the risk-utility model has been described as "the manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility." Wade, *supra* note 92, at 837.

98. *Piper*, 282 Or. 61, 69, 577 P.2d 1322, 1327.

cumulative risks and benefits. In other words, although alternative principles might be inserted in the knowledge base to solve one problem, such a modified knowledge base could create different, perhaps even more costly risks in other areas. Hence, where a medical expert system is carefully constructed, it is unlikely that mere differences of opinion in the medical community would lead to a conclusion that a design defect exists under the risk-utility model.<sup>99</sup>

The availability of more advanced or sophisticated technology may also be relevant to risk-utility analysis. For example, *Swiss Air Transport Co. v. Benn*,<sup>100</sup> though not a strict liability case, assigned liability based on the availability of more advanced computer programming techniques. In that case the defendant had purchased illegitimately altered airline tickets. The airline sued to recover the price of the tickets and explained its own failure to detect the alterations prior to the use of the tickets by claiming it was unable to connect the computer database for reservations with the database for sales. The court shielded the innocent buyer from liability based on principles of estoppel, stating:

[p]laintiff could have prevented the passengers from using altered tickets by maintaining a system capable of confirming which passengers are scheduled for a particular flight. In light of the advanced computer technology available today, this is not an unreasonable burden to place on the plaintiff.

. . . I do not recognize Swiss Air's reliance on its computer system as a legally cognizable defense. Had [it] been properly equipped with a more sophisticated computer system, it could have promptly discovered [the alteration].<sup>101</sup>

Even though the *Swiss Air Transport* holding was not founded upon products liability theory, it does suggest that the choice of a particular computer program design, and the data or capabilities that it does and does not utilize, are subject to judicial review. By analogy, a conclusion that the knowledge base or processes of a medical expert system generate liability might rest upon an assessment of the availability of alternative systems.<sup>102</sup>

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99. This final drawback could be entirely circumvented by a developer if he opted for the safest possible route and instructed the expert system to exhort a user to visit a physician whenever there was the slightest doubt as to the severity or nature of the user's complaint. Such a system might be less useful to consumers, though, because it would not always be able to differentiate between situations that require professional assistance and those that do not.

100. 467 N.Y.S.2d 341 (N.Y. Civ. Ct. 1983).

101. *Id.* at 344.

102. See *Exceptional Children's Home & Nursery, Inc. v. Fortuna*, 414 So.2d 1130 (Fla. Dist. Ct. App. 1982).

However, in the medical expert system market, weighing the attractiveness of alternative designs could insulate manufacturers from product liability. The revolutionary nature of in-home medical expert systems makes the existence in the marketplace of similar alternative designs highly unlikely. Proof of alternative design options would have to concentrate upon the body of medical knowledge that comprises the system's operational rules. And, as stated above, substituting one set of health care principles for another will probably only serve to replace one group of risks with another. Thus, strict liability would probably not be imposed solely on the basis of more attractive available designs.

### C. Product Liability for Manufacturing Flaws

In addition to liability for a defective design, a manufacturer can incur liability for products that are dangerous because they have not been produced as designed.<sup>103</sup> When such manufacturing defects cause products to deviate from the producer's own safety specifications they render the product unreasonably dangerous as a matter of law, because the product as marketed is more dangerous than originally planned.<sup>104</sup>

The celebrated case of *Henningsen v. Bloomfield Motors*<sup>105</sup> demonstrates the relatively light burden of proof that a plaintiff must bear under this branch of product liability law. In that case the only evidence submitted to show that the plaintiff's automobile was unreasonably dangerous was testimony that "she heard a loud noise" from underneath the hood, felt "something crack," and lost control of the vehicle when the steering wheel "spun in her hands."<sup>106</sup> The court did not require any showing of negligence,<sup>107</sup> and permitted recovery against the manufacturer because the account supported an inference that a defect attributable to a malfunction in the production process had caused the mishap.<sup>108</sup>

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103. W. PROSSER & P. KEETON, *supra* note 19, § 99 at 695. See also *MacPherson v. Buick Motors*, 217 N.Y. 382, 111 N.E. 1050 (1916); *Chandler v. Anchor Serum Co.*, 198 Kan. 571, 426 P.2d 82 (1967).

104. W. KIMBLE & R. LESHNER, *PRODUCTS LIABILITY* §155, at 178-80 (1979); Keeton, *supra* note 81, at 38-37; see also UNIF. PRODUCT LIABILITY ACT § 104(a), Fed. Reg. 62,714, 62,721 (Oct. 31, 1979) (the determination of whether a product was unsuitably altered during fabrication hinges upon a comparison between the actual condition of a particular item and the design specifications of the manufacturer).

105. 32 N.J. 358, 161 A.2d 69 (1960).

106. *Id.* at 369, 161 A.2d at 75.

107. *Id.* at 417, 161 A.2d at 102.

108. *Id.* at 409, 161 A.2d at 97. This strict standard was intended to counterbalance the difficulty of uncovering circumstances indicating negligence in manufacturing. W. PROSSER & P. KEETON, *supra* note 19, § 99 at 695.

In general, a *prima facie* case for strict liability for manufacturing defects can be based on any one of three types of evidence: (1) expert testimony pinpointing the flaw which caused the injury;<sup>109</sup> (2) proof of the destruction or disappearance of the offending product;<sup>110</sup> or (3) proof of circumstances of the accident that point to a manufacturing defect.<sup>111</sup>

A strict judicial reading of the manufacturing flaw test will effectively curtail production of defective medical expert systems while keeping liability within reasonable bounds. Classifying the debugging and related intermediate stages of development as an element of product design will limit strict manufacturing liability to inconsistencies in the final, packaged program. These defects can be regulated by the adoption of stringent quality and production controls. The desire to limit product liability should prompt software manufacturers to implement safe, efficient production strategies.

In those instances where improper production techniques create a dangerous expert system, the flexibility of the manufacturing flaw quantum of proof will lead to compensation of the injured user. The goals of accident prevention and loss spreading will be furthered without ending the development of properly conceived medical expert systems.<sup>112</sup>

#### D. Product Liability for a Failure to Warn

A manufacturer or seller has a duty to warn and is subject to liability for a failure to provide adequate admonitions about a risk inherent in a product's intended or reasonably foreseeable functions.<sup>113</sup> A warning that lacks the information necessary to make a product safe, or to fully inform a consumer of the risks attendant upon a product's use, can thus result in liability.<sup>114</sup> However, according to the generally accepted view, liability for a failure to warn is similar to negligence in that a plaintiff must prove that the manufacturer knew or should have known of the risks generated by the product.<sup>115</sup>

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109. *Holloway v. General Motors Corp.*, 403 Mich. 614, 271 N.W.2d 777 (1978) (expert testimony explaining a break in a ball joint assembly).

110. *Henningsen*, 32 N.J. at 410-12, 161 A.2d at 98-99 (accident destroyed both the vehicle and allegedly flawed steering mechanism).

111. *Lindsay v. McDonnell Douglas Aircraft Co.*, 460 F.2d 631 (8th Cir. 1972), *on remand* 352 F. Supp. 633, *aff'd on rehearing* 485 F.2d 1288 (new Navy jet caught fire for no apparent reason and crashed into the sea).

112. See *infra* notes 144-50 & 161-66 and accompanying text.

113. *Wright v. Carter Prods., Inc.*, 244 F.2d 53, 57 (2d Cir. 1957); *Moran v. Fa-berge, Inc.*, 273 Md. 538, 543, 332 A.2d 11, 15 (1975).

114. *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1088-89 (5th Cir. 1973), *cert. denied*, 419 U.S. 869 (1974); *Midgley v. S.S. Kresge Co.*, 55 Cal. App. 3d 67, 127 Cal. Rptr. 217 (1976).

115. W. PROSSER & P. KEETON, *supra* note 19, § 99; see, e.g., *Borel*, 493 F.2d 1076;

The extent of the duty to warn will depend upon the obviousness of the danger and the character of the intended or foreseeable use of the product.<sup>116</sup> Where a hazard is blatantly obvious there is simply no duty to warn.<sup>117</sup> If the danger is not obvious or discoverable by an unenlightened consumer, liability may be obviated by an adequate warning, provided that in the ordinary course of events it will reach and be understood by the consumer.<sup>118</sup> However, a warning need not be directed towards an individual who possesses enough knowledge to apprehend a product's perils without warning.<sup>119</sup>

For a warning to be adequate, it must notify a user, exercising reasonable care for his or her own safety, of the possible consequences of use or misuse of the product.<sup>120</sup> The gravity of potential dangers in light of the foreseeable uses of a product may also affect the definition of adequacy.<sup>121</sup> Additionally, a warning must be specific and comprehensive: directions which merely tell how to use the product, but say nothing about the inherent and specific dangers if the directions are not followed are not sufficient.<sup>122</sup> Adequate instructions must therefore educate a consumer about both the efficient and safe use of a product and any dangers likely to emanate from any foreseeable use of the item.<sup>123</sup>

Marketing a well-thought-out medical system for the general public should not create any substantial liability for failure to warn. As previously discussed, a safe medical expert system will continually urge a user to seek expert medical help in any ambiguous situation.<sup>124</sup> However, an in-home expert system that does not warn a user of the dangers in relying exclusively on computer information will generate tremendous liability. It is clear that a user of such an expert system purchases the software as a means to supplement, or even replace, traditional health-care services. Hence, it is readily foreseeable that a user will be injured if he relies on erroneous or incomplete computer information and is not cautioned to see a physician if a condition persists or worsens.

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*Moran*, 273 Md. 538, 332 A.2d 11.

116. W. PROSSER & P. KEETON, *supra* note 19, § 96; *see, e.g.*, *Murphy v. Cory Pump & Supply Co.*, 47 Ill. App. 2d 38, 197 N.E.2d 849 (1964).

117. *McCabe Powers Body Co. v. Sharp*, 594 S.W.2d 592, 595 (Ky. 1980).

118. *Ulrich v. Kasco Abrasives Co.*, 532 S.W.2d 197 (Ky. 1976).

119. *See Ford Motor Co. v. McCamish*, 559 S.W.2d 507, 512 (Ky. App. 1977) (manufacturer did not need to disclose torque pressures to automobile mechanics since pressures not unusual).

120. *Post v. American Cleaning Equip. Corp.*, 437 S.W.2d 516, 520 (Ky. App. 1968).

121. *Id.*

122. *Hiiigel v. General Motors Corp.*, 190 Colo. 57, 63, 544 P.2d 983, 988 (1975).

123. *Bituminous Casualty Corp. v. Black & Decker Mfg. Co.*, 518 S.W.2d 868, 873 (Tex. Civ. App. 1974).

124. *See supra* note 99 and accompanying text.

Similarly, professional systems could lead to liability if marketed without adequate warnings. Professional medical expert systems are normally designed to complement a physician's own personal skill and analytical prowess;<sup>125</sup> therefore, a nonphysician who obtains a professional system, and who relies on information provided by the software, could be severely harmed. Since it is foreseeable that a nonphysician may secure this type of program, adequate warnings would at the very least instruct lay persons about the perils attendant upon nonphysician use.<sup>126</sup>

### E. User Risk: Comparative Negligence and Strict Products Liability

There is no consensus among the various American jurisdictions as to whether a plaintiff's own negligent conduct will reduce a manufacturer's strict products liability.<sup>127</sup> A few courts have held comparative negligence concepts inapplicable to strict products liability actions because reducing a manufacturer's liability to account for consumer negligence would undermine the goal of encouraging manufacturers to anticipate consumer misconduct.<sup>128</sup> Most courts apply unrestricted comparative negligence apportionment principles to strict products liability actions.<sup>129</sup> Those courts which have accepted comparative negligence concepts in strict liability analysis have done so because "fairness and equity are more important than conceptual and semantic consistency."<sup>130</sup>

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125. See *supra* notes 12-17 and accompanying text.

126. If the expert system is one designed for use by a specialist, as is arguably the case with MYCIN, adequate warnings would probably also have to inform a non-specialist physician of the risks connected with unassisted solo operation.

127. See Twerski, *The Use and Abuse of Comparative Negligence in Products Liability*, 10 IND. L. REV. 797, 797-98 (1977).

128. A Fifth Circuit panel first found comparative negligence inapplicable to a strict products liability action in admiralty. However, the entire circuit disagreed and recognized a comparative fault defense. Even so, the panel ultimately held as a matter of fact and law that the plaintiff was guilty of no proximate act of negligence and did not reduce the plaintiff's award. *Lewis v. Timco*, 697 F.2d 1252, 1255-56 (5th Cir.), *rev'd en banc*, 716 F.2d 1425, 1433 (1983), *modified*, 736 F.2d 163, 167 (1984); *cf.* *Kinard v. Coats Co.*, 37 Colo. App. 555, 557, 553 P.2d 835, 837 (1976).

129. See, e.g., *Caterpillar Tractor Co. v. Beck*, 593 P.2d 871 (Alaska 1979); *Daly v. General Motors Corp.*, 20 Cal. 3d 725, 144 Cal. Rptr. 380, 575 P.2d 1162 (1978). The defense of assumption of risk is still a complete bar to recovery in a few jurisdictions. In these states, a manufacturer may still completely avoid liability if a user knowingly and voluntarily abuses the system in a way that supplants the manufacturer's fault. However, most jurisdictions have modified the defense of assumption of risk and contributory negligence to one of comparative fault so that plaintiff misconduct is no longer a complete bar. W. PROSSER & P. KEETON, *supra* note 19, §§ 65, 67.

130. *Keneko v. Hilo Coast Processing*, 654 P.2d 343, 352 (Haw. 1982); see also *Suter v. San Angelo Foundry & Mach. Co.*, 81 N.J. 150, 406 A.2d 140 (1979).

In the context of medical expert systems, comparative negligence precepts will have little validity in regard to a physician's use of a medical expert system. Because an injured victim of this type of program would not have operated the system, the plaintiff's conduct would not be at issue.<sup>131</sup> As a consequence, comparative negligence will have its greatest impact upon claims generated by the use of an in-home medical expert system.

However, a manufacturer might encounter difficulties in asserting a comparative negligence defense against an in-home expert system user. Viable proof of user misconduct may often be unobtainable. Where a user simply inputs the wrong information into a computer, it may be impossible to reproduce in court exactly what responses were fed into the expert system. Similarly, a user may incorrectly answer an expert system query because of the user's failure to recognize a particular symptom. Again, actual proof of such a mistake may be impossible to discover.

Even so, comparative fault principles will be relevant in a number of situations involving in-home medical expert systems. One of the more serious forms of misuse of a medical expert system would be unwavering user reliance upon a computer opinion in the face of a clearly worsening physical condition. A manufacturer can combat this hazard by equipping each expert program with a plethora of clear and comprehensible warnings that inform each user of the severe risks associated with naive, unquestioning belief in computer information. A failure to heed such warnings may aggravate or precipitate an injury and can properly be accounted for by reducing the total amount of a plaintiff's damages.<sup>132</sup>

#### IV. EXPERT SYSTEMS AS A SERVICE: PROFESSIONAL LIABILITY FOR MEDICAL MALPRACTICE

In addition to strict liability, a theory of professional liability may apply to program developers and physicians who use medical expert

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131. Questions of the physician's proper or improper use of the software will not intrude upon the relationship between the injured patient and the manufacturer. Although this issue may have some bearing upon the physician's relationship to the program manufacturer, claims of physician negligence would normally be resolved in a separate indemnity or contribution action. *Tromza v. Tecumseh Prods. Co.*, 378 F.2d 601 (3d Cir. 1967); *Frank R. Jelleff, Inc. v. Pollak Bros.*, 171 F. Supp. 467 (N.D. Ind. 1959). However, because this Comment focuses on the claims of a user or patient, these related problems are beyond the scope of this discussion.

132. See RESTATEMENT (SECOND) OF TORTS §402A comment k (1965) (discusses unavoidably unsafe products). Cf. *Kaempfe v. Lehn & Fink Prods. Corp.*, 21 A.D.2d 197, 202-03, 249 N.Y.S.2d 840, 847 (1964) (court found that it was not necessary to give a warning to hypersensitive users of deodorant); *Merrill v. Beaute Vues Corp.*, 235 F.2d 893, 897 (10th Cir. 1956).

systems. According to this standard, practitioners of the healing arts are required not only to exercise ordinary reasonable care in what they do but are also required to possess a minimum level of medical skill and knowledge.<sup>133</sup> In the absence of an express contract to cure a patient, however, a doctor neither warrants nor guarantees a correct diagnosis or a successful treatment.<sup>134</sup> By undertaking to render medical services, a physician merely holds himself out as having a minimum level of professional ability and knowledge. This threshold level is usually defined as the skill and care ordinarily exercised by members of the medical profession in good standing; thus, a physician who does not possess or use these basic qualifications will be liable for injuries to patients caused by the lack thereof.<sup>135</sup>

The greatest difficulty in applying professional negligence principles to medical expert systems arises in connection with the patient-physician relationship—the cornerstone of a malpractice claim. In order to pursue a medical malpractice claim against a physician, a plaintiff must normally be in a consensual relationship with the physician.<sup>136</sup> This relationship demands actual or implied consent to diagnose or be diagnosed, to treat or be treated.<sup>137</sup> If such a direct relationship between a health care provider and a patient is lacking, a plaintiff will not normally be allowed recovery for professional negligence.

In *Smith v. Linn*,<sup>138</sup> for example, a Pennsylvania court examined the importance of the patient-physician relationship in circumstances strikingly similar to the commercial distribution of a medical expert system. The defendant, Dr. Robert Linn, was the author of a very specialized protein diet book called *The Last Chance Diet*. Plaintiff alleged that his wife's death was caused by her adherence to the wantonly dangerous weight-loss program espoused in Dr. Linn's book. Consequently, the plaintiff initiated a lawsuit under a variety of theories, including a claim

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133. See, e.g., 1 LOUISELL & WILLIAMS, *supra* note 51, § 8.03; McCoid, *The Care Requirement of Medical Practitioners*, 12 VAND. L. REV. 549, 558-59 (1959).

134. See *Salis v. United States*, 522 F. Supp. 989 (M.D. Pa. 1981); *Greenberg v. Michael Reese Hosp.*, 83 Ill. 2d 282, 415 N.E.2d 390 (1980); *but cf. Hawkins v. McGee*, 84 N.H. 114, 146 A. 641 (1929) (recovery for breach of contract to cure but no malpractice liability).

135. See *Sullivan v. Henry*, 160 Ga. App. 791, 800, 287 S.E.2d 652, 659 (1982); *McPherson v. Ellis*, 305 N.C. 266, 270, 287 S.E.2d 892, 895 (1982). Generally, the minimum skill and knowledge possessed by the medical community as a whole is looked to when determining if a physician breached his professional duty to a patient. However, where the practitioner is a specialist, the standard is higher. See *Salis*, 522 F. Supp. at 994; *Coyne v. Cirilli*, 45 Or. App. 177, 182, 607 P.2d 1383, 1386 (1980).

136. See 1 LOUISELL & WILLIAMS, *supra* note 51, §8.02; see also *Brown v. Moore*, 247 F.2d 711.

137. See, e.g., *Brown v. Moore*, 247 F.2d 711.

138. 414 A.2d 1106 (Pa. Commw. Ct. 1980).

of professional negligence against Dr. Linn for advocating a perilous medical course of treatment.<sup>139</sup>

The court initially observed that medical malpractice actions arise "out of the relationship between the health care provider and the patient," and that "[s]uch a relationship customarily requires an immediate connection between the health care provider and the patient and involves an actual or implied consent to diagnose and to be diagnosed or to treat and to be treated."<sup>140</sup> The court concluded that this relationship did not exist in the sale of a diet book because there was no two-way, mutual communication between the physician author and the patient. "The relationship was therefore that of an anonymous reader to an author."<sup>141</sup>

Similarly, the relationship between the user of an in-home expert system and its designer does not meet the requirements of a professional patient-physician relationship.<sup>142</sup> The large-scale introduction of medical expert system software into the marketplace will not create direct patient-physician interaction. Consequently, as was the case in *Smith v. Linn*, the relationship between a medical expert system developer and a software buyer is that of an author to an anonymous reader.

## V. POLICY IMPLICATIONS OF STRICT PRODUCTS LIABILITY

The ultimate decision to subject a manufacturer or others in the chain of distribution to strict liability is a matter of public policy.<sup>143</sup> Indeed, few courts have based strict liability decisions wholly on a technical distinction between products and services<sup>144</sup> but have instead predicated liability upon the furtherance of recognized public policy goals. Among the most important of these goals are loss-spreading, compensation, judicial economy, equitable allocation of the burden of proof, the encouragement of valuable new technologies, and the prevention of accidents. This Section analyzes these policy concerns and

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139. *Id.* at 1109.

140. *Id.* at 1107-08 (quoting 1 LOUISELL & WILLIAMS, *supra* note 51, § 8.02).

141. *Smith v. Linn*, 414 A.2d at 1109.

142. In respect to a physician who uses an expert system, the quality of the interaction involved satisfies the relationship requirement of a professional liability theory of recovery. A patient does not see a physician with the belief that the visit is for the purpose of putting a medical expert system into operation. Thus, the physician's decision to use an expert system does not affect the consensual relationship that already exists.

143. *Greenberg v. Michael Reese Hosp.*, 83 Ill. 2d 282, 290-91, 415 N.E.2d 390, 394 (1980) (imposition of strict liability is a question of policy); *see also Johnson v. Sears, Roebuck & Co.*, 355 F. Supp. 1065, 1067 (E.D. Wis. 1973) (public policy argument that forcing charitable institutions to bear loss threatens their survival).

144. *See supra* notes 19-62 and accompanying text.

concludes that strict liability for defects should apply to manufacturers of expert medical systems but not to the physicians who design or use such programs.

### A. Loss-Spreading and Compensation

One of the well-recognized and long-accepted goals of strict products liability doctrine is "to minimize the costs of accidents and to consider who should bear those costs."<sup>145</sup> As a result, the twin concepts of spreading the costs resulting from a business activity over a large group and compensating injured victims have emerged as the basis of the doctrine.<sup>146</sup> In particular, courts have long believed that an entrepreneur who makes and sells an article can best prepare for and shoulder the costs of a damaging event.<sup>147</sup>

In the realm of medical expert systems, the manufacturer is usually in a better position to spread the costs of a risk over a large group than is a consumer or an individual program designer or developer. A software manufacturer can ordinarily obtain insurance to cover the costs of marketing a program and can pass the cost of user injury through to consumers by charging higher prices.<sup>148</sup> Thus, the policy aim of allocating costs to the party best able to bear and spread the risk supports subjecting manufacturers to strict liability for medical expert systems.

However, holding the physician developer strictly liable may not result in such a favorable allocation of loss. To begin with, a physician who develops an expert system cannot pass the costs of the risk on to consumers since it is the program manufacturer who establishes the price of the final product. Furthermore, a physician who develops an expert system will only be able to shoulder the costs of user injury through malpractice insurance. This solution is problematic for several

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145. *Suter v. San Angelo Foundry & Mach. Co.*, 81 N.J. 150, 173, 406 A.2d 140, 151 (1979).

146. *See, e.g., Escola v. Coca-Cola Bottling Co.*, 24 Cal. 2d 453, 462, 150 P.2d 436, 441 (1944) (Traynor, J., concurring); *Goldberg v. Kollsman Instrument Corp.*, 12 N.Y.2d 432, 240 N.Y.S.2d 592, 191 N.E.2d 81 (1963); *Helene Curtis Indus., Inc. v. Pruitt*, 385 F.2d 841 (5th Cir.), *cert. denied.*, 391 U.S. 913 (1967).

147. *See, e.g., Escola v. Coca-Cola Bottling Co.*, 24 Cal. 2d 453, 150 P.2d 436 (1944) (Traynor, J., concurring); *Magrine v. Krasnica*, 94 N.J. Super. 228, 227 A.2d 539 (1967), *aff'd sub nom. Magrine v. Spector*, 100 N.J. Super. 223, 241 A.2d 637 (1968), *aff'd*, 53 N.J. 259, 250 A.2d 129 (1969) (as compared to an innocent victim, a manufacturer is in a better position to bear the costs of injuries).

148. *See Freed, supra* note 34, at 477. Furthermore, the number of consumers should be large enough to increase only minimally the price of an individual unit. *Cf. La Rossa v. Scientific Design Co.*, 402 F.2d 937, 941-42 (3d Cir. 1968) (company not liable for product because no impact on public at large, and victim's employer was better insurer than manufacturer).

reasons. First, insurance carriers may be unwilling to extend malpractice insurance to cover the sale of computer software for home use because the pool of potential claimants would extend to all program purchasers and users.<sup>149</sup> Second, even if a physician is able to obtain malpractice insurance to cover expert systems, policy premiums may be prohibitively expensive.<sup>150</sup> Finally, the insurance carrier may well cancel the policy after a few successful claims.<sup>151</sup> Thus, the developer of an expert system is not the appropriate party to assume liability for consumer injuries because, relative to the manufacturer, the developer is not in a good position to bear the risk of user injury through insurance.

In the professional context, though, a physician who simply *employs* a medical expert system may be in a good position to shoulder at least some of the burden of consumer injuries. A physician who uses an expert system to facilitate treatment of patients will probably have malpractice insurance covering the group of potential victims. The mere use of a medical expert system will not increase the number of a physician's patients, nor the magnitude of their potential injuries. As a result, by spreading the cost through insurance, an attending physician using an expert system can easily bear the liability for the portion of patient injuries resulting from the physician's negligence. Thus, the goal of placing burdens on those best able to bear and spread the costs favors the imposition of professional malpractice liability on attending physicians.

## B. Judicial Economy and Burdens of Proof

In general, imposition of strict liability as opposed to negligence has a severe impact upon the amount and sufficiency of the proof demanded of an injured plaintiff.<sup>152</sup> The requirements of proof under a negligence standard are much more stringent.

One reason that a negligence trial may be more costly in the case of medical expert systems is that fault will often be extremely difficult to prove.<sup>153</sup> Execution of computer software involves a series of both

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149. See American Medical Association, Special Task Force on Professional Liability and Insurance: Professional Liability in the 80's, Report 3 (1985).

150. Liability insurance premiums for all physicians have increased 236% over the last decade. American Medical Association, Special Task Force on Professional Liability and Insurance: Response of the American Medical Association of Trial Lawyers of America Statements Regarding the Professional Liability Crisis, at 3 (1985).

151. See American Medical Association, Special Task Force on Professional Liability and Insurance, *supra* note 149.

152. Courts favor a standard that tends to reduce the overall cost and complexity of litigation. See, e.g., *Phipps v. General Motors Corp.*, 278 Md. 337, 363 A.2d 955 (1976).

153. See *supra* notes 73-79 and accompanying text.

hardware and software components, any one of which may fail to perform properly.<sup>154</sup> In deciding whether injuries caused by an in-home expert system were a result of the developer's negligence, a judicial inquiry might focus upon the caliber of the medical art represented by the program's knowledge base. A trier of fact would then be faced with the unenviable task of deciding whether the medical expertise programmed into a system conforms with the prevailing standards in the medical community. Because doctors are often loathe to provide evidence that may compromise a colleague,<sup>155</sup> it may be difficult for a plaintiff to secure expert physician testimony to support a claim. These difficulties are largely alleviated by a strict liability standard. Under this measure, the user of an in-home medical expert system would not have to prove a failure to exercise the care that a reasonable practitioner would have under the circumstances.<sup>156</sup>

Proving negligence in the instance of a professional system designed for physician use may not be as difficult because a claimant can allege that the physician used the software improperly or that the physician negligently relied upon the computer information. A plaintiff would not have to prove that the program itself was negligently fabricated, but would instead merely have to demonstrate that the physician utilized the program incorrectly. As is the case in an ordinary malpractice action, an injured claimant would focus upon the conduct of the physician who used the system and would not be compelled to undertake a tedious and perhaps futile analysis of the program.

### C. Encouraging Advances in Medical Science

One problem with the application of strict liability doctrine to all parties connected to the expert system enterprise is that the resulting liability may discourage advances in medical technology.<sup>157</sup> Justice Traynor realized that the careless expansion of a physician's liability could produce an "undesirable limitation on the use of procedures involving inherent risks of injury even when due care is used."<sup>158</sup> Thus, courts which have confronted the task of apportioning liability for the use of

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154. See Gemignani, *Product Liability and Software*, 8 RUTGERS J. COMPUTER TECH. & L. 173, 181-87 (1981). Many experts believe that errors can arise as the result of inapplicable external influences. See Raloff, *Sick Chips*, SCI. NEWS, Nov. 23, 1985 at 332.

155. W. PROSSER & P. KEETON, *supra* note 19, § 32 at 188 n.50 and cases cited therein.

156. See *supra* notes 64-68 and accompanying text.

157. "One objective of contemporary law should be to encourage innovation and development within the computer and other technical industries." R. NIMMER, *supra* note 75, § 7.05(2) at 7-21.

158. *Clark v. Gibbons*, 66 Cal. 2d 399, 424, 426 P.2d 525, 542, 58 Cal. Rptr. 125, 142 (1967) (Traynor, J., concurring).

medicines and medical implements have stressed that public policy unequivocally favors a theory of liability that fosters improvements in the healing arts.<sup>159</sup>

In *Greenberg v. Michael Reese Hospital*,<sup>160</sup> the Illinois Supreme Court addressed the issue of whether the doctrine of strict liability should be applied to physicians when injuries are caused by exposure to X-ray radiation during the course of medical treatment. The court concluded that public policy dictated that physicians should not be subject to strict liability because such liability would discourage the use of new medical technologies and procedures.<sup>161</sup>

Similarly, the policy goal of encouraging technological advancement indicates that physicians who design medical expert systems should not be held strictly liable. The concerns indicated in *Greenberg* are equally valid in the realm of expert systems; the physician who designs a medical expert system might be discouraged from pursuing his discoveries by the prospect of strict liability for user injury.

The argument that strict liability will inhibit the development of medical expert systems is also valid when applied to physician users. The use of a medical expert system to generate or check a diagnosis is similar to a physician's use of X-rays to plan treatment—the situation in *Greenberg*. Thus, as in *Greenberg*, strict liability for physician users would conflict with the goal of encouraging medical advances.

#### D. Preventing Accidents

Several courts have indicated that the imposition of strict liability for defective products can further accident prevention by eliminating the necessity of proving negligence.<sup>162</sup> These courts reason that if a manufacturer is held strictly accountable for the safety of its products, the manufacturer will be motivated to test its products more thoroughly prior to marketing and impose more stringent quality controls in the production process.<sup>163</sup>

Commentators have countered that strict liability may not be an effective deterrent to unsafe product design in many instances.<sup>164</sup> These

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159. See RESTATEMENT (SECOND) OF TORTS §402A comment k (1965).

160. 83 Ill. 2d 282, 415 N.E.2d 390 (1980).

161. *Id.* at 290-91, 415 N.E.2d at 394.

162. See, e.g., *Phillips v. Kimwood Mach. Co.*, 269 Or. 485, 525 P.2d 1033 (1974); *First Nat'l Bank of Albuquerque v. Nor-Am Agricultural Prods.*, 88 N.M. 774, 537 P.2d 682, cert. denied, 88 N.M. 29, 536 P.2d 1085 (1975).

163. *Phillips*, 29 Or. at 502-03, 525 P.2d at 1041-42.

164. See, e.g., *Raleigh, The State of the Art in Product Liability: A New Look at an Old Defense*, 4 OHIO N.L. REV. 249 (1977); *Plant, Strict Liability of Manufacturers for Injuries Caused by Defective Products: An Opposing View*, 24 TENN. L. REV. 938 (1957).

writers point out that the accident prevention rationale is valid only if a manufacturer can make an informed choice based on the safety of alternative designs.<sup>165</sup> If a particular risk is unforeseeable due to the state of the art or undiscoverable until the product is used in a unique manner, the imposition of strict liability will have little impact upon safety decisions.<sup>166</sup> Moreover, many design choices merely produce a trade-off in safety features; hence, it may be impossible to predict which of two options will be less costly in terms of injury until after the product is marketed.<sup>167</sup>

These criticisms of the accident prevention justification for strict products liability have particular relevance in regard to medical expert systems. A "bug" in a computer program may be detectable only under a very specific, rather unusual set of circumstances. Additionally, any choice between alternative rules or facts in the knowledge base will be merely an exchange of risks and benefits; each heuristic rule will be valid in some situations and not in others. It is unlikely that a program manufacturer will be able to foresee and predict all the unique situations that each user will encounter. Thus, accident prevention may not be furthered by a policy of strict liability.

In the case of a medical expert system designed for physician use, imposition of strict liability upon the practitioner user may actually undermine accident prevention because strict liability will discourage physicians from using expert systems as a means of double-checking and verifying diagnoses and planned treatments. A physician is unlikely to use a medical implement which generates liability independently of the degree of professional care and skill exercised.

By contrast, holding a physician responsible only for the negligent misuse of software will allow professional use of programs while simultaneously promoting caution and an awareness of system limitations. Thus, strict liability would not improve the level of accident prevention beyond that achieved by an ordinary negligence standard.

However, if plaintiffs claim that their injuries were caused by a *defect* in either an in-home or a professional program, rather than by the physician's operation of the system, the manufacturer, sellers, and other nonprofessional links in the distribution chain should still be held strictly liable. Holding a manufacturer strictly liable for defective professional software may help prevent the distribution of dangerous programs. Thus, the policy of reducing the risk of harm suggests a flexible

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165. Owen, *Rethinking the Policies of Strict Products Liability*, 33 VAND. L. REV. 681, 714 (1980).

166. *Id.*

167. See *supra* notes 93-96 and accompanying text.

approach to professional medical expert systems, whereby physicians are liable only for negligent use of expert programs yet manufacturers are strictly liable for injuries caused by defective product safety and design.

## CONCLUSION

The commercial promotion of medical expert systems designed for use either by an average consumer or by trained health care providers will present the courts with novel, thorny questions about the nature and extent of liability for personal injuries sustained using such software. In particular, thorough scrutiny of liability for expert systems highlights the blurred legal distinctions between product and service; strict liability and negligence; and impersonal market transactions and professional relationships.

A nationally distributed program for in-home use is akin to a product in many important respects: the ultimate software sold to a user is of tangible form, is subject to ownership, and can be periodically adjusted through the debugging process. Classifying professional systems, however, is not as straightforward because this type of program involves a combined product-service transaction. The essence of a bargain between a patient and her physician is health maintenance services, not the transmittal of a good. Yet, neither the developer of a medical expert system nor the system itself can be said to practice medicine in any traditional sense.

In addition, the variety of technologies and expertise which go into the fabrication of a medical expert system blurs the distinction between strict liability and professional negligence. After assessing various policy factors, this Comment concluded that strict products liability doctrine is appropriately suited to assessing the responsibility of the manufacturers, retailers, and sellers of all types of expert programs. Careful analysis of the components of strict liability doctrine, including the distinction between design and manufacturing flaws, will facilitate the fair and equitable apportionment of liability associated with medical expert systems.

At the same time, traditional professional negligence doctrine is well-suited to claims involving a physician's use of an expert system. Proof of physician negligence in such circumstances would be little different from that required in an ordinary malpractice action, provided a patient-physician relationship has been established. In the instance of a physician who uses an expert system as an aid in treating patients, the professional relationship clearly exists. A patient visits the doctor in order to receive care; the mere fact that the attending physician uses a computer program in rendering these services does not undermine the original purpose of the transaction.

By contrast, there is no direct interaction between consumers and physicians who develop expert systems. A professional relationship customarily requires an immediate connection between the health care provider and the patient as well as actual or implied consent to diagnose and treat. As any communications between a medical expert system developer and a patient or a user will flow wholly in one direction via the mass electronic communications market, mutual consent to form a professional medical relationship is absent. Therefore, this Comment argued that physicians who help develop medical expert systems should not be liable under professional medical malpractice standards to users of the software.

Despite the ambiguous nature of these legal distinctions, certain clear policy goals have emerged. This Comment considered the policy goals of allocating the costs of a risk, minimizing the demands and burdens placed upon judicial resources, encouraging the development of medical technology, as well as the ambivalent desire to reduce accidents. The basic framework established in this Comment for assessing liability addresses five analytically distinct categories of defendants: the designers of in-home systems; the designers of professional systems; the manufacturers of in-home systems; the manufacturers of professional systems; and, finally, the physicians who use professional systems.

Under this framework, the designing physicians would be subject only to negligence standards because of their limited control over marketing and production. Attending physicians who utilize expert systems would only be subject to liability for professional malpractice because even with the aid of a sophisticated tool such as an expert system, they are essentially still providing services rather than goods.

Finally, the framework suggests that courts should adopt a products liability approach towards the manufacturers of expert systems, whether for in-home or professional use. Because a manufacturer can spread the risk of loss through pricing or insurance, they are in a much better economic position to bear these costs than is the program user or the physician who developed the system. Furthermore, applying products liability principles to manufacturers of medical expert systems will discourage the manufacture of dangerous, all-encompassing programs sold as a replacement for physician services while simultaneously encouraging development of medical software intended as a supplement to traditional health care.