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NOTES

COMPUTER-AIDED MEDICINE: PRESENT AND FUTURE ISSUES OF LIABILITY

I. INTRODUCTION

The use of computers has become integral to the development of modern medicine. Computers are used to schedule appointments, maintain inventory lists of drugs, bill patients, and store medical records. More sophisticated computers are used to produce computerized axial tomographs (C.A.T. scans) and to monitor electrocardiograms continually in intensive care units.[1] An expanding area of computer application in the medical field is the use of expert systems to perform diagnostic functions. Expert systems, also referred to as artificial intelligence, are computer software systems that incorporate human expertise into their programs. In developing expert systems, researchers input the knowledge of experts into computer programs, enabling them to reach the same conclusions as the experts, using the same cognitive methods.[2] These expert systems can ask questions, discard irrelevant information, and produce a reasoned conclusion with a credible explanation of how that conclusion was reached.[3] When computers are used in the medical field, patients can be injured if the systems are defective or if the person using and interpreting the information is negligent.

This Note addresses liability in computer-aided medicine, focusing on expert systems currently used in diagnostics as well as future uses for computers in medicine. Presently, hospitals use expert systems to aid physicians and other medical personnel in the diagnosis and monitoring of patients. It is anticipated that expert systems for home diagnostic use also will become a reality in the near future. Other uses for

1. *See* Brannigan & Dayhoff, *Liability for Personal Injuries Caused by Defective Medical Computer Programs*, 7 AM. J. L. & MED. 123, 127 (1981) [hereinafter Brannigan & Dayhoff].

2. *See* Shurkin, *Expert Systems: The Practical Face of Artificial Intelligence*, TECH. REV., 72, 74 (Nov. 1983).

3. *See* Comment, *Medical Expert Systems: Grappling With Issues of Liability*, 1 HIGH TECH. L.J. 483, 484 (1986) (authored by Gill).

computers and expert systems are developing in the new biology area. "New biology" refers to certain new biological technologies rapidly developing in the medical field including new methods of human reproduction and complex technologies for prolonging life, such as organ transplantation. Computer systems that network information about organs available for transplant already have been developed, and it is conceivable that similar systems could be implemented to assist physicians in other areas of new medicine, such as searching for compatible surrogate mothers. In anticipation of these computer systems, it is useful to analyze the applicability of traditional tort theories of liability when injuries result.

Based on public policy and fairness rationales, this Note argues that manufacturers of mass-produced computer systems should be held to a strict liability standard for defectively produced systems. A negligence standard should govern when a computer system is custom-made or when a physician's services are used in conjunction with the system.

Two very likely defendants in a lawsuit for personal injuries are the program manufacturers and the doctors and/or hospitals that use these systems. This Note focuses on liability pertaining to these two classes of defendants. In assessing the appropriate theory of liability, one must first determine whether the expert system or computer program is considered a product or a service, and whether a physician's services intervened.

When a physician uses a computer system and injury results to his patient, the plaintiff should be allowed only to use a negligence or professional liability theory against the physician. If the system were specifically tailored for a physician and found to be defective, the plaintiff also might use a negligence claim to hold the programmer liable for his services. However, if the plaintiff were injured due to a manufacturing defect in the program, he could bring a strict products liability cause of action against the manufacturer.

When an expert system is mass produced without customization and sold for in-home diagnostic use, strict products liability should apply. In the new biology area, computer networking systems may be vitally important. A strict products liability standard would then be too inhibitive of new production. If a vital service were involved, policy rationales may dictate a liberal negligence standard in order to encourage development in this new area.[4]

4. A liberal negligence standard requires a finding of "gross negligence" or "recklessness" as opposed to ordinary negligence. The jury might also be instructed that since this is a new area of technology, the "due care" required differs from that in established medical procedures.

A. How Expert Systems Work and Examples

Expert systems also are referred to as artificial intelligence because of their ability to use judgmental knowledge or "heuristics."[5] The word heuristics comes from the Greek word for "discover" but is simply expressed as "the art of good guessing."[6] Heuristics combines knowledge with the rules of thumb that human experts gain from experience in solving problems. Heuristics enables experts, human or machine, to recognize promising approaches to problems, to break problems into smaller ones, to get around incomplete data, and to make educated guesses when necessary.[7] Deductive principles which have been extracted from human experts into models of clinical problem solving are logically applied to the data entered into the computer system.[8] Many of these systems use an "if-then" induction statement which takes the form of a conditional. These if-then rules increasingly narrow a search by guiding the program's attention to the correct solution.[9] For example, IF running nose, temperature, and sneezing are present, THEN patient has a cold; IF the patient has a cold, THEN prescribe aspirin.[10] The developers of expert systems realized that the computer had to be able to weigh decisions by their plausibility.[11] The conclusion reached by the series of rules is accepted when a numerical scoring factor exceeds some critical threshold.[12] The program actually prioritizes possible decisions by using its deductive principles to come up with the most plausible solution.

One of the first expert systems developed was "MYCIN" by Edward Shortliffe of Stanford University. MYCIN diagnoses blood and meningitis infections and advises physicians on antibiotic therapies. MYCIN is an example of a professional system which is designed to augment a physician's own personal skill and reasoning.[13] It uses a base of 500 heuristic rules to diagnose bacterial blood infections. The "CADUCEUS" program at the University of Pittsburgh is another expert system. It is designed to diagnose more than 800 diseases. An important step in artificial intelligence development is the trial-and-error con-

5. *See* Schwartz, Patil & Szolovits, *Artificial Intelligence in Medicine Where Do We Stand?*, 27 JURIMETRICS J. 362, 363 (1987) [hereinafter Schwartz]. These authors assert that rule-based systems incorrectly have been termed "artificial intelligence."

6. Shurkin, *supra* note 2, at 74.

7. *See id.*

8. *See* Schwartz, *supra* note 5, at 363.

9. *See* Buetel, *Government Regulation of Diagnostics Software: A Threat to Artificial Intelligence Software Developers*, 2 COMPUTER LAW. 22, 23 (1985).

10. *See* Shurkin, *supra* note 2, at 74.

11. *See id.* at 75.

12. *See* Schwartz, *supra* note 5, at 363.

13. *See* Comment, *supra* note 3, at 487.

sultation between expert and programmer which codifies the hundreds of rules and exceptions that human experts learn from theory and practice.[14] The generalized logic of the MYCIN system is like a skeleton which could be separated from the medical database and connected to a new database from other fields.

Another system named "INTERNIST" has a large database that includes information on about 500 diseases which constitute about seventy-five percent of all major medical diagnoses. In clinical tests, this system correctly diagnosed as many cases as most ordinary physicians.[15] While many of these systems are in the developmental stage, some are used on a day-to-day basis. "PUFF," an offshoot of MYCIN, is now being used at the Pacific Medical Center in San Francisco to diagnose lung disease.[16]

B. EXAMPLES OF HOME-USE EXPERT SYSTEMS

Home medical diagnostic expert systems, not in use at this time, would function like those used in hospitals or doctors' offices, but would be produced with family use in mind. Hypothetically, the user enters his symptoms into the computer. The computer then selects relevant principles based on the input, asks questions to find out any additional pertinent facts, and generates answers.[17] In a medical expert system for home use, the software places an ailment in one of three categories: (1) life-threatening emergency situations; (2) problems requiring professional evaluation; and (3) situations likely to self-resolve.[18] In-home medical expert systems likely will be used to supplement a regular health care program and could help mitigate the costs of medical care.

II. INTRODUCTION TO LIABILITY

When injury results from the use of an expert system, traditional tort theories apply. Before liability can be traced to some class of humans, however, many threshold questions must be answered. One determinative question is whether the system is a product or a service. If the system is a product, strict liability arguably applies. A defective product can result from a manufacturing defect or a design defect, an

14. *See* Nycum, Fong, Snow & Bartlett, *Artificial Intelligence and Certain Resulting Legal Issues*, 2 COMPUTER LAW. 1, 2 (1985) [hereinafter Nycum & Fong].

15. *See* Shurkin, *supra* note 2, at 76. In this test, hundreds of cases from the *New England Journal of Medicine* were entered into the program. Panels of physicians and experts were matched against the computer. Nineteen cases involving 43 different diagnostic problems were chosen. INTERNIST was correct 25 times. The physicians who had tended the patients were correct 28 times, and clinical experts were correct 35 times.

16. *See id.*

17. *See* Comment, *supra* note 3, at 486.

18. *See id.* at 487.

important distinction that is discussed below. If a physician's service accompanies the expert system, the actual cause of the injury might be the physician's negligence in interpreting the information. In addition, the expert system might be considered neither a product nor a service but a hybrid of the two.

Injuries can be traced to patients as individual users, physicians, distributors, or manufacturers/programmers. Issues of liability surround the physician/hospital and the program manufacturer. In many cases where and how the program is used will determine the applicable theory of liability.

For policy reasons, professional medical expert systems and in-home diagnostic systems should be considered products when sold as turn-key systems (individual hardware systems) to hospitals and consumers. Strict products liability should apply to manufacturing defects in the programming and production stage. Mistakes in actual design of the program should be analyzed under a negligence standard.[19] A negligence or professional liability theory should apply when a physician intervenes and improperly uses or relies upon an expert system. Negligence or professional liability also is appropriate where a programmer custom designs an expert system for a particular hospital or physician and breaches the duty of care in designing the program.

A. PROFESSIONAL MEDICAL EXPERT SYSTEMS

Computer systems are used to perform a wide variety of medical functions that skilled and unskilled individuals once performed.[20] Some functions such as the C.A.T. scan (computerized axial tomography) never could be performed manually, while other routine functions are now computerized —such as appointment scheduling and hospital bed use or maintaining inventories of drugs and supplies. Programs such as C.A.T. scans are programs upon which medical personnel routinely rely without questioning their accuracy — no independent human intervention is expected. Medical procedures increasingly are controlled by computers including fully-automatic intensive care units and devices for monitoring such activities as anesthesia administration and constant reporting to medical personnel.[21] In these situations, a hospital might be held strictly liable when injury results. However, the first part of this Note focuses on expert systems used to perform deductive operations, such as computers that interpret laboratory test results,

19. *See infra* text accompanying notes 70-76 for a more thorough explanation of the differences between manufacturing defects and design defects.

20. *See* Brannigan & Dayhoff, *supra* note 1, at 126.

21. *See* Freed, *Products Liability in the Computer Age*, 17 JURIMETRICS J. 270, 273 (1977).

and expert systems that provide the user with a list of possible diagnoses. In particular, this Note addresses programs that provide information and guidance to physicians.

When a patient is injured because of a physician's incorrect diagnosis or treatment, two types of liability could follow. There could be strict products liability against the program manufacturer and distributor, if the expert system is considered to be a product and is defective. Alternatively, there could be negligence liability for the defective program. A plaintiff could recover only if the defendant failed to meet the appropriate standard of care, and that failure caused the patient's personal injury.[22] The negligence action addresses the defendant's conduct under the circumstances and would be an appropriate cause of action if a medical computer program were classified as a service.[23]

Consequently, one first must ask whether medical diagnostic services are products or services. Some argue that "[m]edical 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."[24] These programs most likely, however, will involve elements of both a service and a product and will be hybrid cases.

B. IN-HOME DIAGNOSTIC MEDICAL EXPERT SYSTEMS

Liability analysis for in-home expert systems is much less complicated than that of professional systems used by physicians and hospitals. There is no professional service provided; there is only the purchase of a mass-produced computer program.

Numerous injuries could result from these systems. For example, a consumer could be injured by a manufacturing defect in the program that misdiagnosed his symptoms or misinformed him that his symptoms were minor when he in fact needed immediate care. An additional problem might occur when the system misinforms the consumer in an emergency situation. If an antihistamine were suggested to a person suffering breathing symptoms without first asking whether the person had a history of asthma, thyroid disease, or diabetes, the ramifications could be disastrous.

Injuries resulting from manufacturing defects in these expert systems probably would be subject to strict products liability. This lessens the plaintiff's burden of proof. Otherwise the plaintiff would not be able to specify the defect in the program under a negligence standard. With a strict products liability standard, all parties in the distribution

22. *See* Brannigan & Dayhoff, *supra* note 1, at 128.

23. *See id.*

24. *See* Comment, *supra* note 3, at 491.

chain — manufacturers/programmers and distributors — would be strictly liable. If, however, the defect were found to be in the program design, the courts might hold the manufacturer/programmer to only a negligence standard.[25]

III. PRODUCTS VERSUS SERVICES

The criteria for determining whether expert systems are services or products include the concepts of tangibility, ownership, possibility for correcting defects, and method of distribution.[26] In addition to these criteria, there are many persuasive policy rationales for labeling a system as a service or a product.

A. TANGIBILITY

Services generally have no tangible existence apart from an end product that may appear in a tangible form such as a book or diskette. This end product has no real intrinsic value of its own apart from the ideas expressed. Conversely, products are tangible, visible items which hold value in their actual physical characteristics. When the end product of a service takes a tangible form that has a value of its own, the product-service distinction is more difficult to make.[27]

Medical expert diagnostic systems are ideas committed to tangible form, and their value emerges only when a computer translates the underlying ideas they contain.[28] "[T]he streams of electrons produced by computers, and hence their print-outs and other forms of tangible output, are the results of machine processing in accordance with identifiable steps and, hence, are the equivalents of manufactured goods."[29] While an expert system developed for professional use is clearly tangible, "its corporeal qualities are only apparent to the physician who uses the program and are not perceived by the patient."[30] However, in-home diagnostic systems have value immediately perceivable by consumers. "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."[31]

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25. *See infra* text accompanying notes 70-76 for a more thorough explanation of manufacturing and design defects.

26. *See* Brannigan & Dayhoff, *supra* note 1.

27. *See id* at 130.

28. *See id.*

29. Freed, *supra* note 21, at 282.

30. Comment, *supra* note 3, at 490.

31. *Id.*

B. OWNERSHIP

One of the hallmarks of a product is its capacity to be held in one's possession.[32] The ownership factor makes a persuasive argument that professional expert systems are less likely to be classified as products for purposes of strict liability. In the case of medical expert systems which are designed for use by medical practitioners and not the general public, ownership belongs to the physician, not to the injured patient. "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."[33] When a computer program is duplicated and sold, it becomes an article of commerce and a large potential group that can be exposed to personal injury comes into existence. Thus arguably, in-home diagnostic programs which are mass produced eventually could be considered items of commerce like food processors or power tools and would be subject to products liability.

C. POSSIBILITY OF CORRECTING DEFECTS

Defective services only sometimes can be countered by performing additional services, but the original service no longer exists to be adjusted. On the other hand, products such as machines can be adjusted, repaired, or altered after production. Computer programs can be debugged. This alterability makes a program more like a product than a service.[34]

D. METHOD OF DISTRIBUTION: HYBRID SITUATIONS WHERE PRODUCTS AND SERVICES ARE COMBINED

One author analogized the computer software market to the market for a suit of clothing.[35] This analogy can be applied to medical expert systems in determining whether they should be considered products or services. There are three ways that an item reaches the consumer. First, a suit may be specifically tailored to fit the consumer's exact measurements. Second, the consumer may buy a ready-to-wear suit and make no alterations. Third, the consumer may buy a suit that is ready-made but must be altered to fit him.[36]

In the first scenario, consumers are patients and the medical expert system is specifically tailored for their use. However since in-home di-

32. *See id.*

33. *Id.* at 491.

34. *See* Brannigan & Dayhoff, *supra* note 1, at 132.

35. *See* Comment, *Negligence: Liability for Defective Software*, 33 OKLA. L. REV. 848 (1980).

36. *See id.* at 853.

agnostic systems probably will be mass-produced programs, it is unlikely that this analogy applies. The only direct consumers of specifically-tailored medical systems would be physicians or hospitals, not patients. Because such expert systems would be developed based on the specific needs of a hospital or physician, it would be designed for only their particular uses. Such expert systems really are not placed in the steam of commerce, because they are distributed to only one customer. Since the product is sold to only one user, the supplier is not in a better position than the user to bear the costs of defects.[37] The programmer is not selling the product *en masse* and cannot spread the cost of a defect over a number of consumers on the same scale as a mass producer. The limited application of this type of system makes it more like a service than a product, and the appropriate liability is negligence.

A second method of distributing the expert systems parallels the purchase of a ready-made suit. In this situation, it is not tailored to the specific user's needs.[38] This analogy applies to in-home diagnostic medical expert systems that are mass produced as "canned software" as well as to prepackaged diagnostic systems such as INTERNIST and MYCIN, which hospitals and physicians use. Since these mass produced products are placed in the stream of commerce, strict liability is the appropriate theory of liability. "Ready to use" expert systems represent a method of distribution analogous to mass distribution of any product.[39] The objective is to sell the identical program to as many consumers as possible rather than to one particular user.

Policy rationales for strict liability enter into this analogy. The supplier is placing the program into the stream of commerce. Thus, if the system is defective, the supplier is creating a risk of harm and receiving a profit. Patients and doctors have comparatively little knowledge of the system's internal structure and rely on the supplier's expertise. The supplier is in a better position both to anticipate the risks and to bear the cost of an injury. The supplier can calculate insurance costs into the price of an expert system. On the other hand, because medicine is not foolproof, why hold a producer that "practices medicine" to a standard higher than the professional's standard?

The third type of distribution is a hybrid of the first two. Professional medical expert systems used by physicians fall into this category because both a service (the physician's professional judgment) and a product (the expert system) are involved. Injury can result in two ways: (1) a defective program is used while providing a service, or inversely, (2) a correctly manufactured program is used, but is interpreted

37. *See id.*

38. *See id.*

39. *See id.* at 854.

or relied on improperly. Those medical expert systems that are intended for general in-home use do not fall into this category, because no additional service, such as by an intervening physician, is rendered once the program is reproduced for mass distribution. "By contrast, when a physician uses a medical expert system the product is inseparable from the service transaction."[40] Categorizing the transaction as hybrid leaves the standard of liability (negligence or strict liability) undetermined. This indeterminateness provides leeway for courts to use discretion in complicated situations where varying standards of liability might be appropriate.

E. LIABILITY IN HYBRID SITUATIONS WHERE SERVICES AND PRODUCTS ARE COMBINED

In determining the standard of liability to apply when a defective product is used while providing a service, courts generally examine three elements: (1) the nature of the activity; (2) whether the defective product was physically conveyed or merely used in providing a service; and (3) whether the service or the product was the primary focus of the bargain.[41] In *Allied Properties v. John A. Blume & Associates*,[42] the court confirmed the settled rule in California that "where the primary objective of a transaction is to obtain services, the doctrines of implied warranty and strict liability do not apply."[43]

In numerous cases where a patient was injured due to a defective instrument used by a medical professional during the course of treatment, the courts do not apply strict products liability to the doctor using the instrument.[44] In *Magrine v. Krasnica*,[45] a hypodermic needle broke in a dental patient's jaw. The court found that the dentist was in no better position than the patient to control, inspect, and discover the defect. The essence of the relationship was for professional services and skill, and the dentist did not put the item into the stream of commerce.[46] The court concluded that liability should be placed on the manufacturer.

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40. Comment, *supra* note 3, at 494.

41. *See* W. PROSSER & P. KEATON, HANDBOOK OF THE LAW OF TORTS, § 104 at 720 (5th ed. 1984).

42. Allied Properties v. John A. Blume & Assoc., 25 Cal. App. 3d 848, 102 Cal. Rptr. 259 (1972).

43. *Id.* at 855, 102 Cal. Rptr. at 264.

44. *See* Note, *Strict Products Liability and Computer Software: Caveat Vendor*, 4 COMPUTER/L.J. 373, 381 (1983).

45. 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 (App. Div. 1968), *aff'd per curiam*, 53 N.J. 259, 250 A.2d 129 (1969).

46. *See* 94 N.J. Super. at 234-35, 227 A.2d at 543.

Alternatively, a patient may bring a negligence cause of action in these hybrid situations. The patient claims not that the professional expert system was defective, but that the physician used it improperly or negligently. The focus of this negligence cause of action would be that the professional service itself, and not the product used, was somehow inadequate.[47] "The physician's reasonable reliance on the functioning of a program is all that normally can be required. If he or she unreasonably relies on a program, liability would be based on negligence."[48] "The physician is expected to use his or her support materials in a critical way and not to rely on them without using independent judgment."[49] An example of this type of situation is *Barbee v. Rogers*,[50] where plaintiff claimed eye injuries caused by the improper fitting of contact lenses. Plaintiff did not prove that the contact lenses were flawed,[51] but that the defendants (two optometrists) incorrectly fitted the lenses to his eyes.[52] The Texas Supreme Court segregated the product from the service. Since the defect arose from the service portion, policy considerations did not mandate imposition of strict liability.[53]

A claim that a physician improperly used an expert medical system in diagnosing a patient should be governed by negligence or professional liability. Because expert systems may be more reliable than human judgment, it is conceivable that physicians could be held liable for not relying upon expert system advice. For example, one function of the INTERNIST system is to provide a checklist that helps the user make certain that a diagnostic possibility was not overlooked.[54]

IV. THE NEGLIGENCE CAUSE OF ACTION

If the courts decide that professional medical expert systems are actually services, the injured patient could bring a negligence cause of action against the physician or, alternatively, against the programmer for providing a defective service. The plaintiff's burden of proof in negligence is more rigorous than in strict liability.[55] A negligence cause of action is more difficult for the plaintiff to prove, because he must show the precise step in the process that caused the defect and prove that a failure to use sufficient care caused the defect. The courts should con-

47. *See* Comment, *supra* note 3, at 496.

48. Brannigan & Dayhoff, *supra* note 1, at 142. *See also* Magrine v. Spector, 100 N.J. Super. 223, 241 A.2d (App. Div. 1968), *aff'd per curiam*, 53 N.J. 259, 250 A.2d (1969).

49. Brannigan & Dayhoff, *supra* note 1, at 139.

50. Barbee v. Rogers, 425 S.W.2d 342 (Tex. 1968).

51. *See id.* at 346.

52. *See id.* at 343-44.

53. *See id.* at 346.

54. *See* Schwartz, *supra* note 5, at 368.

55. *See infra* text accompanying notes 67-80 for a discussion of strict liability.

strue professional medical diagnostic expert systems as services only when they are individually tailored to a specific task. Thus, negligence or professional liability (malpractice) would be applicable only to (1) physicians for improper use or unreasonable reliance (or non-reliance on) the expert system, or (2) to manufacturers for design defects in those systems specifically tailored for a hospital or physician.

Addressing the issue of what constitutes proper reliance, two authors analogized professional medical computer programs to navigational charts which convert data into a more accessible or usable form, the results of which may be passed on for professional evaluation.[56] The professional must be able to rely on the data's accuracy but is expected to use his professional judgment in evaluating the information, not blindly rely on the computer or the charts. For example, if a program were designed to flag certain test results, a physician would be justified in relying on this signal. However, if the patient had a certain susceptibility that ordinarily would not elicit a computer alert, the physician must supplement the program results with his own etiological and diagnostic expertise.[57]

The negligence cause of action requires that the plaintiff prove "(1) the existence of a duty of care, (2) conduct below the appropriate standard of care, and (3) a [proximately] resulting injury that should be compensated by damages."[58] Proving who in the process of creating the computer program is responsible for the defect is a very heavy burden of proof for an injured plaintiff. Perhaps the only way to show that the defendant breached his duty of care is to produce an expert witness who can delineate the precise location and cause of the defect, *i.e.*, precisely what the allegedly negligent manufacturer failed to do and the exact circumstances.[59] "This burden might include pointing out the very mistake among the thousands of bits of information in the program and proving that injury is reasonably foreseeable. This would have to be done although the injured person might have no idea how or why a computer operates."[60] The shortcut of *res ipsa loquitur* probably would not apply to assist the plaintiff with the burden of proof. Given the complexities of computers, one cannot say that errors usually do not occur in the absence of negligence.[61]

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56. *See* Brannigan & Dayhoff, *supra* note 1, at 131.

57. *See id.*

58. *Id.* at 133.

59. *See* Gemignani, *Product Liability and Software*, 8 RUTGERS COMPUTER & TECH. L.J. 173, 190 (1981).

60. Comment, *Computer Software and Strict Products Liability*, 20 SAN DIEGO L. REV. 439, 441 (1983).

61. *See* Nycum, *Liability for Malfunction of a Computer Program*, 7 RUTGERS COMPUTER & TECH. L.J. 1, 11-12 (1979).

In addition to the negligence theory that attaches to a medical expert system classified as a service, physicians and program manufacturers might be subject to a professional liability theory. Under this theory, a plaintiff seeks recovery for injuries caused by negligently delivered professional services. Although at present no case or standard exists for a computer program, negligence theory is often applied in medical situations. "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."[62] A physician is held to the same degree of skill, knowledge, and care ordinarily possessed and exercised by members of their profession under similar circumstances.[63]

Policy rationales favorable to strict liability are not incongruent when applied to professional liability. In terms of risk spreading, a physician who employs a medical expert system may be in a good position to shoulder at least some of the burden of patient injuries.[64] Also, in terms of insurance, a physician probably would have malpractice insurance. Concededly, society pays heavily for such insurance in the form of increased medical bills.

Using a standard of professional liability, one important issue is the care put into a physician's selection of an expert system. For example, if a new expert system appeared on the market and a physician purchased it without first checking the medical community's reaction, a jury might conclude that the physician was negligent. Alternatively, since expert systems are innovative, perhaps the standard of liability should be similar to one where a physician attempts a new procedure in surgery or new techniques for cancer patients.

Normally, a plaintiff must be in a consensual relationship with a physician to pursue a medical malpractice claim. This consensual relationship requires actual or implied consent to diagnose and be diagnosed, to treat and be treated.[65] Patients injured by a physician's misuse of an expert system would fall into this category, since they clearly would have a mutual consensual relationship to be treated. In contrast, "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."[66]

Unlike professional medical liability, which is a well-developed theory of liability, computer malpractice has not been established as a legit-

62. Comment, *supra* note 3, at 512.

63. *See* Qunital v. Laurel Grove Hosp., 62 Cal. 2d 154, 159-60, 397 P.2d 161, 164, 41 Cal. Rptr. 577, 580 (1964).

64. *See* Comment, *supra* note 3, at 515.

65. *See id.* at 512.

66. *Id.* at 513.

imate cause of action. If a professional liability standard applies to manufacturers, it is only speculative. With respect to custom tailored medical expert systems, when the manufacturers are subjected to a negligence theory they probably will be expected to perform with the same degree of care as the others in their profession. However, this case is different from a typical professional liability theory, because the elements of a consensual relationship are lacking between the patient and the programmer who designs a system exclusively for the hospital or physician.

V. THE STRICT LIABILITY CAUSE OF ACTION

The manufacturer of either a professional medical expert system or an in-home system should be subject to strict products liability when a patient is injured due to a manufacturing defect. A physician who improperly uses such equipment is subject to a negligence doctrine. According to the *Restatement (Second) of Torts*, a manufacturer or seller is strictly liable for any injuries resulting to the ultimate consumer from a product that is (1) in a defective condition when sold, (2) unreasonably dangerous to the user of consumer, and (3) expected to reach and does reach the user or consumer without substantial change in the condition in which it was sold.[67] In addition, the *Restatement* suggests that liability be imposed when an injury results from the manufacturer failing to adequately warn of the dangers inherent in the program.[68] Strict liability is imposed upon manufacturers and sellers even if they exercised all possible care in the preparation and sale of the product.[69] Defects can occur in one of two ways: a manufacturing defect or an error in the design of the product.

A. DESIGN VERSUS MANUFACTURING DEFECT

Strict liability focuses primarily on manufacturing defects, while design defects usually are evaluated under a negligence standard. A manufacturing defect occurs when products are not produced as designed. After a system is designed, it must be encoded into a workable program. If an error was made during data input or conversion from source code, or if a flaw was discovered in the physical diskette or hardware, a manufacturing defect would occur. Manufacturing defects can render a product unreasonably dangerous as a matter of law when it deviates from the producer's own safety precautions.[70] Under this

67. *See* RESTATEMENT (SECOND) OF TORTS § 402A(1) (1965).

68. *See id.* § 402A comment j.

69. *See id.* § 402A(2)(b).

70. *See* Comment, *supra* note 3, at 507 (citing W. KIMBLE & R. LESHER, PRODUCTS LIABILITY § 155, at 178-80 (1979)).

branch of products liability, the plaintiff has a light burden of proof. The prima facie case for strict liability for manufacturing defects can be based on one of three types of evidence: (1) expert testimony pin-pointing the defect which caused the injury, (2) proof of destruction or disappearance of the defective product, or (3) proof of the accident's circumstances that point to a manufacturing defect.[71] One can argue that professional expert systems used by physicians involve no direct interaction between the patient and the expert system so the product does not reach the consumer in its defective condition. It also can be argued that expert systems are not unreasonably dangerous where a human must intervene. However, patients as third parties are intended to benefit from these systems. Thus, patients injured by the use of a defective professional medical expert system or by a defective in-home diagnostic system would be able to recover without encountering an insurmountable burden of proof.

It is much less difficult to apply strict products liability to manufacturing defects than to design defects. "In the case of a design defect . . . an injured consumer must prove that a nondefective design was reasonably available."[72] This is a more difficult burden of proof for the plaintiff who must provide expert witnesses who can compare the reasonableness of design options that were available to the program's designer. The Uniform Product Liability Act suggests that when a design defect is involved, it really is a case of negligence rather than true strict liability.[73] With computer programs, this task becomes complicated because of difficulty in distinguishing the design phase (reducing the cognitive methods and knowledge of experts into algorithms) from the production phase (actual programming or encoding) and the nearly impossible task of determining whether a particular program characteristic was a conscious or an inadvertent design choice.[74] Before any computer program is released for sale or use, it is perfected through a process known as debugging. Because most program errors are not discovered until the program is used extensively, this process tests the program repeatedly. Brannigan and Dayhoff suggest that any system used to perform patient-related functions should be designated a productions system, so that it would be subjected automatically to strict liability and thus discourage premature use of a still-defective system.[75] On the other hand, if society greatly needs the use of expert systems to expedite diagnosis or assist in curing, such delay is a high cost to pay.

Similar to the negligence theory, liability in design defect cases

71. *See id.* at 508.
72. Brannigan & Dayhoff, *supra* note 1, at 135.
73. *See* Uniform Product Liability Act, 44 Fed. Reg. 62,714, 62,723 (1979).
74. *See* Brannigan & Dayhoff, *supra* note 1, at 136.
75. *See id.*

turn on the reasonableness in choice of design. "When a jury decides that the risk of harm outweighs the utility of a particular design . . . it is saying that in choosing the particular design and cost trade-offs, the manufacturer exposed the consumer to greater risk of danger than he should have. Conceptually and analytically, this approach bespeaks negligence."[76] However, one Oregon court placed a greater burden on the manufacturer than would be applied under a negligence theory, assuming that the manufacturer foresaw the possibility that the product's design might cause the injury that occurred.[77] Under this holding, the plaintiff need not show that the manufacturer could foresee the article's dangerous propensity. Applying this to expert systems, any ordinary mistakes by data encoders in carrying out the system designer's instructions would qualify as manufacturing defects and would be subject to strict liability.

B. DUTY TO WARN

The sale of a product carries with it an implied warranty that the product is reasonably fit for its intended use.[78] This creates a duty to warn the ultimate user or consumer of an unsafe product. Since it usually is impossible to completely debug a program, the manufacturer must warn of possible defects. Nondisclosure of such a risk alone can put a product in a defective condition. Warnings should be plain and explicit, but this may be difficult or impossible when it comes to unpredictable bugs. "Unlike the possible adverse side effects that drug manufacturers must warn against . . . which can usually be pin-pointed with some particularity, computer problems must be left somewhat vague and uncertain."[79] "The warnings must go beyond mere notification that at some point something might go wrong. They must serve to keep the program from being unreasonably dangerous by making clear its safe and proper use."[80] Thus, the inadequate warning itself might make the expert system "defective."

VI. POLICY REASONS FOR IMPOSITION OF STRICT LIABILITY ON MANUFACTURERS/PRODUCERS

Strict liability law developed in response to modern marketing methods where the consumer relies on the skill and judgment of a dis-

76. Birnbaum, *Unmasking the Test for Design Defect: From Negligence to Warranty to Strict Liability to Negligence*, 33 VAND. L. REV. 593, 610 (1980).

77. *See* Roach v. Kononen, 264 Or. 457, 525 P.2d 282 (1974).

78. *See* U.C.C. § 3-318.

79. Gemignani, *supra* note 59, at 192.

80. Nycum, *supra* note 61, at 19.

tant manufacturer.[81] "Society has decided that it is not too much to ask that an item not injure people."[82] Consumer reliance is high in the area of computers and expert systems, because this technology is beyond the comprehension of the average consumer. The manufacturer/developer of the expert system is far more informed than users and consumers about risks of errors. Consequently, the manufacturer is in a better position to avoid the harm, either by extensive debugging or by purchase of insurance. Yet due to the complexity of all but very elementary programs, it is nearly impossible to debug a program completely.[83] Nevertheless, the manufacturer can spread the cost of an injury by adjusting the system's selling price. The cost of insurance can be absorbed into the system's price. On the other hand, insurance is not always available. When it is available, it may make the product prohibitively expensive. Nevertheless, the manufacturer placed these systems into the stream of commerce in order to earn a profit so it is justifiable to require him to bear the risk of injury.[84] "If, indeed, a technology is so sophisticated that no one fully understands or is able to control it, but is so necessary that modern society must employ it, then it would seem that the risks inherent in its use ought to be spread evenly among all the users. Such risk spreading is one of the principal goals of strict liability."[85] Also, making diagnostic expert systems available to the public, implicitly assures that the product is safe.[86]

Categorizing an expert system as a product which is subject to strict liability would reduce uncertainty about who is liable and would promote responsible action by manufacturers.[87] "Under a negligence theory, there are widely differing standards of care for manufacturers and sellers, based on different standards of care in each field."[88] Under strict liability, however, every defendant in the distribution chain would be liable to an injured consumer. The strict liability standard alleviates many of the plaintiff's burdens that are inherent in the negligence standard. "Because doctors are often loathe to provide evidence that may compromise a colleague, it may be difficult for a plaintiff to secure expert physician testimony to support a claim."[89] On the other hand,

81. *See* Note, *supra* note 44, at 390.

82. *Id.*

83. *See* Freed, *supra* note 21, at 275.

84. It should be noted that the manufacturer is found liable only if it can be shown that but for the malfunction, the patient would not have been injured.

85. Gemignani, *supra* note 59, at 197.

86. *See* Comment, *supra* note 35, at 850.

87. *See* Brannigan & Dayhoff, *supra* note 1, at 133.

88. *Id.*

89. Comment, *supra* note 3, at 516.

strict liability may deter the continued production of much needed expert systems.

The rationales for using a strict liability standard become more persuasive when applied to the field of medical care and the preservation of life. While the practice of medicine is an imperfect science, manufacturers should be expected to perform thorough testing. "Judicious use of conditional statements and error checking codes can greatly minimize the chance of danger to life."[90] Arguably, if imposition of strict liability in tort would force computer hardware and software manufacturers to be more careful in the race to develop an ultimate product, this alone would justify its application.[91] On the other hand, one might argue that irrespective of the liability standard, given the free market's inherent checks and balances physicians would not use expert systems unless they were safe, and manufacturers could not sell systems that the medical community did not approve. However, until these programs become more widely used, it will be impossible for physicians to know in advance how safe they really are.

A. ARGUMENTS AGAINST STRICT LIABILITY FOR MANUFACTURERS

"[I]ndividual physicians have an effective monopoly, enforced by the legal system, on primary medical decisionmaking. Physicians have jealously guarded their control . . . of diagnosing and treating diseases."[92] In-home diagnostic expert systems would encroach upon this monopoly, resulting in less expensive medical care for patients. Medical expert systems would help bypass the monopoly of medical expertise. Consequently, a strict liability standard might deter manufacturers from producing systems and thus reinforce the physician's traditional monopoly. "If courts continue to apply strict liability, it may dampen industry enthusiasm for greater use of technology."[93] Imposing strict liability on manufacturers of expert systems may stifle innovation, as does the federal regulation on drug development. "The consequences are ironic: a system designed to eliminate bad products now drives vital products from the market."[94] Many scientists and lawyers oppose imposition of the strict liability standard to important innovative products. One lawyer/engineer asserts that "[t]oday technology itself is put on trial."[95] [96] Because large established corporations could self-insure in-

90. Note, *supra* note 44, at 396.

91. *See* Gemignani, *supra* note 59, at 204.

92. Brannigan & Dayhoff, *Medical Informatics*, 7 J. LEGAL MED. 1, 3 (1986).

93. Nycum & Fong, *supra* note 14, at 5.

94. Walsh & Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 FOOD DRUG & COSMETIC L.J. 171, 178 (1986).

95. Huber, *Memo to Scientists: Stop Innovating!*, SCIENTIST, Jan. 11, 1988, at 13.

96. *Id.*

novative endeavors, strict liability would concentrate production of new computer systems among leading firms, and force out smaller producers who could not find or afford insurance.

Two defenses to strict liability are product misuse and assumption of the risk. Mere use of a complicated expert system by one without expertise in the specific area might constitute an implied assumption of the risk. Due to the high risk of failure and the arguably intolerable burden on computer manufacturers[97] to protect against these risks, manufacturers may insist on a total liability disclaimer. Like the warning on a cigarette package, warning of this high risk could insulate manufacturers from strict liability for malfunctions.[98] "In the case of a medical expert system designed for physician use, imposition of strict liability upon the practitioner user may actually discourage physicians from using expert systems as a means of double-checking and verifying diagnoses and planned treatments."[99]

VII. POLICY REASONS WHY PHYSICIANS AND HOSPITALS SHOULD NOT BE SUBJECT TO STRICT LIABILITY

The reasons for applying strict products liability to hospitals and physicians are outweighed by opposing reasons. The first step in determining liability is deciding whether the hospital is the manufacturer or the purchaser of the program. One argument states that a hospital is in a position to inspect a program upon delivery and also when it is modified or repaired; it selects the program initially and can readily protect itself through insurance.[100] In most cases where injured patients have sued hospitals, courts rejected strict liability for injuries caused by medical products supplied by hospitals, and held the product manufacturer liable rather than the hospital.[101] However, if the hospital itself was the manufacturer of the expert system, there would be no reason for not treating it like any other manufacturer. Arguably, strict liability would not prevent the risks that negligence law currently does not cover. It also can be argued that holding doctors and other medical professionals strictly liable could actually reduce the quality of medical care because they would have less incentive to purchase time saving equipment.[102]

Overall, the best theory of liability for a physician's use of a defec-

97. *See* Gemignani, *supra* note 59, at 201.

98. *See id.*

99. Comment, *supra* note 3, at 518.

100. *See* Brannigan & Dayhoff, *supra* note 1, at 138-39.

101. *See id.* at 140. *See also* Morris, *Physician and Hospital Liability for Defective Products Used in the Treatment of Patients*, 46 INS. COUNSEL J. 566 (1979).

102. *See* Comment, *Computer Software and Strict Products Liability*, 20 SAN DIEGO L. REV. 439, 450 (1983).

tive expert system is professional negligence. A defect in a medical expert system does not immediately produce an injury. The harm results when the physician fails to realize that the program's diagnosis or suggested treatment is inaccurate and proceeds with the system's suggestions.[103] "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."[104] Also, a patient contracts for the physician's services, and the physician is not using the system to earn a profit. However, it might be argued that he is using the expert system to save time and increase accuracy, and thus enhance his earnings per unit of time which does make him an entrepreneur, like the manufacturer. Nevertheless, "forcing a physician to internalize higher insurance costs under a strict liability standard will contribute to an increase in medical expenses that may be unwarranted."[105]

Such potential liability would thwart use and development of expert systems. If physicians were subject to strict liability when using expert systems, then they might refuse to use these systems and instead research medical records by hand and use medical books for diagnostic purposes. This would cost patients more money as more time is spent. It is arguably economically more efficient to hold the physician to a negligence or professional liability standard for his service in interpreting the expert system's advice. In addition, under a professional negligence standard, *res ipsa loquitur* aids the plaintiff's burden of proof. With *res ipsa loquitur*, if the expert system is found to be nondefective, then the only reasonable conclusion is that the physician was negligent in his professional judgment. Physicians also might be held negligent in using a defective system if they knew or should have known that it was defective. Finally, if the expert system was defective, the plaintiff could recover from the manufacturer separately on a products liability theory.

VIII. COMPUTER SYSTEMS AND THE NEW BIOLOGY

The previous legal analysis and policy considerations can be applied to injuries resulting from computer systems used in the area of the new biology. Are these systems considered services or products? Many of the same questions and policy considerations applied above will be instrumental in determining the most appropriate standard of liability.

An expert system already has been developed to handle one area of the new biology: the role of consent in medical ethics. Although computer systems have not reached the sophistication of the expert systems

103. *See* Comment, *supra* note 3, at 497.
104. *Id.*
105. *Id.*

used for medical judgment, they are presently utilized in procuring organs donated for transplantation. Another area where use of an expert system or computer networking system someday might be utilized is surrogate parenting. It is likely that a surrogate searching and matching system would incorporate functions of the existing expert systems used for consent as well as a networking service.

A. EXAMPLE OF A NEW BIOLOGY EXPERT SYSTEM

The British Medical Association, with the endorsement of the Central Ethical Committee published COMET (an acronym for Consent to Medical Treatment), the first expert system to incorporate a comprehensive set of rules of law and medical ethics relating to consent to medical treatment.[106] COMET does not address many controversial topics such as euthanasia, human procreation, or abortion; it deals only with the legal and moral obligations of the medical professional involved in the case.[107] COMET uses over one hundred rules and is configured as an interactive question-and-answer program. Once the system acquires enough information through its questioning, it reaches a final conclusion on whether it would be ethical for the medical professional to treat the patient in the circumstances described.

On its opening screen, COMET announces the names of its authors and publisher, explains the program's limitations, and sets forth what appears to be a disclaimer stating that the user is ultimately responsible for making decisions; at the end of each session a postscript explains that the user may well disagree with the system's reasoning and should therefore discuss the case with teachers or colleagues.[108] One author describing COMET held this opinion as to the liability issue:

> "Like all expert computer systems, COMET can only be an *aid*, either for teaching or for decision-making. In any real case, a decision affecting the life or health of others can only be made by the individuals whom the law authorizes to make it, and the responsibility for making such decisions, and for their consequences, is theirs and theirs alone."[109]

Also programmed into COMET is a bias *against* medical intervention when there is any question about the legal or ethical position of consent to treat. Its authors have suggested that COMET will be useful as a teaching aid for medical students to familiarize themselves with the questions that ought to be asked and as an aid to doctors in difficult

106. *See* Sieghart & Dawnson, *Computer Aided Medical Ethics*, J. MEDICAL ETHICS 185, 185 (1987).

107. *See id.*

108. *See id.* at 187.

109. *Id.*

cases. The program is written in BASIC language, is available on diskette, and can be purchased by mail from London.

The COMET expert system is packaged as a finished product in a tangible diskette. It is available by mail-order and placed in the stream of commerce. Arguably, it is a product and should be subject to strict products liability. However, whether or not that liability extends beyond the physical diskette rests a good deal upon how its disclaimer will be interpreted. Its advice is directed solely to medical personnel and because of its bias against medical treatment when consent is uncertain, injury would result only in the case of nontreatment. Since a physician's professional judgment is required, this arguably breaks the chain of causation necessary for strict liability. However, if medical personnel rely upon COMET as a standard tool, it may achieve the status of any other medical instrument, and then the manufacturer's liability for injury due to a manufacturing defect might be similar to the liability of a manufacturer of a defective scalpel.[110]

B. COMPUTER NETWORKING SYSTEM FOR ORGAN TRANSPLANTS

Organ transplantation is one area of the new biology that presently employs a computer system to assist in searching for donors. About ten years ago, Jean-Francois Borel discovered the drug Cyclosporin. This drug inhibits the donee's rejection of transplanted organs without destroying the body's ability to fight infection. Since the drug minimizes the danger of rejection, the demand for organs has rapidly increased.[111]

The medical profession has realized the need for a fair and equitable system of distribution. In the past, media campaigns by families, pleading for organs to save a loved one's life were necessary. "[H]ow deftly someone [could] manipulate the media to get public attention" often determined who lived and who died.[112]

In response to this need for fair and equitable distribution and procurement of organs, the United Network for Organ Sharing ("UNOS"), a non-profit organization, was developed. The National Organ Transplant Act of 1984[113] (the "1984 Act") gave the Secretary of Health and Human Services authority to assure the establishment and operation of an organ procurement and transplantation registry and provided federal

110. *See* 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 (App. Div. 1968), *aff'd per curiam*, 53 N.J. Super. 259, 250 A.2d 129 (1969) (the manufacturer of a defective hypodermic needle should be liable, not the dentist).

111. *See* Chapman, *The Life-and-Death Question of an Organ Market*, FORTUNE, Jun. 11, 1984, at 111.

112. *Id.*

113. National Organ Transplant Act, Pub. L. No. 98-507 (1984), *reprinted in* 1984 U.S. CODE CONG. & ADMIN. NEWS (98 Stat.) 2339.

grants to organ procurement organizations. In 1986, the federal government awarded UNOS a contract to establish the Organ Procurement Transplant Network ("OPTN"), a nationwide computer networking system. To accomplish this, UNOS utilizes the VAX computer system (manufactured by Digital Equipment Corporation).

Regional organ procurement agencies register with UNOS to gather information on every possible donor and recipient. A single national priority list for particular organs is produced based on the recipients' medical status, blood type, antigenic types, length of time on the waiting list, and logistics.[114] A matching system accompanies the computerized registry of potential recipients. This links available organs with recipients and provides a national, coordinated mechanism for efficient distribution of all available organs.[115] The law requires hospitals with transplant centers and facilities for organ donations to become members of UNOS in order to receive Medicare and Medicaid payments.[116] Although the federal government closely regulates the UNOS organization, the 1984 Act does not insulate the organization from liability.[117]

The UNOS organ networking system has become an established tool in aiding physicians and hospital personnel, but who is liable when something goes wrong?[118] Since hospitals must register with UNOS, a physician who fails to use the system would be held liable for professional malpractice under the doctrine of negligence *per se*. Policy rationales similar to those that apply when a physician negligently uses or fails to use a diagnostic expert system apply here. To encourage use and development of this program, physicians must comply with established practices.

It is imperative not to apply too stringent a liability standard to the computer system manufacturer, because authorization of the grant program is based on a three-year appropriation. If the federal government should decide to contract with a different organization in the future, it is important not to inhibit competition among organizations. If one company was held strictly liable for a malfunction that led to an improperly matched or unprocured organ, other manufacturers would be

114. Telephone interview with Kelly Straw, Public Relations Department, United Network for Organ Sharing (Mar. 25, 1988) [hereinafter Telephone Interview with UNOS].

115. *See* S. REP. NO. 98-382, 98th Cong., 2d Sess. 4, *reprinted in* U.S. CODE CONG. & ADMIN. NEWS 3975, 3978 [hereinafter SENATE REPORT].

116. Telephone Interview with UNOS, *supra* note 114.

117. *See* H.R. CONF. REP. NO. 98-1127 (1984), *reprinted in* U.S. CODE CONG. & ADMIN. NEWS 3989, 3940.

118. *See supra* text accompanying notes 3,4. This Note focuses on the liability pertaining to two classes of defendants — manufacturers of the computer systems and the doctors and/or hospitals that use them. It should be noted that there are many additional intermediary parties, such as tissuing labs, that could be held negligent in the handling or distribution of information to UNOS.

discouraged from developing comparable computer systems. Irrespective of the inhibiting effects strict liability likely would procure, the VAX system is arguably a computerized service (not a product) and thus subject to a negligence doctrine. Because the networking system requires constant input and flow of new data, it is arguably a service, rather than a product. The essence of the system is not a tangible, mass-produced, finished product, but an on-going service. Hospitals do not own the system; they pay user fees. Although one can argue that the system is put into a stream of commerce, this stream is strictly confined to hospitals and medical personnel. When such a service is involved, negligence is the appropriate theory of liability.

C. COMPUTER SYSTEMS AND SURROGATE PARENTING

In addition to consent to medical treatment, another new biology area which involves a myriad of legal and ethical questions is surrogate parenting. A computer service developed in this field of medicine could borrow ideas for function capabilities from both COMET (an expert system) and VAX (a computer networking system). Before a physician offers services in a surrogacy case, a large number of medical and ethical questions must be answered. Questions to be considered might be: Is the adopting woman unwilling to gestate her own children? Is she biologically incapable of bearing children? Have the appropriate tests confirmed this? Is she emotionally unable to handle her own pregnancy? Or would the rigors of pregnancy interfere with her career? The format of these questions will have to wait for specific legislative enactments.

Some states do not permit money to change hands in a surrogate arrangement.[119] In its report to the Department of Health, Education and Welfare, the Ethics Advisory Board[120] unanimously agreed that alternative forms of reproduction could be obtained only if certain specific items of information were identified, such as the availability of potential effective alternative therapies.[121] The California Civil Code, for example, requires the supervision of a licensed physician for artificial insemination and the consent of the mother's husband; it treats the semen donor as if he were *not* the natural father.[122]

When legislative guidelines are settled for surrogate parenting, an expert system designed to ascertain whether a surrogate relationship

119. *See* Doe v. Kelly, Cir. Ct. of Wayne County, Michigan (1980) (quoted in SHAPIRO & SPENCE, CASES MATERIALS AND PROBLEMS ON BIOETHICS AND LAW 537-542 (1981)).

120. 45 C.F.R. § 46.204 (1987).

121. *See* Ethics Advisory Board (HEW) Report and Conclusions: HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer, 44 Fed. Reg. 35,033, 35,041, 35,045-46 (1979).

122. CAL. CIV. CODE § 7005(a) (West Supp. 1988).

conforms to legal and ethical standards may be developed. Using COMET as a prototype, the system could use an interactive question-and-answer format to aid a physician in deciding whether to assist in a surrogate arrangement. Like COMET, this type of expert system could be sold as a finished product in the form of a diskette with legal changes updated by supplements.

If surrogacy becomes an established practice, expert systems may be useful not only in monitoring procedures once a surrogate has been found, but also in initially searching for the surrogate. Data, such as a surrogate's race, RH factor, geographic location, and genetic history, could be matched with an adopting couple's specific requests. This data could be prioritized using the expert system's deductive principles to find the most suitable surrogate. A list could be generated to aid the physician in narrowing the search for a suitable gestator, similar to the INTERNIST system[123] which generates a list of possible diagnoses.

Like the search for compatible organs, the search for surrogate mothers could be developed into a networking agency which receives and coordinates information from both adopting parents and surrogate mothers. Because the search for a compatible surrogate is not a life and death situation and does not require the speed essential in the search for organs, the federal government probably will not assume control and funding of this practice. In addition, while surrogate parenting is a developing practice, it is estimated that as much as ten percent of our population may be candidates at some time for transplantation surgery.[124] Because of its smaller scope, surrogate searching agencies presumably would develop as private organizations. As independent private services, liability will be a crucial issue in inhibiting or encouraging development of computerized networks.

Arguably, if an expert system that mimics COMET is used to ascertain legal and ethical concerns in surrogacy, it also would be subject to strict liability if distributed as a product. Yet as with COMET, if a disclaimer is used and a physician must intervene to interpret the data, this arguably breaks the chain of causation for strict liability.

With respect to the computer networking services, a physician who negligently relies on data offered by the computer service without using his own professional judgment or performing his own tests could be held liable for professional malpractice in the event of injury to the surrogate or infant (*i.e.*, injuries from overlooked genetic defects or blood type incompatibilities). Providing this service to trained medical personnel, the manufacturers displace liability to the physician who must intervene and use his professional judgment to decide whether the sur-

123. *See supra* text accompanying note 15.

124. *See* SENATE REPORT, *supra* note 115, at 3985.

rogate is medically acceptable. Yet until such networking services are established, public policy may dictate that a more liberal negligence standard should apply, such as when a physician attempts a new procedure in surgery or an experimental cancer treatment. Perhaps such a standard would hold a doctor liable only if he were grossly negligent or displayed intentional misconduct.

Could the computer system manufacturer be held to a products liability standard if the computers routinely mismatched RH types? Since a surrogate searching service is arguably a service and not a product, probably not. Unlike COMET, this is not a static, finished, tangible product, and if a plaintiff actually could pinpoint the defect to this hypothesized degree, he could recover on a negligence theory. Manufacturers and suppliers of this system probably would supply only to hospitals and licensed physicians rather than to the general public. Policy also dictates that surrogate searching services be subjected to a negligence standard rather than to a strict liability standard. Manufacturers of computer systems used in this service probably would be unable to find or afford liability insurance to cover the risks involved. If, due to error in an expert system, a surrogate was improperly matched and gave birth to a defective child, an entire class of plaintiffs would bring suit — the adopting parents, the surrogate parent, the child's guardian *ad litem*, and perhaps the state, which might be required to provide for the child's care. To further encourage development of a networking system and to comply with policy concerns, a negligence standard might even be too inhibiting. Because the area is so new, manufacturers may be unable to obtain liability insurance. A liberal negligence standard which requires the manufacturer to develop the system in good faith, without gross negligence or intentional misconduct would encourage development of this important tool. Under a liberal negligence standard, a jury would be instructed to relax the due care element.

With respect to both an expert system designed to ascertain whether a surrogate relationship conforms to legal and ethical standards and computer networking systems, physicians held to a professional negligence theory might refuse to use these systems if it would entail an added risk of liability. They would espouse the theory that "Americans can't afford to correct or improve upon our current stores of knowledge. The Wright brothers wouldn't get off the ground today."[125] Unlike established diagnostic systems which truly perform traditional diagnostic functions and like the Wright brothers, these expert systems and services embark upon an entirely new field in medicine. Thus, to encourage development of this new technology, a li-

125. Huber, *supra* note 95, at 13.

ability standard should inspire maximum care without inhibiting development.

IX. CONCLUSION

The utilization of computers in medicine has brought increased accuracy, efficiency, and life-saving technologies to this area of science. However, computer-aided medicine also can contribute to an increased risk of injury, particularly when humans rely on computers too much. Diagnostic expert systems, which mimic the cognitive methods of experts, are especially vulnerable to over-reliance.

When a professional diagnostic expert system or an in-home system causes injury to a patient or consumer because of a manufacturing defect, the manufacturer should be held to a strict products liability standard. Manufacturers also are liable for defects in design; however, this is a modified version of strict liability, more closely resembling negligence. If the injury resulted from negligence in the physician's professional judgment, then a plaintiff is limited to a professional negligence theory against the physician. A negligence standard is also the appropriate cause of action when a system is custom-made for a hospital or physician. Arguably, when a computer system is specifically tailored for one consumer, it should be classified as a programmer's service, not a mass-produced product. Computers also are making their way into new areas of medicine. As with diagnostic systems, when an expert system in this field takes the form of a mass-produced product, strict liability is the appropriate cause of action to bring against manufacturers. Conversely, if the computer system is really an on-going service operation, a negligence standard applies.

In determining the theory of liability that legally and ethically is most appropriate, many variables are involved. These variables include whether the computer system is a service or a product; whether the defect is one of design or manufacture; whether the party at issue is best situated to prevent injury; the affordability and availability of insurance; customer expectations; and whether the intervention of a physician breaks the chain of causation. The applicable liability theories ideally should provide incentives to doctors and manufacturers to maximize safety while at the same time stimulate innovation and reduce the cost of medical care.

Hope Mortimer