

Foreword

REMOVING SOME IMPEDIMENTS TO DEVELOPMENT OF AMERICA'S THIRD- AND FOURTH-GENERATION HEALTH CARE DELIVERY SYSTEMS: LEGAL ASPECTS OF COMPUTER MEDICINE†

ABSTRACT

In this full-length Foreword, John Norris and David Szabo discuss the trend towards the development of substantially integrated and automated multi-institutional health care delivery systems. The authors then address the legal, economic, and policy implications of regulating medical computer systems. They conclude by noting that the rational allocation of costs and risks is a necessary step in developing new systems for health care delivery.

I. ADDRESSING THE LEGAL IMPLICATIONS OF MULTI-INSTITUTIONAL SYSTEMS AND COMPUTER MEDICINE

On several occasions during recent years, John Norris has spoken or written (sometimes in the *Journal*) of the critical need for our country, as well as for many other countries—especially certain Third World countries—to begin using innovative techniques for restructuring their health care delivery systems to obtain more and better health services at a lower aggregate cost. In these appeals, two techniques have always been stressed.

The first technique is the increased integration (vertical as well as horizontal) of health-care “cottage” facilities into comprehensive single hospital and multi-hospital regional health care delivery systems and shared-services organizations—both important components of third-generation health care delivery systems.¹

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¹ Physicians' offices were the first-generation systems. Unintegrated hospitals, clinics, nursing homes, homes for the aged, clinical laboratories, and the like constitute the second-generation systems. The horizontally (generally multi-hospital) and vertically (generally single hospital) integrated multi-institutional systems now being developed will constitute the third-generation systems.

The second technique is the increased automation (primarily through computerization) of significant elements of second- and third-generation health care delivery systems to produce so-called fourth-generation health care delivery systems that are both integrated and automated.

An important objective of both techniques is reduction of the aggregate cost of health care skilled labor (and thereby the aggregate cost of health care). In small part, this objective could be achieved through the elimination of nonessential personnel positions by increased integration of systems and of resources. In large part, it could be achieved, as technology advances, through substitution, where appropriate, of relatively abundant and inexpensive automated systems for relatively scarce and expensive skilled labor.

This Foreword focuses primarily on certain legal aspects of health care automation. It is the authors' strong conviction, however, that more widespread availability of cost-effective computer-assisted medicine is essential if the first technique (the use of third-generation integrated health care delivery systems) is to realize fully its quality-enhancing and cost-reducing potential. The authors hold an even stronger conviction that, unless both techniques are applied on a large scale, during this decade the price of advanced health care services will become (or in many instances will remain) totally unaffordable to the overwhelming majority of the world's populations.

Such a pivotal role for computer-assisted medicine produces a vital role for computer health law: providing a mechanism for distributing appropriately the costs and benefits of progress in health care computer technology. For this reason, a discussion of computer health law has current importance.

II. COMPUTER HEALTH LAW

Computer health law is relatively new: the first national conference on the subject was held in 1974.² The topics covered by that conference are still the nation's major computer health law concerns. They include the computer health law implications of computer assistance in (1) medical interviewing, (2) medical diagnosis, (3) selection and application of therapeutic procedures, (4) maintenance of patient records, (5) review of physician performance (through PSROs, medical audits, and medical review), (6) administration of hospitals and physicians' offices, and (7) medical education.

Future editions of the *Journal* will contain information on the legal implications of the implementation and operation of horizontally or vertically integrated single hospital and multi-hospital regional health care delivery systems and shared-services organizations. One source of such information will be the National Conference on the Legal, Managerial, and Financial Aspects of Multi-Institutional Systems, to be held in Boston on October 22-23, 1981, and chaired by John Norris. Materials flowing from this conference will be submitted to the *Journal* for possible publication.

²This 1974 National Conference on the Legal Aspects of Automated Health Care Systems was held in Boston and was co-chaired by John Norris.

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The computer health law implications of each of these uses are of increasing importance. However, since 1974, the implications of the uses affecting clinical practice—medical diagnosis, and selection and application of therapeutic procedures—have emerged as the most important. This emphasis has occurred primarily because of a rapid increase in technology in these areas.³

Unfortunately (some would say ironically), the clinical use of medical computer systems can be obtained only at the cost of new forms of professional and product liability risks for hospitals, physicians and nurses, and computer hardware and software distributors and manufacturers. These risks are of at least two types: (1) the risks arising from the failure to adopt and to make appropriate decisions as to the use of the new computer-medicine technology, and (2) the risks arising from the malfunction of medical computer systems.

III. THE PROFESSIONAL, JUDICIAL, OR ECONOMIC MANDATE TO USE MEDICAL COMPUTERS

As new developments in medical practice become more widely accepted, standards of required conduct applicable to medical professionals and hospitals gradually evolve to embrace these new developments. Usually, the medical profession itself alters these standards to fit new developments. Occasionally, however, the courts have become impatient with the slow evolution of professional standards. The well known case of *The T.J. Hooper*,⁴ and later cases, such as *Helling v. Carey*,⁵ are examples of the courts' willingness to take the lead in setting minimum legal standards of care. Although the courts have been reluctant to enter that realm, as the use of computers becomes more common in medical practice, possibly the medical profession, but, if not, later the courts, are likely to decide that the use of computer systems in certain clinical practice situations is part of the "legal" standard of "due care."

Given the current unavailability of reliable, low-cost computer systems for diagnosis and treatment, present chances of a court's imposing liability for failure to use a computer are relatively remote. As computer technology advances, however, the likelihood grows that a court will find that minimally acceptable levels of care demand the use of medical computer systems by hospitals, physicians, and nurses.

Long before the use of such systems is either professionally or judicially mandated, however, medical computer systems probably will become com-

³ In recent years medical computers have gone well beyond the role of passive physician's assistants and, in some American hospitals, have been used to control directly the administration to patients of drugs and whole blood or plasma.

⁴ 60 F.2d 737 (2d Cir. 1932), cert. denied, 287 U.S. 662 (1933).

⁵ 83 Wash. 2d 514, 419 P.2d 981 (1974).

monplace in hospitals and medical practice due to economic considerations. Current pressures to reduce hospital costs are intense. Recent advances in computer-assisted medicine offer the promise of making health care substantially less skilled-labor intensive, and ultimately, less expensive. At the same time, advances in computer technology are increasing the uniformity, comprehensiveness, quality, and effectiveness of health care delivery.

In our view, this potential for increased quality and effectiveness and decreased aggregate cost, more than any other factor, enhances the likelihood that widespread use of computers in clinical medicine will become a reality during this decade.

IV. LIABILITY FOR INJURIES CAUSED BY MEDICAL COMPUTER MALFUNCTIONS: NEGLIGENCE OR NO-FAULT STANDARD?

As the role for computers in medical practice increases, so does the probability that a medical computer system will, within the next few years, be found by a court to be a contributing factor in a provider-caused personal injury. Such a finding undoubtedly will be of great importance to all defendants in the case. An error in a medical computer program, for example, could cause the computer to suggest an incorrect diagnosis, to miss a potentially dangerous drug interaction, or to fail to call for necessary treatment, such as the administration of needed whole blood or plasma. The result, if relied upon by the health care providers, could be catastrophic to the patient, and the damages payable by the defendants could be substantial.

Under a negligence theory of liability, if a hospital installs a computer system, makes it available to staff physicians and nurses (and thereby to their patients), and is negligent in the selection, installation, operation, or maintenance of the system, or in deciding when it is to be used, the institution would be liable directly to the patient (or if deceased, to the patient's estate) for any resulting injury. Similarly, a physician who negligently relies on an improper computer diagnosis, or who negligently supervises computer-controlled treatment, probably would be liable directly to the patient for the patient's injury.

Under a no-fault theory of liability, if a provider, either a hospital or a physician, could appropriately be characterized as a manufacturer or distributor of a computer system, the provider would be liable for resulting injuries, whether or not it was negligent. A court might find, for example, that a hospital that makes a computer-medicine system available to patients is in the business of selling computer programs as products. It could then hold the hospital liable for design defects in the system, even though the hospital could not have prevented or removed those defects.

Widespread development, installation, implementation, and operation of hospital-based systems capable of providing computer-assisted health care,

therefore, could open up a whole new area of hospital and physician malpractice litigation.

Physicians working with computers will, in most jurisdictions, be required to continue relying most heavily on their own medical judgment, just as they now must rely on their own medical judgment when interpreting the results of clinical laboratory tests, whether or not the results are the product of an automated system.

It is unclear under a negligence theory whether health care professionals who rely on a physician's judgment, such as nurses, are less likely to be held liable if they negligently rely on a diagnosis by a computer-assisted physician than if they negligently rely upon a diagnosis by an unassisted physician. The law, however, needs a person to whom liability can be attached when negligence is present. Therefore, it is clear that nurses are more likely to be held liable for negligently relying upon an improper diagnosis when only a medical computer (and no physician) has been involved. Fortunately for nurses, it seems unlikely that any computer system will be developed soon that can be trusted to diagnose or to treat independently of physician input, or that the public soon would accept such an advance.

Perhaps the most interesting aspect of computer-caused malpractice is its relationship to the possible liability of medical computer software (program) developers and distributors. One major problem with the concept of computer software liability is the difficulty of characterizing legally the production, use, and distribution of such software. As a result, there is much confusion about which legal theory of liability should be applied. Plausible legal theories for allocating the costs of medical computer software caused injuries include (1) breach of warranty, (2) breach of contract, (3) ordinary negligence, (4) professional negligence, and (5) strict product liability in tort. The eventual judicial choice of the most appropriate legal theory for use in the medical computer area will have far-reaching consequences for health care providers, for medical-computer hardware and software manufacturers, and for patients.

V. COMPUTER-CAUSED MALPRACTICE AND THE "MEDICAL-MALPRACTICE INSURANCE CRISIS"

Attorney Brannigan and Dr. Dayhoff, in an Article appearing in this issue of the *Journal*,⁶ make a persuasive argument for the application of strict product liability rules to hardware and software manufacturers of medical computer systems. One question not touched upon in their Article, however, is how the application of strict liability rules to computer-caused iatrogenic personal injuries would effect the price and availability of hos-

⁶ Brannigan & Dayhoff, *Liability for Personal Injuries Caused by Defective Medical Computer Programs*, 7 AM. J. L. & MED. 123 (1981).

pital, physician, and nurse liability insurance. Because of such developments, would we, for example, again be confronted with a version of the 1970s "medical malpractice insurance crisis?"

In many jurisdictions, it is now extremely difficult to insure physicians practicing high-risk specialties against professional liability. Conceivably, it would be even more difficult to insure the manufacturer or distributor of a medical-computer system against strict product liability risks. In all probability, application of strict liability rules to medical-computer systems would increase the initial costs of making those systems generally available. As a result, economic considerations could force us into the unfortunate position of having to choose between two nearly equally undesirable alternatives. First, we could reduce the availability to patients of legal redress for computer-caused personal injuries. Second, we could make certain kinds of computer-assisted medical services totally unavailable to them. In a sense, the choice of applying a product liability theory rather than a negligence liability theory to such situations is a choice of how to allocate limited health care resources and the associated social and economic costs.

VI. CONCLUSION

In our view, computer-assisted medicine is one of today's most exciting and dynamic areas of medical progress. The social benefits of such systems, particularly when used in conjunction with the development of multi-institutional systems, should far outweigh their social and economic costs. In drawing the attention of attorneys, health care providers, hospital trustees, and computer developers, manufacturers, distributors, and programmers to such important computer health law topics as the potential legal liability of such persons for computer-caused personal injuries, Brannigan and Dayhoff are performing an important function. Moreover, they remind us not only that all progress has social costs, but also that there are many intelligent and socially productive ways to distribute those costs.

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