HARVARD JOURNAL
on
LEGISLATION

VOLUME 15 APRIL 1978 NUMBER 3

HEALTH CARE SYMPOSIUM

STATUTE

INFORMED AND SUBSTITUTE CONSENT TO HEALTH CARE PROCEDURES: A PROPOSAL FOR STATE LEGISLATION
Susan K. Gauvey, Susan B. Leviton, Nancy B. Shuger & Judith K. Sykes 431

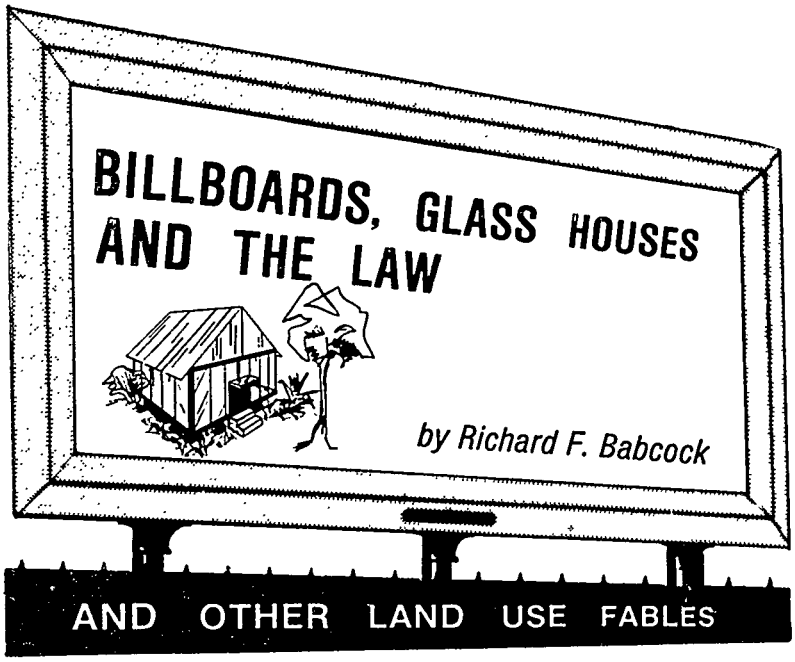
NOTES

REGULATING MEDICAL SERVICES AND THE PROSPECTS FOR MEDICAL GOODS
David B. Hingstman 497
PRICING BAD BLOOD: REASSESSING LIABILITY FOR POST-TRANSFUSION HEPATITIS
Edward R. Wiest 557
HOSPITAL COST CONTROL: SINGLE-EDGED INITIATIVES FOR A TWO-SIDED PROBLEM
Ronald Greenspan 603

BOOK REVIEWS

Feldstein, HEALTH ASSOCIATIONS AND THE DEMAND FOR LEGISLATION: THE POLITICAL ECONOMY OF HEALTH
Joanna Lion 669
RECENT PUBLICATIONS 685
BOOKS RECEIVED 691

Published four times during the academic year (December, February, April, and June) by the Harvard Legislative Research Bureau, Langdell Hall, Harvard Law School, Cambridge, Mass. 02138. ISSN 0017-808x. Second-class postage paid at Boston, Mass.
Subscriptions per year: United States, $7.50 (single copy, $2.50); foreign, $9.00 (single copy, $3.00). Subscriptions are automatically renewed unless a request for discontinuance is received.
Back issues prior to the current volume are available from Fred B. Rothman & Co., 10368 W. Centennial Road, Littleton, Colorado 80123, at $5.00, check with order. For prices of complete back volumes or of sets, please inquire of Fred B. Rothman & Co.



A collection of insightful and humorous essays which have previously been published in leading professional magazines. This work is a quotable source by a knowledgeable and nationally known professional in an important and controversial field. Because the tone is both scholarly and light in treatment, the work is easy to read as well as interesting. The author's goal in compiling this collection is to make the reader rethink his or her conventional position and perhaps initiate new ideas and concepts in the field of zoning and urban planning.

1 Volume, 1977, paper cover, over 200 pages $7.95
Plus postage and handling . . . . . $ .50

- ☐ Please send me BILLBOARDS, GLASS HOUSES AND THE LAW: AND OTHER LAND USE FABLES.
- ☐ In 15 days, I will send $7.95 plus 50¢ postage and handling ($8.45).
- ☐ Payment of $7.95 enclosed. Shepard's to pay postage & handling.

NAME .....

FIRM .....

STREET .....

CITY..... STATE.....ZIP.....

Subject to acceptance in Colorado Springs, Colorado

shepard's, inc. **of Colorado Springs**

P. O. BOX 1235, COLORADO SPRINGS, COLORADO 80901

STATUTE

INFORMED AND SUBSTITUTE CONSENT TO HEALTH CARE PROCEDURES:

A PROPOSAL FOR STATE LEGISLATION

SUSAN K. GAUVEY*
SUSAN B. LEVITON**
NANCY B. SHUGER***
JUDITH K. SYKES****

The controversy surrounding increasingly sophisticated artificial life support systems reflects, in part, the uncertainty and frustration of many patients and health practitioners confronted with complex medical procedures. Common law recognition of the right to informed consent — choosing to be treated with an understanding of the treatment's implications — has failed to keep pace with advances in medical technology. Moreover, recognition of the right to informed consent presents special problems in cases in which an adult patient may be incapable of consenting to proposed medical treatment. As dramatized by the recent case of In re Quinlan, *current procedures for obtaining substitute consent are lacking. The authors define the*

---

* Co-director, Community Mental Health Legal Services Program of the Legal Aid Bureau, Inc., Baltimore, Maryland. B.A. 1970, Rosary College; J.D. 1973, Northwestern University.

** Deputy Director, Developmental Disabilities Law Project, University of Maryland School of Law. B.A. 1969, J.D. 1972, University of Maryland.

*** Staff Attorney, Developmental Disabilities Law Project, University of Maryland School of Law. B.A. 1971, Cornell University; J.D. 1974, University of Maryland.

**** Assistant Attorney General for the State of Maryland with the Department of Health and Mental Hygiene. B.A. 1951, Goucher College; J.D. 1969, University of Maryland. The opinions stated in this article are those of the author in her personal capacity and should not be construed as representing the opinion of the Attorney General or his office.

issues involved in the informed and substitute consent controversy, focusing on the need for a comprehensive and systematic approach in this area. They explore in detail current judicial and legislative responses to the problem noting their failure to provide efficient mechanisms whereby substitute consent may be obtained without unduly delaying treatment or sacrificing patient rights. The desirability of legislative rather than judicial resolution of the controversy is then discussed. After noting that legislative initiatives to date have been inadequate, the authors present a unique Model Act designed to remedy the problems of the current approach to substitute consent.

Introduction

Recent advances in the treatment of degenerative diseases have increased public recognition of and heightened sensitivity to the rights of persons receiving medical care. Perhaps the most important of these rights is the right to informed consent. The right to informed consent is the right of a person to receive all of the information relevant to the making of a rational decision concerning proposed medical treatment, to have that information explained to him in terms he can reasonably be expected to understand, and to make his own decision whether to undergo or to forego treatment.

Attempts of health practitioners and hospital administrators to respect the right to informed consent have brought into focus a number of problems. One of the most pressing of these problems is that of the adult patient who, as a result of temporary or permanent mental incapacity, cannot give informed consent either to the institution or withdrawal of medical treatment. The patient's incapacity may arise from a variety of causes, including mental illness, mental retardation, or a state of unconsciousness or semi-consciousness related to a physical ailment. Regardless of the immediate cause of the incapacity, it is necessary in these cases to have someone substitute for the patient in deciding whether to consent to treatment.

Some might wish to place the patient's physician in the position of substitute decision maker. But such a policy would be inappropriate in the absence of a life-threatening

situation. A physician is apt—and arguably ought[1]—to choose to treat any medical condition and to treat it ag-

---

1 Dr. Alan Stone, Professor of Law and Psychiatry, Harvard Law School and Harvard Medical School, has argued in favor of such a role for physicians:

> Most of us, patients and physicians alike, would agree with the spirit of the first section of the medical canons of ethics: "The principal objective of the medical profession is to render service to humanity with full respect for the dignity of man. Physicians should merit the confidence of patients entrusted to their care rendering to each a full measure of service and devotion." AMERICAN MEDICAL ASSOCIATION, THE PRINCIPLES OF MEDICAL ETHICS § 1 (1973).
>
> It is when we attempt to apply this canon to the dying patient that we recognize the potential conflict between the "dignity of man" and the "full measure of service." Many now believe that the development and general use of mechanical life support systems which sustain biological existence without sentient life demeans the dignity of both man's life and his death. *See, e.g.,* Brown & Truitt, *Euthanasia and the Right to Die,* 3 OHIO N. L. REV. 615 (1976). There are other instances as well where the advances of modern medicine have brought with them a true ethical dilemma for physicians: the choice between two right actions — doing everything one can against all odds and allowing the patient to die in dignity. *See* Heymann & Holtz, *The Severely Defective Newborn: The Dilemma and the Decision Process,* 23 PUB. POL'Y 381 (1975).
>
> Whatever moral calculus is used to resolve this ethical dilemma and whatever procedures are adopted to implement solutions should take into account the role of the physician and the connotations of that role for society at large.
>
> The patient is helpless and dependent when serious life-threatening illness occurs. At such moments it is crucial both to the patient and family that they can turn to their personal physician with absolute confidence that he is on the side of life. Given the bureaucratization of medicine it is equally important that the patient feel the same way about the hospital — that the institution is on the side of life. This is a moral good and a utilitarian benefit for society at large. It makes sense for all of us to define physician and hospital as worthy repositories of trust and confidence — on the side of life when any of us is facing death.
>
> This role definition is sufficiently valuable to society that it must be taken into account in resolving the dilemma between full service and human dignity. That means that we should not leave it to the physicians to resolve their dilemma or encourage them to deal with it behind closed doors.
>
> Obviously, I do not mean to suggest that physicians are incapable of resolving the dilemma properly; indeed they may in some respects be the best suited to make the painful decision. However, I am suggesting that as we move toward public recognition of the dilemma and adopt formal approaches to resolving it the personal physician should not be defined as the central figure charged with choosing between life and death. Should the physician's role achieve such a new definition, all of us would face the threat of illness and the possibility of a death that could be averted with a lessened sense of confidence and with the anxious feeling that the physician is a double agent who serves death as well as life.

Unpublished Statement of Dr. Alan Stone (October 7, 1977) (on file with *Harvard Journal on Legislation*).

gressively. Moreover, placing the physician in the role of substitute decision maker involves an implicit presumption that a patient would consent to anything his physician would prescribe. This presumption, whether true or false, fails to respect the patient's interest in informed consent. A substitute decision maker acting in the patient's stead must be guided by rational choices which he perceives would be in the patient's best interests. In a given case, foregoing treatment might be one such rational choice. Undergoing treatment disapproved by a particular physician, or by the majority of the medical profession, may be another. The personal physician cannot be expected to consider adequately the full range of alternatives when some may violate his personal beliefs or professional standards.[2]

Automatic appointment of a relative of the incapacitated patient also does not ensure that the patient's right to informed consent will be protected. The patient may have no family, or family members may be too emotionally distraught to decide complex questions of medical treatment. Additionally, there may be conflicts of interests which would preclude the family from making decisions in the patient's best interests.

Judicial response to the problem of substitute consent has not provided satisfactory resolution of the complex issues at the core of the controversy. Illustrative of judicial initiatives in this area is the New Jersey Supreme Court's decision in the *Quinlan*[3] case. Although the question of the patient's competence to decide for herself was not at issue in *Quinlan* as it is in more "routine" cases, that case dramatized both the

---

2 Dr. Seymore Halleck states, in his article that: "The decision to impose treatment upon a nonconsenting patient requires extraordinary, complex medical and ethical judgments. I do not believe that such decisions should be made by a single doctor except in emergencies." Halleck, *Legal and Ethical Aspects of Behavior Control,* 131 AM. J. PSYCH. 381, 383 (1974).

3 *In re* Quinlan, 70 N.J. 10, 355 A.2d 647 (1976). In *Quinlan,* the court declared that if, upon the concurrence of the guardian and family, the attending physicians determined that there was no possibility of Quinlan's returning to a cognitive, sapient state and that the life-support apparatus should be discontinued, they had to consult with the hospital "Ethics Committee" or like body of the institution where Quinlan was hospitalized. If that body agreed with the determinations of the

substantive and procedural difficulties associated with providing for substitute consent. The court struggled to devise a solution to the problem which *Quinlan* presented, but articulated no rules which can be readily applied in substitute consent cases. As *Quinlan* illustrates, the problems of substitute consent are complex and become even more so as medical procedures become more intrusive and irreversible, as in cases of amputations and major surgery, and still more complex when fundamental constitutional rights are also involved, as in the cases of sterilizations and psychosurgery.

Although the legislature is the logical forum for developing the comprehensive and systematic approach the problem of substitute consent demands, legislative initiatives in this area have also been inadequate. The development of legislatively-sanctioned procedures for obtaining substitute consent generally has not kept pace with the recognition of the need to obtain them. Absent such procedures, neither the health care profession nor the legal profession can fulfill its obligation to respect a patient's right to informed consent. It is unrealistic to expect health care professionals and administrators to be meticulous about obtaining informed consent in the absence of clear guidelines. Without relatively simple and efficient rules, it is similarly unrealistic to expect medical practitioners and courts to heed the necessity for informed or substitute consent when doing so may prevent timely treatment.

Mechanisms must be developed to protect the patient from arbitrary deprivation of his right to make his own decisions and must assure that, any decisions made on his behalf will be in his best interest. At the same time, these mechanisms must provide clear guidelines for determining when a patient is incapable of giving informed consent and provide for the

---

treating physicians, then the life support system could be withdrawn without civil or criminal liability to any participant. 70 N.J. at 54, 355 A.2d at 671.

In fashioning this relief, the court declined to act as the substitute decision maker, although it recognized that earlier courts had so acted. The court's decision was based on its belief that health care decisions should be controlled primarily from within the patient-doctor-family relationship. 70 N.J. at 44-45, 50, 355 A.2d at 666, 669.

designation of a substitute decision maker who will protect the patient's rights.

Development of these mechanisms would be facilitated by legislative consideration of and responses to the problems which are at the heart of the substitute consent controversy. These problems are first, the initial problem of determining a patient's capacity to give informed consent; second, the problem of selecting a substitute decision maker in whom responsibility for deciding for an incapacitated patient can be vested; third, the problem of limiting the authority of a substitute decision maker to decide for the incapacitated patient and choosing the criteria to guide him in making his decision; fourth, the problem of the standard of, and procedure for, review of and appeal from the substitute decision maker's choices; and finally, the problem of which medical procedures to allow prior to the resolution of questions concerning capacity to consent. If these problems were addressed systematically, procedures for obtaining substitute consent would be readily forthcoming.

The law in most states simply does not provide such procedures. The proposed model statute, set out and discussed in this Article, has been drafted in an attempt to fill the gap.[4]

4 For example, in Maryland, where many persons have recognized for some time that the present statutory scheme is inadequate, the impetus for the drafting of the new statute came as a result of the work of an Informed Consent Committee which was established by the Maryland Department of Health and Mental Hygiene in July, 1974.

The Committee, charged with the responsibility to formulate a departmental policy on informed consent, included representatives from the health care and legal professions as well as from interested community organizations. The representatives met over a period of twenty-one months and formulated a policy on informed consent. The policy required each health facility under the jurisdiction of the Department of Health and Mental Hygiene to obtain informed consent before performing treatment procedures. It defined informed consent as "the knowledgeable voluntarily signed permission from the patient or the patient's legally authorized representative for any and *all preventive, diagnostic and/or therapeutic* procedures . . . at least under non-life-threatening circumstances," and set forth requirements for obtaining informed consent. Maryland Department of Health and Mental Hygiene, Informed Consent Committee, Policy on Informed Consent for Preventive, Diagnostic and Therapeutic Procedures (1976) (unpublished; on file with the *Harvard Journal on Legislation*) (emphasis in original). The policy was, however, incomplete because no section covering situations in which certain physical or mental conditions preclude obtaining informed consent from a patient was drafted. The Committee recognized that there was a need for a procedure whereby substitute consent could be obtained without the judicial declaration of incompetence which is

The primary purpose of this work is to focus on the deficiencies in current state law, and to propose and discuss a Model Act against this legal background. The existing state of the law will be summarized, and attempts which have been made to correct the problems which have arisen[5] will be reviewed. Sections of the Model Act will then be examined in depth, and the reasons for the approach taken will be explored.

---

presently required by Maryland law. Since establishment of a new procedure would require a change in the present law, it was decided that completion of the policy would have to await such a change, and a Substitute Consent Committee would be appointed to draft appropriate legislation.

The fact that the proposed legislation grew out of the work of the Informed Consent Committee is important to bear in mind. In drafting this legislation, the members of the Substitute Consent Committee which was subsequently appointed started with certain premises set forth in the Informed Consent Policy. The most significant of these was the provision that the informed consent requirement was applicable to any and all preventive, diagnostic and therapeutic procedures. Because of this requirement, the drafters were faced with the necessity of arriving at a mechanism for substitute consent which would be applicable to all procedures. They did not have the option of proposing a more limited statute applicable only to the most intrusive or hazardous procedures. Similarly, since the policy was applicable to all health facilities, the legislation could not be limited to those where the problem most often arises, such as mental health or mental retardation facilities.

The Substitute Consent Committee, which included physicians, attorneys, and a psychologist, met over a period of twelve months. After thoroughly researching statutory and case law in the area, the Committee drafted a proposed act, attempting throughout to strike a proper balance between the preservation of individual rights and the need for timely delivery of health care. A draft of the proposed legislation was widely circulated to members of the Informed Consent Committee, health care providers in the public and private sectors, legislators interested in the health field, attorneys, public interest groups, and other individuals who had expressed a particular interest in the issues of informed and substitute consent. The proposed Act reflects many of the suggestions and comments which were received.

The proposed Act was introduced into the Maryland legislature in the 1977 session as a departmental bill of the Department of Health and Mental Hygiene. It was introduced in the upper house, as S. 734. It received careful consideration from the Senate Judicial Proceedings Committee, where it was amended to some extent. It was reported out of that committee favorably, debated on the Senate floor and finally defeated in the Senate by a vote of 21 to 20.

It is anticipated that a similar bill will be introduced in the 1978 session. However, in light of some of the comments concerning the cumbersomeness of the substitute consent mechanism as applied to all medical procedures, the drafters are considering limiting these mechanisms to cover only the most serious medical procedures; consent would be presumed, with documentation, to all other procedures to which the patient did not object.

5 Neither the article nor the model statute addresses informed consent to human experimentation, an area which is already extensively regulated on the federal level and by a few states. For federal regulation, *see* Protection of Human Subjects, 45 C.F.R. § 46.101-.122, .201-.211, .301 (1976). For state statutes, *see, e.g.*, CAL. HEALTH & SAFETY CODE 26668-69 (West Supp. 1977); N. Y. MENTAL HYG. LAW § 15.03 (McKinney Supp. 1976-77).

I. SUBSTITUTE CONSENT: DEFINING THE PROBLEMS

It is no longer subject to debate that, except in certain very serious emergency situations,[6] informed consent must be obtained prior to administering medical treatment. But understanding judicial and legislative regulation of the administration of medical treatment requires a discussion of the evolution, function, and operation of the concept of informed consent.

The consensual nature and fiduciary character of the doctor-patient relationship are established common law principles.[7] To a certain degree informed consent is simply a refinement of these principles. The doctrine of informed consent serves other functions as well, and consequently, it has spawned significant legal debate and popular reaction.[8] It promotes individual autonomy and integrity of the patient; it encourages him to engage in rational decision-making; and it enhances health care delivery by increasing doctor-patient communication and reducing physician liability.[9] Indicative of the importance of informed consent is the fact that the requirement of informed consent was articulated expressly in the Nuremberg Code,[10] and has since formed the basis of

6 Consent is not required in an emergency. The settled common law rule is that where an emergency arises calling for immediate action for preservation of the life or health of the patient, and it is impracticable to obtain his consent or the consent of anyone able to speak for him, it is the duty of the physician to administer without consent the treatment which, in his judgment, good medical practice demands. 70 C.J.S. *Physicians and Surgeons* § 48 (1951). The statutory provisions which recently have been enacted in about one-quarter of the states reflect the common law without changing it. Usually such statutes set forth the circumstances describing an emergency, and declare that if a physician judges such circumstances to exist, he may treat without obtaining legally valid consent first. *See, e.g.,* ARIZ. REV. STAT. § 36-512 (1974). CAL. WELF. & INST. CODE § 5358 (West Supp. 1977); GA. CODE ANN. § 88-2905 (1971); IDAHO CODE § 39-143 (1977); LA. REV. STAT. ANN. § 40:1299.54 (West Supp. 1977); MISS. CODE ANN. § 41-41-7 (1972); NEV. REV. STAT. § 433.484 1(d) (1975); N.Y. PUB. HEALTH LAW § 2504 (McKinney 1976-77) and N.Y. ATTY. GEN. MEMORANDUM No. 77-2 (1976); N.C. GEN. STAT. § 143-507(c) (1974); OHIO REV. CODE ANN. § 5123.86(D) (Page Supp. 1976), § 5122.271(d) (Page Supp. 1977); S.D. COMPILED LAWS ANN. § 27A-12-19, § 27B-8-19 (1977).

7 *See, e.g.,* Schloendorff v. Society of N.Y. Hosp., 211 N.Y. 125, 105 N.E. 92 (1914); Slater v. Baker & Stapleton, 95 Eng. Rep. 860 (K.B. 1767).

8 *See* Editorial, *Informed Consent,* N.Y. Times, Aug. 22, 1976, § 4 at 16, col. 2; M. TAUBENHAUS, THE RIGHTS OF PATIENTS (Public Affairs Pamphlet No. 535, 1976); AMERICAN ASSOCIATION ON MENTAL DEFICIENCY, INC., SPECIAL PUB. NO. 3, CONSENT HANDBOOK (1977).

9 J. KATZ, EXPERIMENTATION WITH HUMAN BEINGS 521-608 (1972).

10 The Code is reprinted in J. KATZ, *supra* note 9, at 305. Although the Code addressed the elements of consent in the context of human experimentation, its principles are also relevant in the treatment context.

countless court decisions concerning civil liability for medical malpractice.[11]

In practice, informed consent requires an exchange of information between the physician and patient which culminates in a decision made by the patient based on this information. Often informed consent is documented by a writing,[12] but the continuing exchange of information — not any particular form of communication — is the crucial characteristic of the process.

Since the 1960's, the concept of informed consent has received general judicial approval.[13] While most courts agree that informed consent must be "knowing, competent, and voluntary" to be legally valid,[14] there is still dispute over the proper interpretation of these elements. Courts have generally chosen not to articulate comprehensive policies on the

11 *See generally* Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093 (1960), *modified*, 187 Kan. 186, 354 P.2d 670 (1960); Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972); Note, *Informed Consent — A Proposed Standard for Medical Disclosure*, 48 N.Y.U. L. REV. 548 (1973); Note, *Informed Consent in Medical Malpractice*, 55 CALIF. L. REV. 1396 (1967).

12 Written documentation is required in regulations, *e.g.*, Protection of Human Subjects, 45 C.F.R. § 46.110 (1976); in statutes, *e.g.*, LA. REV. STAT. ANN. § 40:1299.40 (West Supp. 1977); OHIO REV. CODE ANN. § 2317.54 (Page Supp. 1977); and in hospital forms, *e.g.*, N.J. DEPT. OF MENTAL HEALTH AND HYGIENE, FORM NO. 104, GENERAL TREATMENT CONSENT (1967). Written documentation also has been suggested in popular medical literature, Horsley & Lavin, *An Up-To-Date Guide to Informed Consent*, MED. ECON., Mar. 21, 1977, at 150-69.

13 The applicability of common law rules concerning battery to the physician-patient relationship has long been recognized. *See, e.g.*, Mohr v. Williams, 95 Minn. 261, 104 N.W. 12 (1905). The fundamental principle that "every human being of adult years and sound mind has a right to determine what shall be done with his own body," Schloendorff v. Society of N.Y. Hosp., 211 N.Y. 125, 128, 105 N.E. 92, 93 (1914) (doctors liable for battery for operating without the consent of adult patient), is the origin of the physician's obligation to inform the patient of the nature and consequences of the proposed treatment and to obtain the patient's consent. Assent to contact negates the existence of the tort. Ford v. Ford, 143 Mass. 577, 578, 10 N.E. 474, 475 (1887).

Recent developments in the area of informed consent have focused on the scope of the physician's duty to disclose information concerning proposed treatment. For example, in Kaimowitz v. Department of Mental Health, No. 73-19434 (Cir. Ct. Wayne Cty., Mich., July 10, 1973), *reported in* 2 PRISON L. REP. 433 (1975), the court ruled that informed consent must be competent, knowing and voluntary to be legally adequate. In discussing the nature of voluntariness, the court stated that the patient must be free of ulterior forms of constraint or coercion. In Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972), the court ruled that a doctor must disclose *all* information about the proposed treatment which a reasonable person in the patient's circumstances would find material to his decision whether to undergo treatment.

14 *See* J. KATZ, *supra* note 9; Meisel, *The Expansion of Liability for Medical Accidents: From Negligence to Strict Liability by Way of Informed Consent*, 56 NEB. L. REV. 51 (1977).

scope and effectiveness of informed consent, focusing instead on narrower issues presented by particular cases. Specifically, the courts have protected children, prisoners, and institutionalized mentally ill or retarded persons[15] by weighing a combination of factors, including age, mental condition, intrusiveness of medical procedure, and coerciveness of institutional environment,[16] in assessing the effectiveness of the informed consent obtained.

The current state of the law concerning informed consent creates special problems in situations in which an adult patient appears to be incapable of consenting to treatment. In nearly every state, there is a presumption that a person is competent to make his own decisions.[17] This presumption continues even after institutionalization (*e.g.*, for treatment for mental retardation or illness), although as a practical matter a serious question could be raised about the ability of such persons to give informed consent to medical treatment. Instead, nearly every state declares that such institutionalization shall neither create a presumption nor constitute an adjudication of incompetency which would cause a person to lose his civil rights,[18] including the liberty to make his own health care decisions. There are generally no provisions for

---

15 These groups of patients have been singled out for protection not only by the courts but also by the National Commission for the Protection of Human Subjects, *see* 42 Fed. Reg. 26318, 26333-34 (1977), because, unlike other patients, they are particularly vulnerable by reason of their chronological age, mental condition, or institutionalization.

16 *See, e.g.*, Kaimowitz v. Department of Mental Health, No. 73-19434 (Cir. Ct. Wayne Cty., Mich., July 10, 1973), *reported in* 2 PRISON L. REP. 433 (1975) (performance of psychosurgery upon involuntarily committed mental patient prohibited); Wyatt v. Aderholt, 368 F. Supp. 1382 (M.D. Ala. 1973) (three-judge court); Wyatt v. Aderholt, 368 F. Supp. 1383 (M.D. Ala. 1974) (sterilization of institutionalized mentally ill and retarded adults and children regulated); Aden v. Younger, 57 Cal. App.3d 662, 129 Cal. Rptr. 535 (4th Dist. 1976) (electro-convulsive therapy and psychosurgery for mentally ill patients regulated).

17 *See generally* R. ALLEN, E. FERSTER & H. WEIHOFEN, MENTAL IMPAIRMENT and LEGAL INCOMPETENCY (1968).

18 *E.g.*, for mentally ill persons, IDAHO CODE §§ 66-346(a)(4),(a)(6) (Supp. 1977); KY. REV. STAT. § 202A.170(4) (1977), and for mentally retarded persons, IDAHO CODE §§ 56-243(a)(4),(a)(6) (Supp. 1977); KY. REV. STAT. §§ 202B.050-.060 (1977). However, in a few states the superintendent or director of institutions for the mentally ill has the discretion to modify the right to be presumed legally competent. *E.g.*, KAN. STAT. § 59-2930 (1977).

substitute consent. Traditionally, the presumption of competency continues unless the patient is adjudicated incompetent and a guardian of the person is appointed. However, the guardianship route, which often involves a jury trial, is time-consuming and cumbersome, and delays needed medical care.

The guardianship process in Maryland illustrates the difficulties that court proceedings can cause. Until July 1, 1977, a jury trial was required in every guardianship case unless waived by the patient.[19] Adherence to this requirement made it impossible to schedule a prompt hearing, especially in

---

19 Until July 1, 1977, when the new Protective Services Act, ch. 768 (July 1, 1977), codified in MD. EST. & TRUSTS CODE ANN. § 13 (1977), went into effect, there was little statutory guidance with respect to guardianship procedures. The only statutory provisions were Section 13-201 and Section 13-704 of the Estates and Trust Article. Section 13-201 applies only to a guardian of property. The only section which applied to guardianship of the person was Section 13-704, which merely provided: "The court may superintend and direct the care of a disabled person, appoint a guardian of the person, and pass orders and decrees respecting them as seems proper, including an order directing the person to a hospital. Procedures in these cases shall be as prescribed by Maryland Rules." MD. EST. & TRUSTS CODE ANN. § 13-704 (1974). Most of the procedures for such a proceeding were, and many still are, set out in the Maryland Rules of Procedure. *See* MD. ANN. CODE Rules R70-R80 (1977). They set out precise requirements for a petition in the appropriate circuit court with certified physicians' certificates as to incompetence. Preparation of the necessary papers, which requires much gathering of information and coordination within a short period of time, can be extremely time-consuming, especially for lawyers who represent institutions where guardianships are often required. Rule R77b 1(a), which has been superseded by a provision of the Protective Services Act, provides for a jury trial unless the alleged disabled person consented to the appointment of a guardian or waived a jury trial. Since it would have been improper for an attorney to waive a jury trial unless his client competently requested him to do so, this made jury trial necessary in most cases. The new Protective Services statute contains a provision as to jury trials which may ease this problem. It provides that the allegedly disabled person *or his counsel* may request a closed hearing without a jury. *See* MD. EST. & TRUSTS CODE ANN. § 13-709(f) (1977) (emphasis added).

While this provision certainly eases the situation, it remains to be seen how effective it will be, since a conscientious or malpractice-wary attorney may be reluctant to waive a jury trial. Another change brought about by the new Protective Services Act is that it creates for the first time in Maryland a procedure for emergency appointments of temporary guardians. The statute provides for court authorization, where an emergency exists, of the provision of protective services for a 72-hour period, and the order would be renewable. "Emergency" is defined in Section 13-101(e) to mean "that a person is living in conditions which present a substantial risk of death or immediate and serious physical harm to himself or others." *Id.* § 13-101(e). The statute provides for notice to be given to appropriate parties at least twenty-four hours before the hearing, but the court may waive such notice under certain circumstances. It provides for the presence of the person unless he has knowingly and voluntarily waived the right to be present or cannot be present because of physical or mental incapacity. *Id.* § 13-709(f)(1). It provides for the right to counsel,

smaller counties. In one case,[20] for example, where an amputation was needed because of gangrene, there was a delay of two and one-half weeks. Another case[21] in a one-judge county involved a guardianship for a mentally ill pregnant woman whose delivery date was imminent and who was refusing medical care. The earliest date at which a jury trial was available was two weeks from the date the petition was filed. Unfortunately, that date was ten days after the birth of the baby. Similar experiences led to the occasional relaxation of the jury trial requirement, especially in situations where delay clearly would have been detrimental to the patient.[22] In such urgent situations, strict compliance with the jury trial requirement defies common sense, is ethically impossible, and consequently weakens confidence in the legal system. A change in the law is essential.

Even in states where no jury trial is mandated, existing guardianship procedures require at least a judicial hearing[23]

---

and if the person lacks capacity to waive counsel or is indigent, the court is to appoint for him. There is no right to jury trial. Other important protections are built into the statute, such as the right to cross-examine witnesses, a statement of findings by the court in support of its order and the requirement of a report by the temporary guardian. It is not entirely clear that the emergency procedure is to be applied in cases where surgery or other such treatment is required, as the words "living in conditions" would not in their ordinary sense apply to a need for surgery, and protective services (which is not defined) would not ordinarily apply to something like surgery. If, as probably will be the case, it is nevertheless interpreted to apply to such situations, it should go a long way to meeting the need for a more practical procedure for serious emergency situations.

20 *In re* Breeding, Eq. No. 11776 (Cir. Ct. Dorchester Cty., Md. April 15, 1976).

21 *In re* Muzyk, Eq. No. 14678 (Cir. Ct. Carroll Cty., Md. June 16, 1977).

22 No statistics of practices in Maryland with regard to jury trials in guardianship cases involving medical treatment are kept by any public agency in the state. The authors did not conduct a formal survey themselves for their conclusion on delay, but instead have drawn on their personal knowledge as practicing attorneys and on discussions with others familiar with the situation.

23 *E.g.*, ALA. CODE tit. 21, § 11 (1958); ALASKA STAT. § 13.26.105(b) (1972); ARIZ. REV. STAT. § 14-5309 (1975); ARK. STAT. ANN. § 57-615(b) (Supp. 1975); CAL. PROB. CODE § 1461 (West Supp. 1976); CONN. GEN. STAT. ANN. § 45-78(d) (West Supp. 1976); D.C. CODE ENCYCL. § 21-1104 (West 1965); DEL. CODE tit. 12, § 3914(b) (Supp. 1975); FLA. STAT. ANN. § 744.331(4) (West Supp. 1976); GA. CODE ANN. § 49-604(3)(b) (Supp. 1976); 1976 HAW. SESS. LAWS § 5-303(b); IDAHO CODE § 15-5-303(b) (Supp. 1977); ILL. ANN. STATS. ch. 3, § 117(c) (Smith-Hurd Supp. 1977); IND. CODE ANN. § 29-1-18-19 (Burns Supp. 1976); IOWA CODE ANN. § 633.555 (West 1964); KANS. STAT. § 59-3008 (1976); KY. REV. STAT. § 387.220(1) (Supp. 1976); MD. ANN. CODE Rule R77b2 (1977); MICH. COMP. LAWS ANN. § 330.1618 (1975); MINN. STAT. ANN. § 252A.08 (West Supp. 1975); N.H. REV. STAT. ANN. § 464:1 (Supp. 1975) (hearing discretionary); N.J. STAT. ANN. tit. 3A, § 6-35 (West 1953); N.M. STAT. ANN. 32-2-2 (1953); N.Y. MENTAL HYG.

and the provision of counsel in the vast majority of cases.[24] The jury trial[25] option is preserved in nearly half the states. In approximately one-quarter of the states, legislation gives a court-appointed guardian specific powers to consent to medical treatment.[26]

Many states have a limited or temporary guardianship of the person[27] used largely in emergency situations or for a

---

LAW § 78.03(e) (Consol. 1976); N.D. CENT. CODE § 30.1-28-03(2) (Supp. 1976); OHIO REV. CODE ANN. § 2111.04 (Page Supp. 1976); OKLA. STAT. ANN. tit. 43A, § 55 (West Supp. 1976); OR. REV. STAT. § 126.007(2) (Supp. 1976); 20 PA. CONS. STAT. ANN. § 5511 (Purdon 1975); S.D. COMPILED LAWS ANN. § 30-27-14 (Supp. 1976); TENN. CODE ANN. § 33-313 (Supp. 1977); VA. CODE § 37.1-128.01 (Supp. 1976); W. VA. CODE § 27-11-1(b) (Supp. 1976); WISC. STAT. ANN. § 880.08 (West Supp. 1977); WYO. STAT. § 3-29.4(a) (Supp. 1975).

24 The term "counsel" here includes guardian *ad litem*. *E.g.*, ALA. CODE tit. 21, § 15 (1958); ALASKA STAT. § 13.26.105(b) (1972); ARIZ. REV. STAT. § 14-5303 (1975); ARK. STAT. ANN. § 57-620 (1971); CAL. PROB. CODE § 1461 (West Supp. 1976); DEL. CODE tit. 12, § 3914(b) (Supp. 1975); FLA. STAT. ANN. § 744.331(4) (West Supp. 1976); 1976 HAW. SESS. LAWS § 5-303(b); IDAHO CODE § 15-5-303(b) (Supp. 1977); KANS. STAT. § 59-3010(A)(3) (1976); MINN. STAT. ANN. § 252A.09 (West Supp. 1976); N.M. STAT. ANN. § 32-3-1 (1953); N.Y. MENTAL HYG. LAW § 78.03(e) (McKinney 1976); N.D. CENT. CODE § 30.1-28-03(2) (Supp. 1976); OHIO REV. CODE ANN. § 2111.02 (Page Supp. 1976); OKLA. STAT. ANN. tit. 43A, § 55 (West Supp. 1976); OR. REV. STAT. § 126.103 (Supp. 1976); R.I. GEN. LAWS § 33-15-9 (Supp. 1969); TENN. CODE ANN. § 33-313 (Supp. 1977); TEX. PROB. CODE ANN. tit. 9, § 417 (1956); WASH. REV. CODE ANN. § 11.88.045 (Supp. 1976); W. VA. CODE § 27-11-1(b) (Supp. 1976); WISC. STAT. ANN. § 880.33(2) (West Supp. 1977); WYO. STAT. § 3-29.5(b) (Supp. 1975).

25 *E.g.*, ALASKA STAT. § 13.26.105(b) (1972); CAL. PROB. CODE § 1461 (West Supp. 1977); D.C. CODE § 21-1107 (1973); ILL. ANN. STAT. ch. 3, § 117(c) (Smith-Hurd Supp. 1977); IND. CODE § 29-1-18-19 (1976); IOWA CODE § 633.555 (1975); KAN. STAT. ANN. § 59-3013 (1976); N.J. STAT. ANN. § 3A: 6-35 (West 1953); N.M. STAT. ANN. § 32-3-1 (1953); N.Y. MENTAL HYG. LAW § 78.03(e) (McKinney 1976); N.C. GEN. STAT. § 35-2 (1976); OKLA. STAT. tit. 43A, § 55 (Supp. 1976); 20 PA. CONS. STAT. ANN. § 5511 (Purdon 1975); TEX. PROB. CODE ANN. arts. 115, 417 (Vernon 1956); VA. CODE § 37.1-128.02 (1976); WASH. REV. CODE § 11.88.045 (1976); WISC. STAT. § 880.33(2)(1975); WYO. STAT. § 3-29.6 (Supp. 1975) (jury trial at court's discretion). In at least two states a jury trial is mandatory in a proceeding for a guardianship of the person. ALA. CODE tit. 21, § 13 (1958); KY. REV. STAT. § 387.220(1) (Supp. 1976).

26 *E.g.*, ALASKA STAT. § 13.26.150(3) (1962); ARIZ. REV. STAT. § 14-5312.A.3 (1975); CAL. WELF. & INST. CODE § 5358 (West Supp. 1977) (if specified by court order); IDAHO CODE § 15-5-312 (a)(3) (Supp. 1977); MINN. STAT. § 252A.11 (1976); NEV. REV. STAT. § 159.079 (1973); N.D. CENT. CODE § 30.1-28-12 (1975); OR. 13.26.150(3) REV. STAT. § 126.137 (1)(c) (1975).

27 *E.g.*, ALASKA STAT. § 13.26.140 (1972); ARIZ. REV. STAT. § 14-5310 (1975); CAL. WELF. & INST. CODE § 5352.1 (West Supp. 1977) (temporary conservatorship); GA. CODE § 49-604(2) (1975).

That these statutory provisions for limited or temporary guardianship are used to obtain consent to medical treatment in at least some instances was confirmed by letters received by the authors from Attorneys General in various states. *See, e.g.*, letter from Richard F. Howard, Assistant Attorney General, Virginia (April 21, 1977);

specified period of time. While it is difficult to gauge the deleterious effect of these cumbersome guardianship laws on the efficient and timely delivery of health care, they undoubtedly cause some delay.[28] Moreover, guardianship, even if temporary, is inappropriate, for it usually denies a patient all of his civil rights for its duration without regard to his ability to exercise any of them.[29]

The problems surrounding the guardianship laws stem from the fact that most of them are extremely brief[30] and poorly written. They appear to have been grafted onto the more carefully written guardianship of the property statutes as an afterthought,[31] and thus were not specifically designed for the determination of capacity to consent to medical care. They have been used for this purpose because no other procedures existed.[32]

---

letter from Stephen J. Josch, Assistant Attorney General, Washington (June 8, 1977) (on file at the Developmental Disabilities Law Project, University of Maryland Law School, 500 W. Baltimore St., Baltimore, Maryland 21201).

28 *See* examples cited in the text accompanying notes 20-21 *supra.*

29 This result is avoided only in the few states where a "limited guardianship" statute provides that the person loses only those rights specifically taken from him by the court. *See, e.g.,* VA. CODE § 37.1-128.1 (1976); WASH. REV. CODE § 11.88.010(2) (1976).

A relatively recent legislative device for providing numerous services, including medical treatment, to disabled individuals without causing them to suffer the disabilities of a full guardianship is the protective service legislation now enacted in at least four states. *See, e.g.,* COLO. REV. STAT. §§ 26-3-101 to 112. (Supp. 1976); 1977 MD. LAWS ch. 768; WISC. STAT. § 55.001-.06 (1975). While these statutes are steps in the direction of the provision of efficient and timely health care, they still fail to address other problems. For example, they neither define the elements of informed consent nor explain the rationale for regulating some procedures but not others. Moreover, they clarify neither the range of prohibited and allowable medical services nor the scope of the powers delegated to the person responsible for consenting to or administering them. Thus, even under these new legislative schemes, further judicial proceedings are often necessary to determine substitute consent to certain medical procedures. *See, e.g.,* MD. EST. & TRUSTS CODE ANN. § 13-708(b)(8) (Supp. 1977). It is too early to assess judicial reaction to both protective service and public guardianship statutes because these laws, all of which are less than five years old, have been the subject of very little litigation generally, and none specifically on the issues of informed and substitute consent to medical care.

30 *See, e.g.,* MD. EST. & TRUSTS CODE § 13-704 (1974).

31 *E.g., compare* MD. EST. & TRUSTS CODE §§ 13-201 to 222 (1974) (protection of property) *with* § 13-704 (1974) (guardian of the person).

32 Almost no guardianship of the person statutes have received judicial construction in the context of consent to medical care. One suit challenged Michigan's guardianship of the person provisions on due process grounds generally but not with regard to consent to medical treatment. *See* Schultz v. Borraidaile, No. 74-40123 (E.D. Mich., filed Oct. 25, 1974).

Another shortcoming of the guardianship route to substitute consent is that it relies on the judicial process to make what are essentially personal medical decisions. Courts are ill-equipped to assume the role of substitute decision maker. The information provided to the court during a typical guardianship hearing enables the court to do little more than rubber-stamp the recommendations of the physicians involved. Moreover, the judicial hearing requirement also inconveniences testifying physicians. Finally, because he may be suffering from a serious physical disability, the patient is often unable to attend the proceeding. The absence of the patient deprives the court of direct impressions which can be extremely important in deciding the case.

The cumbersomeness of the court procedure virtually ensures that it will be employed only in the most serious cases, such as when surgery is to be performed. As a result, except in the most serious cases, either the patient will be left without treatment — a clearly undesirable alternative — or someone, perhaps a physician or a family member, will authorize the treatment. The latter solution both exposes physicians to possible malpractice actions and fails to protect adequately the patient's right to informed consent.[33] Furthermore, although physicians and institutions have often turned to family members for substitute consent, such persons are not legally entitled to give consent in the absence of any statutory authorization.

A final problem with the guardianship approach is that it is often difficult to find an appropriate guardian for the court to appoint. While a distressing number of non-institutionalized incapacitated persons lack family or friends who are sufficiently disinterested, qualified, and willing to serve as guardians, this problem is especially acute in cases of institutionalized incapacitated persons. This problem also arises among elderly patients in private nursing homes where many are senile, ill, and without interested relatives. A few states have recognized the problem of finding a suitable guardian,

---

33 *See* text accompanying note 1 *supra.*

but have not addressed it satisfactorily.[34] In some states, the superintendents of state facilities are given authority to consent to such treatment.[35] This approach, which presumes that patients are incompetent to decide, both ignores patient rights and creates an unnecessary conflict of interest, for the superintendent must both set policy for the whole institution and act as decision maker for one patient. In other states, the problem is not addressed and the assumption seems to be that a guardian must be appointed in every case. This requirement is especially impractical for mental health facilities, where problems involving lack of capacity to consent to treatment are frequently encountered.

In summary, the guardianship procedure, which evolved in response to the need for a long-term substitute decision maker with authority to act in a variety of matters, has many built-in procedural protections against abuse. These guardianship procedures are inappropriate, however, where a careful, yet prompt and efficient, determination of capacity is

---

34 Letters received by the authors from the offices of several state Attorneys General and health departments indicate that the problem of incapacitated persons lacking potential guardians is a matter of special concern. *See* letters to the authors from James P. Pons, Assistant Attorney General, Alabama Department of Public Health (April 25, 1977); Ralph Colburn, Staff Attorney, California Department of Public Health (June 10, 1977); Honey S. Golby, Assistant Attorney General of Delaware (June 6, 1977); Richard F. Howard, Assistant Attorney General of Maine (April 21, 1977); Shirley Smith, Deputy Attorney General of Nevada (April 28, 1977); Michael D. Reynolds, Assistant Attorney General of Oregon (April 26, 1977); Mary Yancey Spencer, Assistant Attorney General of Virginia (May 3, 1977); Stephen J. Hosch, Assistant Attorney General of Washington (June 8, 1977) (letters on file at the Developmental Disabilities Law Project of the University of Maryland Law School, 500 W. Baltimore St., Baltimore, Maryland 21201).

35 *See, e.g.,* HAW. REV. STAT. § 333-34 (1968) (pursuant to which the director of health is made the guardian of the person of any mentally retarded individual committed to the state institution); CAL. HEALTH & SAFETY CODE §§ 38223, 38452, 38500 (West Supp. 1977) (which allow regional centers for developmentally disabled persons to give medical consents and make placements in facilities for their clients). *See also* N.J. STAT. ANN. §§ 30:4-7.1 to 7.6 (West Supp. 1977). An Attorney General's opinion will be issued in New Jersey which will require guardianship proceedings for institutional patients notwithstanding the statute. Letter to the authors from Elaine W. Ballai, Deputy Attorney General, New Jersey (April 28, 1977) (on file at the Developmental Disabilities Law Project of the University of Maryland Law School, 500 W. Baltimore St., Baltimore, Maryland 21201). A similar Attorney General's opinion has already been issued in Oklahoma with respect to its statute. *See* OKLA. OPP. ATT'Y GEN. NO. 77-102, Feb. 2, 1977.

needed, and the appointment of a substitute decision maker and a decision about the proper course of treatment must be undertaken. The current state of the law inconveniences all parties, including physicians, directors of institutions, and administrators of nursing homes, who are responsible for providing good medical care and are subject to liability if they fail to do so. The current law also fails to protect patient rights. Finally, the current law provides no guidance for resolving such controversial questions as whether and under what conditions substitute consent can be given to discontinuation of life support systems or sterilization. A new approach is necessary.

II. LEGISLATIVE ATTEMPTS TO CORRECT THE PROBLEM

A review of legislative attempts to correct the problem created by the lack of procedures other than the ill-suited guardianship route to substitute consent will be facilitated by a brief discussion of legislative approaches to the problem of informed consent. This discussion will review legislative developments in the area of substitute consent and examine some of the problems implicit in these developments.

A. *Definition of Informed Consent*

While courts have long articulated rules concerning informed consent, legislatures have been slower to codify the concept of consent or its full implications. Although nearly every state has enacted some statute relating to informed consent, the provisions vary widely in scope and purpose. Only nine states have legislated the definition of informed consent,[36] drawing largely upon the meaning courts have given the term. Specification of informed consent requirements for certain groups of people and types of procedures has been the

---

36 ARIZ. REV. STAT. § 36-501(13) (1974); COLO. REV. STAT. § 27-10.5-102(2)(a) (Supp. 1976); CONN. GEN. STAT. ANN. § 17-206a(h) (West 1975); FLA. STAT. ANN. § 393.13(3)(h) (West Supp. 1976); IDAHO CODE § 39-4302 (1975); NEV. REV. STAT. § 433.484(1)(b) (1975); OHIO REV. STAT. § 2317.54 (Supp. 1976); S.D. COMPILED LAWS ANN. § 27A-1-2(8) (Supp. 1976).

more prevalent approach.[37] For example, at least two states give certain classes of patients, such as mental patients, the right to adequate and current information concerning their treatment.[38] The vast majority of states have codified the concept of informed consent by departing from the common law rule that only a parent or guardian may consent to non-emergency medical treatment of a minor.[39] These states allow minors who have attained a certain status[40] or received treatment for certain physical conditions or diseases[41] to give lawful consent. A few states merely require informed consent to specific medical procedures without defining the elements of valid consent, while others define the elements of informed consent wherever it is specifically required.[42]

B. *Substitute Consent*

Just as legislatures have delayed drafting informed consent statutes or have adopted a piecemeal approach to the problem of which persons or procedures are subject to the informed consent requirement, so have they also neglected either to revise guardianship laws systematically to clarify their applicability to determination of substitute consent to treatment, or to draft new and comprehensive substitute consent legislation. Some states have introduced legislation intended to ameliorate specific aspects of the substitute con-

---

37 Other approaches, not relevant to this article, also have been used. Approximately one-quarter of the states describe informed consent generally in the malpractice context to indicate either what a patient must establish in order to prove medical malpractice or when a presumption is created that informed consent was given. *See, e.g.,* COLO. REV. STAT. §§ 13-20-302 to 305 (Supp. 1976); FLA. STAT. ANN. § 768.46 (West Supp. 1976).

38 MD. ANN. CODE art. 43, § 565C (Supp. 1977) (nursing home patients); N.Y. PUB. HEALTH LAW § 2803-.2(e) (McKinney Supp. 1976) (nursing home patients).

39 *See, e.g.,* CAL. CIVIL CODE § 34.5 (West Supp. 1977), *interpreted in* Ballard v. Anderson, 4 Cal.3d 873, 484 P.2d 1345, 95 Cal. Rptr. 1 (1971); Bonner v. Moran, 126 F.2d 121 (D.C. Cir. 1941) (common law rule).

40 *E.g.,* marriage or parenthood, CONN. GEN. STAT. § 19-142a(a) (1977); MONT. REV. CODES ANN. § 69-6101 (1) (Supp. 1976); or financial emancipation, ALASKA STAT. § 09.65.100(a)(1) (Supp. 1976); COLO. REV. STAT. § 13-22-103(1) (1973).

41 *E.g.,* pregnancy, venereal disease, or drug abuse. ALA. CODE tit. 22, § 104(17) (Supp. 1974); ARIZ. REV. STAT. §§ 44-132.01, -133.01 (Supp. 1976); FLA. STAT. § 458.215(1) (Supp. 1976); MD. ANN. CODE art. 43, § 135(a)(3) (Supp. 1977).

42 *E.g., compare* ORE. REV. STAT. § 435.435 (1975) *with* 35 PA. CONS. STAT. ANN. § 6602 (Purdon 1977) (abortions).

sent problem. A substantial minority of the states[43] has modified the common law rule that makes consent of the patient determinative unless he has been adjudicated incompetent.[44] These statutes allow certain relatives[45] to provide consent in specified circumstances.[46] Unfortunately, these statutes produce difficulties because they fail to establish an objective measure of capacity[47] and decline to state who determines whether sufficient incapacity exists to trigger the substitute consent power. Almost no litigation has arisen from these very general consent provisions; judicial attention has been focused on consent to specific medical procedures.

Another aspect of substitute consent subject to regulation in many states[48] is consent by certain groups of patients to

---

43. *See, e.g.,* ALA. CODE tit. 22, § 104 (20) (Supp. 1973); GA. CODE ANN. § 88-2904 (Supp. 1976); ARK. STAT. ANN. § 82-363 (1976); IDAHO CODE § 39-4303 (1975); KAN. STAT. ANN. § 59-2929(a)(6) (1976); LA. REV. STAT. ANN. § 40:1299.53 (West Supp. 1976); MASS. GEN. LAWS ANN. ch. 123, § 23 (West Supp. 1977); MICH. COMP. LAWS ANN. § 330.1716 (1974); MINN. STAT. ANN. § 253A.18 (West 1971); MISS. CODE ANN. § 41-41-3 (1972); MONT. REV. CODES ANN. § 69-6406 (Supp. 1975); OKLA. STAT. tit. 43A, § 6341 (West 1951); PA. STAT. ANN. tit. 50, § 4417(a) (Purdon 1969); R.I. GEN. LAWS § 23-43.2-6 (Supp. 1976); S.C. CODE § 32-994 (Supp. 1975); S.D. COMPILED LAWS ANN. § 27A-12-20 (1976); VT. STAT. ANN. § 8702 (1968).

44 *See, e.g.,* Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), *cert. denied,* 409 U.S. 1064 (1972); State v. Housekeeper, 70 Md. 162, 16 A. 382 (1889).

45 *See, e.g.,* MISS. CODE ANN. § 41-41-3 (1972); S.C. CODE § 32-994 (Supp. 1975).

46 *E.g.,* when the patient is institutionalized, PA. STAT. ANN. tit. 50, § 4417 (Purdon 1969); or when the patient is of an "unsound mind," MISS. CODE ANN. § 41-41-3 (1972).

47 *See, e.g.,* ALA. CODE tit. 22, § 104(20) (Supp. 1973) ("physically . . . or mentally unable to consent"); MISS. CODE ANN. § 41-41-3 (1972) ("unsound mind").

48 *See, e.g.,* ALASKA STAT. § 47.30.130(b) (1975); ARIZ. REV. STAT. § 36-540(e) (1974); CAL. HEALTH & SAFETY CODE § 38223 (West Supp. 1976); CAL. PENAL CODE § 2670 (West Supp. 1976); COLO. REV. STAT. § 27-10.5-114 (Supp. 1976); CONN. GEN. STAT. ANN. § 17-206d (Supp. 1976); FLA. STAT. ANN. § 393.13(4)(f)(6) (West Supp. 1976); GA. CODE ANN. § 88-2904 (Supp. 1976); KAN. STAT. ANN. § 59-2929(a)(6) (1976); ME. REV. STAT. tit. 34, § 2461 (1965); MICH. COMP. LAWS ANN. §§ 330.1716, .1718 (1974); MINN. STAT. ANN. §§ 252A.11-.13 (West Supp. 1977); MO. ANN. STAT. § 105.700 (Vernon 1976); MONT. REV. CODES ANN. § 38-1322 (Supp. 1977); MONT. REV. CODES ANN. § 69-6401 (1970); N.H. REV. STAT. ANN. § 174:1 (1964); N.J. STAT. ANN. § 30:4-7.1 (West Supp. 1976); N.Y. MENTAL HYG. LAW § 15.03(b)(4) (McKinney Supp. 1975); N.C. GEN. STAT. § 122-55.6 (Supp. 1975), §§ 35-36 (Supp. 1976); S.D. COMP. LAWS ANN. § 27A-12-20, § 27B-8-20 (Supp. 1976); TENN. CODE ANN. § 33-307 (Supp. 1977); VT. STAT. ANN. tit. 18, § 8701 (1968); VA. CODE § 32-424.1 (Supp. 1977); WASH. REV. CODE ANN. § 71.05.3707 (1975); W. VA. CODE § 27-16-1 (Supp. 1976); WISC. STAT. ANN. § 46.12 (West 1957).

The regulation of consent to specific medical procedures overlaps the approach of allowing substitute consent generally by some relatives or public officials. In some states the same statute permits both consent mechanisms.

medical procedures which are considered unusually evasive, irreversible, or dangerous, such as surgery, sterilization or psychosurgery.[49] Such laws usually create a decision-making scheme of dual consent[50] or substitute consent of a relative or public official[51] often pursuant to an order from a specified administrative or judicial proceeding.[52] Though aimed at solving the substitute consent problem for some of the most serious medical procedures, these statutes are significantly deficient. Rarely is the rationale set forth for including one treatment and excluding another from the statute's purview.[53] The treatments mentioned are expansive in scope yet undefined; "major medical treatment in the nature of surgery"[54] or a "hazardous procedure" could include a large number of treatments.[55] Because the elements of informed consent are also undefined, the nature and degree of incapacity necessary to trigger these substitute consent procedures generally is unclear. In addition, a justification for applying

---

49 Other treatments similarly regulated in these statutes include aversive treatment procedures, electro-convulsive therapy, hazardous treatment procedures, major treatment in the nature of surgery, and surgery. *See* note 48 supra.

50 *See, e.g.,* ARIZ. REV. STAT. § 36-540(E) (1974) (consent of civilly committed patient or legal guardian and court order required for psychosurgery); MONT. REV. CODES ANN. § 38-1322 (Supp. 1975) (consent of civilly committed patient and of one other person consulted is required for procedures like lobotomy and aversive reinforcement conditioning).

51 *See, e.g.,* ALASKA STAT. § 47.30.130(b) (1975) (spousal consent to surgery upon a civilly committed patient); CAL. HEALTH & SAFETY CODE § 38223 (West Supp. 1977) (director of a regional center may consent to medical, dental, or surgical treatment of a developmentally disabled client).

52 *See, e.g.,* N.C. GEN. STAT. §§ 35-36 to 35-50 (1976) (involuntary sterilization requires judicial hearing and court order); S.D. COMP. LAWS ANN. § 27B-8-20 (1976) (performance of psychosurgery or electroconvulsive therapy upon an institutionalized mentally retarded person requires court order if no one eligible to consent can be located); WASH. REV. CODE § 71.05.370 (1975) (performance of shock treatment of non-emergency surgery upon institutionalized mental patient requires judicial hearing and court order if patient does not consent).

53 For example, without any explanation, Missouri's statute regarding consent to treatment for prisoners regulates, *inter alia,* "standard medical, surgical and psychiatric treatment," MO. ANN. STAT. § 105.700 (Vernon Supp. 1977), whereas California's consent provisions regarding the administration of "organic therapy" to prisoners regulates, *inter alia,* psychosurgery, shock therapy, and aversive stimuli, CAL. PENAL CODE § 2670 (West Supp. 1974).

54 *See, e.g.,* N.Y. MENTAL HYG. LAW § 15.03(b)(4) (McKinney Supp. 1977).

55 *See, e.g.,* COLO. REV. STAT. §§ 27-10.5-114(f) (Cum. Supp. 1976); KAN. STAT. § 59-2929(a)(6) (1976); MONT. REV. CODES ANN. § 38-1322 (Cum. Supp. 1975).

substitute consent procedures arbitrarily to patients within certain classes, such as minors, mentally ill, or developmentally disabled persons, is rarely articulated in these statutes.[56]

A handful of states[57] have drafted fairly comprehensive[58] statutes specifically designed for the determination of capacity to consent to medical treatment and for the appointment of a substitute decision maker when necessary. Michigan,[59] New York,[60] and Minnesota[61] have promulgated detailed

---

56 For example, although there are often no differences between "involuntary" and "voluntary" civil committees except for the label, markedly different regulations may apply to the administration of the same treatments, *e.g.*, medical and surgical procedures, including electroschock therapy, to each group. *See, e.g.*, CONN. GEN. STAT. ANN. § 17-206d (West Supp. 1977).

57 N.M. Health & Devel. Disab. Code, ch. 279, §§ 1-19, 21-23, 1977 N.M. Laws 2177. N.Y. MENTAL HYG. LAW § 15.03(b)(4) (McKinney Supp. 1976-77); Quality of Care and Treatment, 14 N.Y.C.R.R. pts. 27.1-27.11 (1975); MINN. DEPT. OF PUBLIC WELF. EMERG. RULE 20 (PROC. GOVERNING THE ADM. OF SPECIFIED THERAPIES TO ST. HOSP. PATIENTS) (1976) [hereinafter cited as MINN. TREATMENT REG.]; MICH. COMP. LAWS ANN. § 330.1716 (1975). Michigan's regulations are no longer effective, since they have expired. However, they have not been replaced, and thus they represent the current policy of the Michigan Department of Mental Health. For a description of the Michigan regulations, *see* letter to the authors from Milton I. Firestone, Assistant Attorney General, State of Michigan (April 28, 1977) (on file at the Developmental Disabilities Law Project, 500 West Baltimore Street, Baltimore, Maryland 21201) [hereinafter cited as Michigan's Ass't Atty. Gen. Letter].

58 The area of concern where the most legislation has been proposed is in regard to decisions pertaining to the withdrawal of life-sustaining procedures. This type of legislation, commonly referred to as "Natural Death Acts," usually provides that a competent adult person may make a written directive instructing his physician to withhold or withdraw life-sustaining procedures in the event of a terminal condition.

However, these statutes and proposed bills do not really solve the problems of substitute consent, since they are effective only for those individuals who are competent at the time they make the written directive to withhold future life-sustaining efforts in the event they suffer from a terminal illness. Thus, they offer no solution to the problem of individuals who at the present time need medical treatment but who do not have the ability to consent to this treatment. *See, e.g.*, CAL. HEALTH & SAFETY CODE, §§ 7185-7195 (West Supp. 1977); Right to Die Act, ch. 287, §§ 1-11, N.M. Laws 2236. Natural Death Acts were introduced in 1976-77, but failed to pass the legislatures, in Delaware, Maryland, Florida, Massachusetts, Montana, Nebraska, and Virginia. *See* letters to the authors from the Office of the Attorneys General of Del., Md., Fla., Mass., Mont., Neb., and Va. (on file at the Developmental Disabilities Law Project, 500 West Baltimore Street, Baltimore, Maryland 21201).

59 MICH. COMP. LAWS ANN. § 330.1716 (1975); Michigan Ass't Atty. Gen. Letter, *supra* note 57.

60 N.Y. MENTAL HYG. LAW § 15.03(b)(4) (McKinney Supp. 1976-77); Quality of Care and Treatment, 14 N.Y.C.R.R. pts. 27.1-27.11 (1975).

61 MINN. TREATMENT REG., *supra* note 57.

regulations, while New Mexico[62] has enacted a comprehensive statute. But glaring defects are common to all four attempts. First, they only cover individuals receiving services for mental disabilities from state-operated or licensed facilities.[63]

Minnesota, for example, requires substitute informed consent and judicial authorization prior to the commencement of intrusive treatment but applies these safeguards only to involuntarily committed patients at state hospitals.[64] This regulation fails to acknowledge that in many cases there is no relevant difference between an involuntary and a voluntary patient, and therefore both groups require the same procedural protections.[65] Second, the statutes regulate only a

---

62 N.M. Mental Health & Devel. Disab. Code, ch. 279, §§ 1-19, 21-23, 1977 N.M. Laws 2177.

63 *Id.* at § 2(B); MICH. COMP. LAWS ANN. § 330.1716 (1975); Michigan's Ass't Atty. Gen. Letter, *supra* note 57; N.Y. MENTAL HYG. LAW § 15.03(b)(4) (McKinney Supp. 1976-77); Quality of Care and Treatment, 14 N.Y.C.R.R. pts. 27.1-27.11 (1975).

64 A possible explanation for the limitation of Minnesota's regulations to involuntarily committed patients at state mental hospitals is that these regulations were developed in response to the Minnesota Supreme Court's decision in Price v. Sheppard, 307 Minn. 250, 239 N.W.2d 905 (1976). In *Price,* the court held that the more "intrusive" therapies could not be administered to involuntarily civilly-committed patients residing at state hospitals without the informed consent of the patient or court authorization.

65 *See, e.g.,* Gilboy & Schmidt, *"Voluntary" Hospitalization of the Mentally Ill,* 66 NW. U. L. REV. 429, 430 (1971), where the authors found that the voluntary admissions to hospitals for mental treatment are in many instances not truly voluntary. As the authors observed:

> In a majority of cases voluntary admission is utilized to hospitalize persons who are already in some form of official custody. Voluntary admission avoids procedural complexity and the need for officials to assume responsibility, both inherent drawbacks to compulsory commitment from the officials' point of view. Individuals are therefore induced to voluntarily commit themselves with the threat of involuntary commitment as the principal means of persuasion, and with little concern for the adequacy of the information on which the individual's decision is based or whether it is "voluntary" at all.

Id. See also Report and Recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 42 Fed. Reg. 26,318, 26,332 (1977) [hereinafter cited as Psychosurgery Report]. Commissioner Patricia King, in her dissenting statement, argues that the protections afforded the involuntarily committed patient prior to the performance of psychosurgery should also extend to the voluntarily committed patient since, in fact, the voluntary patients may not really be "voluntary." For example, as part of the plea bargaining process in the criminal justice system, some persons may "agree" to voluntarily commit themselves to mental institutions in exchange for reduced or dropped charges.

limited number of medical procedures.[66] For example, although New Mexico has established an excellent court proceeding for determining ability to consent and for appointing a treatment guardian if a patient is unable to consent, its statutory safeguards do not apply to the administration of any medication, including psychotropic drugs.[67]

Finally, the regulations fail to provide procedural protections for the patient during the initial determination of capacity. For example, the New York regulations are deficient because the director of the facility determines whether a

---

66 New Mexico's statute requires proper consent prior to the administration of psychosurgery, convulsive therapy, experimental treatment or a behavior modification program involving aversive stimuli or substantial deprivations. N.M. Mental Health and Devel. Disab. Code, ch. 279, § 14(A) 1977 N.M. Laws 2177, 2195.

Michigan's statute requires informed consent prior to the performance of surgery, electro-convulsive therapy, or any other procedure intended to produce convulsions or coma. MICH. COMP. LAWS ANN. § 330.1716(1) (1975).

Minnesota's regulations require informed consent prior to the administration of psychosurgery, electroshock therapy, coma or insulin therapy, behavior modification utilizing aversive therapies designed to produce physical pain, and medically prescribed maintenance therapy using highly addictive substances such as morphine or methadone. MINN. TREATMENT REG., *supra* note 57, at (c)1-5.

New York's statute requires that consent be obtained prior to administration of surgery, shock treatment, major medical treatment in the nature of surgery, or the use of experimental drugs or procedures. N.Y. MENTAL HYG. LAW § 15.03(b)(4) (McKinney Supp. 1976-77).

67 Rather than requiring informed consent prior to the administration of psychotropic medication, the New Mexico statute seeks to control the giving of excessive or unnecessary medication by: (1) limiting the type of people who may prescribe and administer medication, (2) requiring written notation by the physician of the behavioral or symptomatic baseline data upon which the medication order was made, and (3) requiring that prescriptions for psychotropic medication have a termination date of not more than 30 days. N. M. Mental Health and Devel. Disab. Code, ch. 279, § 5(I) 1977 N.M. Laws 2177, 2184.

These statutory guidelines, however, do not protect the patient who does not want to take psychotropic medication or who may prefer to try alternative forms of treatment first. *See, e.g., In re* Cleo F. Lundquist, No. 140151 (Prob. Ct. Ramsey Cty., Minn., Apr. 30, 1976), where a Minnesota court permitted a civilly committed patient at the state hospital to refuse to take the drug prolixin. In reaching this decision, the court held that the petitioners had failed to show that the use of prolixin was reasonable and necessary under the circumstances. Therefore, the patient had the right to determine for herself whether or not she wished to accept the proposed form of treatment or refuse it. The fact that New Mexico failed to require informed consent prior to the administration of psychotropic medication is a major deficiency in the statute since the major form of treatment in state mental hygiene facilities is the use of psychotropic medication. For example, a recent audit performed by the Michigan Department of Mental Health found that ninety-eight percent of institutional residents in the audit sample were receiving psychotropic medication. Mich. Dep't of Mental Health, Use of Psychotropic Drugs (Mar. 4, 1976).

patient has the ability to consent and no provision exists for review of this determination.[68]

C. *Summary — A Legislative Concern*

With the partial exception of the four states discussed above, attempts by legislatures to deal with the problem of consent for the incapacitated patient are nonexistent or grossly inadequate. It should not be surprising that this is the case in both the areas of informed and substitute consent. Given the legislative failure to take the initial step of codifying the elements of informed consent, legislative hesitation or neglect in the area of substitute consent is to be expected.

There is, nonetheless, no clearly articulated and widely accepted judicial doctrine which could serve in the absence of a comprehensive legislative approach to the problem of substitute consent. Moreover, informed consent is not the kind of problem which should be left to the judicial process to resolve.[69] First, the evolution from isolated precedents to prevailing rules may well proceed too slowly to be useful in this area. Second, as the *Quinlan*[70] case demonstrates, problems of substitute consent may generate highly charged public debate and controversy. A legislative decision would be more thoroughly debated and representative of public opinion than a court decision.

The proposed Model Act attempts to fill the gaps in existing law on substitute consent. It is a comprehensive

68. New York's regulations fail to provide a uniform standard to determine whether a patient has the capacity to give informed consent. Rather, each facility director is to develop standard procedures to evaluate the decisions made on the mental capacity of individual patients to give consent. If it is unclear whether the patient has sufficient mental capacity to give consent, an independent opinion about the patient's mental capacity must be obtained from a qualified consultant who is not an employee of the facility. After considering the opinion of the consultant, the director determines whether the patient has the capacity to give consent and proceeds accordingly. If the patient objects, he has a right to appeal to the head of the service, the director, and the regional director in the department. Quality of Care and Treatment, 14 N.Y.C.R.R. pts. 27.8(b), (3)(b), (d), 27.9(d),(e),(f) (1975).

69 *But see* Superintendent of Belchertown State School v. Saikewicz, 1977 Mass. Adv. Sh. 2461, 2499-2500, 370 N.E.2d 417, 434 (courts have the responsibility to make substitute judgments as to medical care for mental incompetents); Kindregan, *The Court as Forum for Life and Death Decisions: Reflections on Procedures for Substituted Consent,* in *Symposium-Mental Incompetents and the Right to Die,* 11 SUFFOLK U. L. REV. 919 (1977).

70 *In re* Quinlan, 70 N.J. 10, 355 A.2d 647 (1976).

legislative response to a problem which is too complex to be amenable to a piecemeal approach and too pressing to be left to time-consuming consideration of the courts.

III. THE PROPOSED ACT: SUMMARY OF PROVISIONS

The proposed Health Care Procedures Consent Act (hereinafter referred to as the Act) establishes an administrative procedure[71] for the determination of a person's capacity to make his own medical decisions, and if he is found mentally incapable of doing so, the appointment of a substitute decision maker to make these decisions on his behalf.[72] The Act in each of its provisions attempts to strike a balance between the preservation of individual rights and the need for the timely delivery of health care. The Act does not neglect the interests of physicians and other health care personnel. If health care personnel follow the Act's procedures, they will be freed from liability for their treatment of patients incapable of giving informed consent.

The Act is premised on the legal requirement that no medical procedures[73] can be performed on a person without his own consent or that of a legally authorized representative.[74] Therefore, the operation of the Act is triggered by the doubt of the treating doctor or other treating personnel as to the capacity of the patient to give, deny, or withdraw informed consent.[75] Should the doctor or other person administering treatment doubt the patient's mental

71 While the proposed statute establishes an administrative procedure, MICH. COMP. LAW ANN. § 330.1600-42 (West 1975); Michigan Ass't Atty. Gen. Letter, *supra* note 57; MINN. TREATMENT REG., *supra* note 57, and N.M. Mental Health & Devel. Disab. Code, ch. 279, 14(B) 1977 N.M. Laws 2177, 2195-97, require a court procedure.

72 Minnesota law does not permit a substitute decision maker to make treatment decisions, but rather requires court authorization. If the patient is incompetent to give consent or refuses consent, then before more intrusive forms of treatment may be utilized, the medical director of the state hospital must petition the court for an order authorizing the prescribed treatment. Price v. Sheppard, 307 Minn. 250, 239 N.W.2d 905 (1976); MINN. TREATMENT REG., *supra* note 57, at (d)1-3.

73 Rather than requiring informed consent for all medical procedures, New York, New Mexico, Michigan, and Minnesota only require it for specific procedures. *See* note 66 supra.

74 Health Care Procedures Consent Act § 3 [hereinafter cited as the Model Act].

75 Model Act § 5. With regard to institutionalized mentally retarded individuals, Michigan's Department of Mental Health has developed a checklist of approximately ten different procedures that a staff member may not perform if he determines

capacity to give consent he is required to refer the case to the Substitute Consent Review Board provided for in the Act. Any number of conditions, ranging from temporary conditions, such as diabetic coma, to longer-term conditions, such as chronic schizophrenia or severe mental retardation, might raise doubts in a physician's mind about requisite mental capacity. By referring the final determination of capacity to the Board, the doctor or other treating personnel is relieved of responsibility for and potential liability from the treatment or non-treatment of a questionably competent, but sick or injured, person.

However, a doctor is not prevented from delivering all medical care until the Board's determination. The Act permits administration of treatment necessary for the preservation of the health and life of the patient, but does not authorize treatments irreversible in effect, significantly invasive, or substantially risky to the individual.[76] For example, the Act permits the administration of antibiotics to a possibly senile person to prevent the further spread of gangrene in a leg, but prohibits amputation of the gangrenous leg before determination of capacity and, if necessary, appointment of a substitute decision maker.

The Act assigns the determination of patient capacity to give informed consent to the Substitute Consent Review Board,[77] an interdisciplinary Board composed of a physician,

---

that the patient is unable to give informed consent to them. Some of the specific procedures are non-emergency surgery or other medical procedures not related to the care and treatment of a person's mental condition, non-emergency use of electroconvulsive therapy or psychosurgery or other treatment of an experimental or extrahazardous nature for a voluntary resident, chemotherapy prior to an adjudication for an involuntary admission, and sterilization. When a staff member does not feel that the patient has the capacity to give informed consent, he must put in writing his reasons for that conclusion. The program director reviews this determination; if he feels that the determination is of substantial weight, he will convene an informed consent board. Michigan Ass't Atty. Gen. Letter, *supra* note 57.

76 Model Act § 5. This permitted treatment prior to an adjudication of capacity is characterized as "interim standard medical care." Model Act § 1(a)(9).

77 In the proposed Act, the Substitute Consent Review Board determines the patient's ability to consent and if necessary appoints a substitute decision maker. This Board is interdisciplinary and independent of the facility. Model Act §§ 4-5.

In Michigan, the Informed Consent Board makes a determination on the patient's capacity to give informed consent. If the Board determines the patient does not

a lawyer, and a lay member. On receipt of the doctor's referral of a case in petition form, the Board sets a hearing date within five days[78] and notifies the patient of the hearing, the contents of the petition, and his right to representation at the hearing. The patient has the right to obtain his own attorney. If he does not do so, the Board appoints a patient advocate to represent the patient in the hearing.[79] The Act mandates a hearing with numerous safeguards to guarantee full fact finding and fundamental fairness, presence of the patient, the patient's right to introduce evidence and cross-examine witnesses, and the patient's right to request additional tests and evaluations from the Board.[80]

After the hearing, the Board must state its findings of fact

---

have capacity to give informed consent, it recommends that a petition for guardianship be initiated. This Consent Board may be either a standing interdisciplinary body drawn from an existing interdisciplinary review board within a facility or program, or a group appointed on a case-by-case basis. The Board members must include two mental health professionals of different disciplines with clinical experience and a third person who is not employed by the facility and who is selected by the facility or program director from qualified volunteers with an interest in mental health or mental retardation advocacy and services. Michigan policy also requires that one Board member have prior clinical contact with the person whose ability to give informed consent is at issue, but that no Board members shall have been involved in either the action or the application for which consent is needed or the decision to evaluate the need for guardianship. Michigan's policies then set out the procedures to be followed in evaluating whether the patient has the capacity to give informed consent. Specifically, the Board must interview the person and other appropriate persons and evaluate clinical records and test results. The Board must submit a written report which includes findings of facts, the patient's desires when possible, and a conclusion as to whether the individual has the capacity to consent. Michigan Ass't Atty. Gen. Letter, *supra* note 57.

78 Model Act, § 5(d)(1). According to the New Mexico statute, a court hearing must be held within three court days from the day the petition is filed with the court. Either the court will hear the case or appoint by general or special order a licensed attorney as special commissioner to hear it and file findings and recommendations with the court.

79 Model Act, § 5(e). In Price v. Sheppard, 307 Minn. 250, 239 N.W.2d 905 (1976), the court held that in those cases where the hospital petitions for court authorization to give "intrusive treatments" to a civilly-committed patient who is incapable of giving consent or refuses to give consent, the court shall appoint a guardian *ad litem* to represent the interests of the patient. Although the decision does not specify whether the guardian *ad litem* must be an attorney, it does not appear that an attorney would be required.

On the other hand, New Mexico's statutory scheme provides for the appointment of counsel to represent clients at all proceedings where determination of capacity and a treatment guardian shall be appointed. N.M. Mental Health and Devel. Disab. Code, ch. 279, § 3, 1977 N.M. Laws 2177, 2181.

80 Model Act § 5(d)-(g).

and conclusions of law in an order setting forth its determination of the patient's capacity; the designation of a substitute decision maker, if applicable; scope of his powers to decide on medical treatment; duration of the order; the appeal and redetermination procedures; and the designation of a continuing patient advocate in cases where a substitute decision maker is appointed.[81] If the majority of the Board finds that clear and convincing evidence does not exist to show that the patient lacks capacity to give informed consent, the Board must issue a written order stating this conclusion.[82] Treating personnel would then be required to defer to the patient's judgment about the recommended treatment. Thus, in the earlier example of the questionably senile person with a gangrenous leg, the doctor would have to respect his refusal of a leg amputation if the Board had found him competent. However, if the majority of the Board finds that clear and convincing evidence exists to show that a person lacks capacity to give, deny, or withdraw informed consent, the individual is deprived of his right to make medical decisions, and another person is appointed to make these decisions in his stead.[83] The substitute decision maker will usually be a family member or close friend.[84] However, in the absence of a qualified substitute decision maker, the Board itself assumes the role of substitute decision maker, making decisions about medical care by majority vote.[85] The substitute decision maker, whether the Board itself or an individual, must consider the necessity and reasonableness of the proposed procedure, as well as the best interests of the patient, in making a decision.[86]

81 Model Act § 6(a).
82 Model Act § 6(b)(1).
83 Model Act § 6(b)(2).
84 Model Act § 6(c).
85 Model Act § 6(c)(3).
86 Model Act § 7(b)(1)-(3). This standard in the proposed Act is similar to the standard utilized by the court in Price v. Sheppard, 307 Minn. 250, 239 N.W.2d 905 (1976).

The New Mexico statute requires the treatment guardian making a treatment decision on behalf of the patient to consider:

1. whether the treatment is in the client's best interest;
2. whether the treatment is the least drastic means for accomplishing the treatment objective;

The substitute decision maker's powers are not plenary. The term of his appointment cannot exceed six months.[87] Moreover, the Board limits the scope of his powers for specific medical procedures.[88] Substitute decision makers are prohibited from making decisions in those medical situations in which it is anticipated that the denial of, withdrawal of, or consent to a procedure by the substitute decision maker will result directly in the termination of life.[89] These cases must Board for decision.[90] Any decision of the Board to deny or withdraw consent must be unanimous. Otherwise the Board must refer the case to the court for determination. Third, where the proposed procedure is either psychosurgery[91] or sterilization,[92] the Act provides that only a court may decide whether the procedure may be performed on a patient lacking the mental capacity to give his personal informed consent. Fourth, the substitute decision maker's consent to medical procedures of an irreversible, significantly invasive, or substantially risky nature, such as abortion, must be reviewed by the patient advocate and approved as "not clearly contrary to the patient's best interest."[94] The continued assignment of a patient advocate to every case after the hearing and

3. the expressed opinions, if any, of the client, even if those opinions do not constitute valid consent or rejection of treatment;
4. previous decisions made by this client in similar circumstances when the client was competent to make treatment decisions.

The treatment guardian shall also consult with the physician or other professional who is proposing treatment, the client's attorney and interested friends or relatives of the client as he deems appropriate in making his decision. N.M. Mental Health and Devel. Disab. Code, ch. 279, § 14(B) 1977 N.M. Laws 2177, 2195-97.

87 Model Act § 6(d). However, he may be reappointed for additional terms.

88 Model Act § 6(a).

89 Model Act § 8(2).

90 Model Act § 7(a).

91 *See, e.g.,* N.M. Mental Health and Devel. Disab. Code, ch. 279, 16(B), 1977 N.M. Laws 2177, 2202, which provides that psychosurgery or convulsive therapy cannot be performed on a minor unless there is a court order based upon a finding that this treatment is necessary to prevent serious harm to the minor. Consent of the minor or his parent without a court order is invalid.

92 *Cf.* CAL. ADMIN. CODE, tit. 22, ch. 1, §§ 7037.1, 70707.1-70707.8, 70736 (West Supp. 1975) (Human Reproduction Sterilization) which provides for an organized chronological process for obtaining informed consent for sterilization. One of the requirements for an elective sterilization is that the patient be able to understand the content and nature of the informed consent process and not have been declared judicially incompetent. *Id.* § 70707.5 (2).

93 Model Act § 3(c)(2).

94 Model Act § 12(a).

appeal period is a fifth check on the substitute decision maker's power.[95]

The decision of the Substitute Consent Review Board is not final. The patient and the petitioner have the right to a *de novo* court hearing on the issues of capacity, appropriateness of the appointed substitute decision maker,[96] and, in some cases, the decision of the substitute decision maker.[97]

The Act's provisions for redetermination of capacity are liberal. Redetermination can be triggered by a petition from any member of the health facility treatment staff where the patient resides, from the substitute decision maker, from the patient advocate, or from the patient. After a petition for redetermination is filed, no medical procedures of an irreversible, significantly intrusive, or substantially risky nature can be performed until the Board acts upon that petition.[98]

Compliance with the statute relieves the physician or other health care provider of civil and criminal liability for the performance of medical procedures absent willful, malicious, or grossly negligent acts or omissions.[99] Thus, the physician or other health care provider may meet the medical needs of the mentally incapacitated patient without fear of incurring liability for treatment without personal informed consent.

---

95 Model Act § 6(a)(7). N.Y. MENTAL HYG. LAW § 29.09 (McKinney Supp. 1977-78), which establishes a mental health information service which is authorized to inform patients of the procedures for admission and retention and of their rights to have a judicial hearing, to be represented by legal counsel, and to seek an independent medical opinion. Also, according to New York's regulations, prior to the administration of treatment over the objection of a patient, the objection must be reviewed by the head of the service. The decision of the head of the service must be communicated to the patient, his representative, if any, and the Mental Health Information Service. Quality of Care and Treatment, 14 N.Y.C.R.R. pt. 27.8(b) (1975).

96 Model Act § 11(b)(2).

97 Model Act § 12(b)-(c). *See, e.g.*, N.M. Mental Health and Devel. Disab. Code, ch. 279, § 14(B) 1977 N.M. Laws 2177, 2195-97, which provides for the client, physician, or other professional to appeal a decision of the treatment guardian. The court may overrule the treatment guardian's decision if it finds that decision to be against the best interests of the client.

98 Model Act § 9(a)(4). However, if the patient, substitute decision maker, patient advocate, and health facility treatment staff member file a joint petition for redetermination, procedures may be performed before the Board's decision with cosignature of substitute decision maker and patient. *Id.* § 9(a)(3).

99 *Id.* § 14.

The problem of substitute consent is a major concern of both the legal and the medical professions and of society as a whole. The Health Care Procedures Consent Act attempts to balance the interests of the patient in self-determination and his right to informed consent against the very real concern of health professionals to provide necessary and timely medical treatment under clear rules whereby liability can be avoided. It attempts to provide a comprehensive solution in an area where piecemeal measures will not work.

AN ACT TO PROVIDE FOR INFORMED AND SUBSTITUTE CONSENT TO MEDICAL TREATMENT PROCEDURES

TABLE OF CONTENTS

Section 1. Definitions.
Section 2. Legislative Purpose and Policy.
Section 3. The Requirement of Informed Consent.
Section 4. The Substitute Consent Review Board: Structure, Composition and Independence.
Section 5. The Substitute Consent Review Board: Its Operations.
Section 6. The Substitute Consent Review Board: Its Decision-Making Responsibility.
Section 7. The Substitute Decision Maker's Powers.
Section 8. Denial or Withdrawal of Consent by the Board If Termination of Life is the Anticipated Result.
Section 9. Redetermination of the Patient's Capacity.
Section 10. Confidentiality of Proceedings and Records.
Section 11. Appellate Review.
Section 12. The Role of the Patient Advocate.
Section 13. The Effect of a Finding of Incapacity on Other Proceedings.
Section 14. Protection from Liability.

Section 1. *Definitions*

(a) In this Act the following words have the meanings indicated, unless the context indicates otherwise:

(1) "Board" means the Substitute Consent Review Board;

(2) "Capacity to give informed consent" means the ability to understand and knowingly, rationally, and voluntarily act on the information required for informed consent under this subtitle;

COMMENT: An objective standard for measuring a patient's capacity[100] to give informed consent has not been previously formulated by any court or legislature. The definition in this subsection specifies that the patient's understanding of disclosed information is a necessary element of informed consent. The definition thus focuses upon the patient's functional ability, not his status. For example, while a diagnostic label such as "mentally ill" or "mentally retarded" may be relevant in assessing a patient's ability to give informed consent, it is not determinative. Rather, the patient's comprehension as expressed during the informed consent process determines his capacity. The subsection also uses the word "rationally" to describe how a patient must act on the information he has received. Use of this word imposes a requirement that patients be capable of making decisions which are reasonable under the circumstances.

(3) "Counsel" means an attorney admitted to practice law in this state, a trained patient advocate, or any person designated by the patient to act in his behalf;

COMMENT: The chief function of counsel is to represent a patient before the Board. The term counsel is defined broadly in subsection (a)(3) to include not only an attorney, but also trained patient advocates or any competent person designated by the patient to act in his behalf.

(4) "Department" means the Department of [ ];

COMMENT: The term "department" in this subsection refers to the highest level organization in the executive branch of state government which establishes and implements health care policy in the state, and the relevant department's name

100 A discussion of the standard by which a patient's capacity to give informed consent should be measured is beyond the scope of this article. In this section the authors merely explain briefly how the concept of capacity operates under the proposed statute.

(*e.g.*, Department of Health and Mental Hygiene in Maryland) should be inserted in this subsection.

(5) "Emergency situation" means a circumstance that calls for immediate action in order to preserve the life or bodily integrity of the patient;

COMMENT: The definition of "emergency situation" in this subsection is consistent with case law in most states[101] that permit immediate action to preserve the patient's life or health. Statutes in jurisdictions which have codified the concept defer to medical judgment and allow intervention where danger to life or health is at stake.[102] Some states permit emergency treatment to prevent disfigurement and impairment of faculties[103] as well as to avert danger to a patient's health.[104] Other states permit treatment in similar situations: "unexpected occurrences";[105] "severe bodily injury";[106] and danger to a "limb"[107] or "member."[108] Such state statutes reflect the concern that the "danger to health" concept alone may be too narrowly construed by health personnel. This intuition is captured by the Act's use of the phrase "bodily integrity." The Act seeks to make clear that an emergency may consist of a situation in which death might not be imminent but where irreparable injury is likely to occur to a part of the

---

101 *See generally* 70 C.J.S. *Physicians and Surgeons* § 48 at 968 (1951).

102 A typical definition of emergency situations is found in 1977 Ark. Acts 805, § 2(a):

> An emergency is defined as a situation wherein, in competent medical judgment, the proposed surgical or medical treatment or procedures are immediately or imminently necessary and any delay occasioned by an attempt to obtain a consent would reasonably be expected to jeopardize the life, health or safety of the person affected, or would reasonably be expected to result in disfigurement or impaired faculties.

For similar definitions, *see* GA. CODE ANN. § 88-2905 (1975); LA. REV. STAT. ANN. § 40:1299.54 (Supp. 1977); MISS. CODE ANN. § 41-41-7 (1977).

103 *See, e.g.*, GA. CODE ANN. § 88-2905 (1971); LA. REV. STAT. ANN. § 40:1299.54 (Supp. 1977); NEV. REV. STAT. § 41A.120 (1975).

104 *See, e.g.*, N.M. STAT. ANN. § 12-25-4 (1953).

105 *See, e.g.*, IDAHO CODE § 39-141(A) (1977); N.C. GEN. STAT. § 143-507(c) (1974).

106 *See, e.g.*, CAL. WELF. & INST. CODE § 5358 (West Supp. 1978).

107 *See, e.g.*, 14 N.Y.C.R.R. § 27.9a-9b (1975) (regulations implementing N.Y. MENTAL HYG. LAW § 15.07(b)(4) (1972).

108 *See, e.g.*, ARIZ. REV. STAT. § 36.512 (1974).

body or its function (*e.g.*, loss of a limb or its use), or a situation in which immediate action is required to maintain or restore the patient's healthy body functions.

(6) "Health facility" means a hospital or related institution, health maintenance organization, or clinic under the jurisdiction of the Department;

COMMENT: The term "health facility" clearly excludes procedures performed in a private office of a physician and other treating personnel. However, it is not the intent of the proposed statute to abrogate the common law which requires informed consent prior to administration of all medical procedures regardless of place of performance. The words "hospital" and "health maintenance organization" should be defined elsewhere in the Health Codes of the State.

(7)(A) "Informed consent" means knowledgeable, voluntary permission in writing from the patient, his parent, guardian, or substitute decision maker for any preventive, diagnostic, or therapeutic measure to be administered in a health facility;

(B) To obtain "informed consent," a physician or other health care provider must give the patient, his parent, his guardian, or a substitute decision maker the following items of information:

(i) a reasonable explanation of the procedure and its purposes in as timely a fashion as circumstances permit, including identification of any procedure that is experimental or irreversible or that has serious or probable adverse effects;

(ii) a description of attendant discomforts, disadvantages, and long- and short-term risks reasonably to be expected, including the risk of failure;

(iii) a description of benefits reasonably to be expected;

(iv) a disclosure of reasonable alternative procedures;

(v) the invitation of questions and provisions of answers to any questions that concern the procedure; and

(vi) instructions that the patient is free to withdraw consent and to discontinue agreement to the procedure at any time without prejudice regarding receipt of any alternative procedure available within the health facility.

COMMENT: The core of the statute is its requirement that informed consent, as defined in subsection be obtained from the patient or his legally-authorized representative prior to initia-

tion of medical treatment.[109] This requirement is based on principles of tort, criminal, and constitutional law. The language of the statute is clear that informed consent must be "knowledgeable" and "voluntary," but further explication of the practical implications of these terms is necessary.

The requirement that consent be "knowledgeable" imposes an obligation on the physician to disclose pertinent information. This obligation to disclose information to the patient has received the most substantial judicial development of any element of the doctrine of informed consent. At this time, the rule as to disclosure as stated in *Canterbury v. Spence*[110] is generally accepted.[111] The physician has a duty to disclose all information about the proposed treatment which a reasonable person in a patient's circumstances would find material to his decision either to undergo or forego the treatment.[112]

The disclosure requirement has received attention in the statutes of eight states.[113] However, with the exception of one provision,[114] the statutes understate the disclosure requirement, focusing mainly on the nature of the proposed procedure and the risks inherent in it.[115]

---

109 *See generally* Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), *cert. denied,* 409 U.S. 1064 (1972); Bonner v. Moran, 126 F.2d 121 (D.C. Cir. 1941). The drafters were aided in their efforts on behalf of this proposal in Maryland, *see* note 3 *supra,* by the recent Maryland decision of Sard v. Hardy, 281 Md. 432, 379 A.2d 1014 (1977), which held that the principle of informed consent should be applied in appropriate cases where there is a claim of professional negligence in failing to meet a duty to disclose. Prior to the *Sard* opinion, no Maryland case had explicitly endorsed the informed consent doctrine.

110 464 F.2d 772 (D.C. Cir.), *cert. denied,* 409 U.S. 1064 (1972).

111 *See, e.g.,* Cobbs v. Grant, 8 Cal.3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972); Wilkinson v. Vesey, 110 R.I. 606, 295 A.2d 676 (1972); Miller v. Kennedy, 11 Wash. App. 272, 522 P.2d 852 (1974).

112. Canterbury v. Spence, 464 F.2d 772, 786-87 (D.C. Cir.), *cert. denied,* 409 U.S. 1064 (1972).

113 *See* ARIZ. REV. STAT. § 36-501(18) (1974); COLO. REV. STAT. § 27-10.5-102(2)(a) (Supp. 1976); CONN. GEN. STAT. ANN. § 17-206a(h) (West 1975); FLA. STAT. ANN. § 393.13(3)(a) (West Supp. 1977); IDAHO CODE § 39-4304 (1975); LA. REV. STAT. ANN. § 40-1299.40 (West Supp. 1977); OHIO REV. CODE ANN. § 2317.54 (Page Supp. 1976); S.D. COMPILED LAWS ANN. § 27A-1-2(8) (1976).

114 COLO. REV. STAT. § 27-10.5-102(2)(a) (Supp. 1976).

115 *See, e.g.,* ARIZ. REV. STAT. § 36-501 (1974); OHIO REV. CODE ANN. § 2317.54 (Page Supp. 1976).

By contrast, the federal Department of Health, Education and Welfare (HEW) regulations on human experimentation[116] and the California regulations on sterilization[117] are explicit in their disclosure requirements. Both of them compel the physician: (1) to disclose information concerning the nature of, the benefits of, and the risks surrounding proposed procedures and appropriate alternative procedures; (2) to discuss any questions the patient may have about the information disclosed; and (3) to instruct the patient that he is free to withdraw his consent at any time.

In setting forth the disclosure requirement, the Act adopts the thorough approach and format of the HEW and California regulations.[118] The Act is designed to stimulate the physician-patient dialogue and exchange of information characteristic of these regulations.

The voluntariness requirement has prompted much discussion in cases, regulations, and statutes. The language of the statute is intended to be consistent with the statement on voluntariness in the Nuremberg Code: "The person involved . . . should be so situated as to be able to exercise free power of choice, without the intervention of any element, force, fraud, deceit, duress, over-reaching, or other ulterior forms of constraint of coercion . . . ."[119] While past concern for voluntariness has focused on the experimental nature of the pro-

---

116 45 C.F.R. § 46.103(c)(1)-(6) (1976).

117 CAL. ADMIN. CODE, tit. 22, § 70037.1, 70707.1-.8, 70736 (1977).

118 It is interesting to note that the negative reaction of the Baltimore medical community to S. 734, introduced in the Maryland state senate, centered on the duty to disclose as well as on the perceived cumbersomeness of the administrative procedure. *See* Miscellaneous Letters and Memoranda, 1977 (on file at the Developmental Disabilities Law Project, University of Maryland Law School, Baltimore, Maryland 21201); 4 THE MD. PSYCH. 1 (1977). The concern most often expressed was that the proposed legislation exemplified the type of governmental regulation which intruded impermissibly upon the discretion with which physicians are invested to give or withhold information from their patients. However, no strong authority exists in the case law for this strong discretion. Cobbs v. Grant, 8 Cal.3d 229, 242, 502 P.2d 1, 9, 104 Cal. Rptr. 505, 513 (1972).

119 40 Fed. Reg. 11,854 (1975), implementing suggestions that the Code be incorporated. *See* 39 Fed. Reg. 18,914 (1974).

In its experimentation regulations, HEW has also incorporated explicitly the Nuremberg Judgment and has required that an individual be "so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion."

cedure in a coercive environment, the possibility of involuntary treatment can arise in any coercive environment and the voluntariness requirement of the Act is not intended to apply only to experimental environments. Health care facilities may be coercive environments even when the proposed procedure is not experimental and the patient is not mentally handicapped, because patients suffer from a general dependency upon their physicians. As one commentator has forcefully stated:

> The patient who comes to the hospital loses freedom of movement, is deprived of his clothes and must literally put himself into the hands of other people and depend on them to care for the needs he normally tends to himself. His passive dependent needs are increased, his usual patterns of adjustment are increased, his usual patterns of adjustment are disrupted, and he often suffers intense conflict. His illness is a threat to the integrity of his body and to his life, and consequently, generates feelings of anxiety. Since he may be unable to cope with these dangers himself, his anxiety is usually accompanied by a feeling of helplessness. Thus, he is forced to rely on the physician for security in ways that resemble his dependence on his parents when he was a child.[120]

It should be noted that although some courts and legislatures have required informed consent only for certain medical procedures, the Act requires it for all procedures.[121]

> **(8) "Interested person" means a parent, spouse, custodian, adult offspring, adult sibling, or other adult responsible for the care of a patient on whom a procedure is to be performed;**
> **(9) "Interim standard medical care" does not include:**
> **(A) any abortion;**
> **(B) any surgical procedure;**
> **(C) any convulsive therapy, which means any electrical, chemical, or physical treatment for a mental disorder that**

---

120 E. Payne, Jr., *Teaching Medical Psycho-Therapy In Special Clinical Settings, reprinted in* J. KATZ, *supra* note 9, at 651.

121 The Model Act requires informed consent for all procedures because the informed consent policy of the Maryland State Department of Health & Mental Hygiene, which provided the drafters' legislative mandate, contained this requirement. *See* note 4 *supra.*

typically is used to produce convulsions, but that does not produce them when used at lower levels;

(D) any aversive treatment procedure, which means any treatment procedure used in an attempt to produce a change in a patient through the delivery, withdrawal, or avoidance of a noxious stimulus; and

(E) any procedure that, in the judgment of the individual responsible for administering it, involves substantial risk to the patient in accordance with prevailing standards of medical practice.

COMMENT: This subsection defines "interim standard medical care" in order to allow a health care provider to administer limited treatment either to prevent the patient's condition from deteriorating or to maintain his health pending the Board's decision about his capacity to consent. Although it is difficult, if not impossible, to devise a litmus paper test to distinguish between permitted and proscribed interim care, certain cases are clear. For example, antibiotics could be administered to a questionably competent patient with a gangrenous leg who objects to treatment, but amputation of the leg would have to await a Board determination. In other cases, however, it is impossible to separate "routine" from "non-routine" or "ordinary" from "non-ordinary" procedures. To provide guidance to health care providers faced with interim care decisions, it is necessary to enumerate at least those procedures strictly prohibited pending the Board's determination of the patient's capacity.

Abortion is singled out for prohibition because it affects the fundamental right to procreate which is constitutionally protected.[122] Surgical procedures are excluded because they are invasive by nature, even when they do not involve high risk.[123] The definition of convulsive therapy is similar to medical[124] and existing statutory[125] definitions.[126] Convulsive

122 Roe v. Wade, 410 U.S. 113 (1973).

123 Abortion was listed separately, in part because not all abortions are surgical procedures.

124 DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1597 (25th ed. 1974) [hereinafter cited as DORLAND'S].

125 *See, e.g.*, N.M. Mental Health and Devel. Disab. Code, ch. 279, § 2(E) 1977 N.M. Laws 2177, 2179.

126 A term used in some statutes, "electro-convulsive therapy," was not selected because the drafters wanted to include within the definition sub-convulsive

therapy is excluded because of the extremely intrusive nature of procedures which affect one's mental processes.

The term "aversive treatment" procedure is defined in a manner similar to accepted medical[127] and existing statutory[128] definitions. Aversive treatment procedures are excluded from the definition of "interim standard medical care" because they may be highly intrusive[129] and because noxious stimuli may produce far-reaching effects on behavior. The term "noxious stimulus" is defined elsewhere in the statute,[130] again in a manner similar to medical[131] and statutory[132] definitions. It includes treatment such as electrical shocks or nausea-producing chemicals used to change undesirable patterns of behavior, such as alcoholism or homosexuality.

Finally, procedures involving substantial risk are excluded. There is no accepted definition of the term as used in existing statutes, court decisions, or the medical community. Two alternatives could be employed: such risk may either be measured quantitatively, solely by the probability of its occurrence, or analyzed qualitatively, not only in terms of its incidence but also in light of the severity of its potential consequences. The Act is intended to be read as employing the latter measure. The Act's chief concern is that procedures considered by physicians to carry a significant risk of serious consequences, even if the risk is of low probability, not be performed before the Board has made its determination. For example, it is contemplated that a procedure such as an angiogram or arteriogram would constitute a procedure involving substantial risk within the meaning of the statute,

---

therapy for treatment of mental disorders, as well as electro-convulsive therapy. The difference between the terms is that the electrical current passed through the brain during electro-convulsive therapy produces convulsions, which is not true of sub-convulsive therapies.

127 DORLAND'S, *supra* note 124, at 1597.

128 *See, e.g.*, N.M. Mental Health and Devel. Disab. Code, ch. 279, § 2(A) (1977) ("aversive stimuli").

129 *See, e.g.*, Mackey v. Procunier, 477 F.2d 877 (9th Cir. 1973).

130 Model Act, § 1(a)(11).

131 DORLAND'S, *supra* note 124, at 1597.

132 *See* note 128 *supra*.

whereas the administration of standard medication for the common cold would not.

(10) "Life Preservation Advisory Committee" means a body formed to aid, counsel, and advise physicians, other hospital personnel, family members, and the Board in handling difficult questions that concern the maintenance, denial, or withdrawal of a life-sustaining procedure;

(11) "Noxious stimulus" means an occurrence that is harmful, damaging, or hurtful to the patient;

(12) "Procedure" means a preventive, diagnostic, or therapeutic measure, including medication, administered in health facility;

(13) "Secretary" means the Secretary of the Department;

(14) "Substitute consent" means the giving of informed consent by the Board or a person other than the patient on whom the procedure is to be performed in accordance with this act;

(15) "Substitute decision maker" means the person or Board appointed to determine whether to give, deny, or withdraw informed consent for a procedure.

Section 2. *Legislative Purpose and Policy*

(a) The State, through the Department, has the responsibility not only to prevent, diagnose, and treat health problems but also to ensure that patients using health facilities understand fully and give their permission to medical procedures performed on them. It is the policy of the State that each of these health facilities shall obtain informed consent before administering procedures. However, the State recognizes that certain physical and mental conditions impair a patient's ability to receive, understand, and correlate information and to formulate a rational judgment. Therefore, a procedure is needed to obtain substitute consent for preventive, diagnostic, and therapeutic measures without obtaining a judicial declaration of incompetence and appointment of a legal guardian. To meet this need, the Legislature hereby establishes a system of substitute consent for patients to receive health care services.

(b) This Act also is intended to preserve individual rights for all patients while permitting the timely delivery of health care services.

(c) This Act does not change any present law which permits the delivery of health care services in emergency situations in the absence of informed consent.

COMMENT: Subsections (a) and (b) set forth the policy on informed consent and explain the purpose to be achieved by this legislation.

Subsection (c) follows the established common law rule that allows a physician to treat without consent if, in his judgment, delay would jeopardize the patient's life or health.[133] Despite wide acceptance of this rule, the courts vary in their treatment of subsidiary issues such as: (1) the circumstances creating an emergency,[134] (2) the rational justifying a physician's decision to act,[135] and, (3) the extent of a physician's authority to treat.[136] Recognizing that the nuances of an emergency doctrine are subtle and depend largely upon considered medical opinion, the Act gives general guidance to treating personnel, leaving individual determinations to their professional judgment.

Section 3. *The Requirement of Informed Consent*

(a) (1) Except as provided in this Act, a procedure may not be administered to a patient unless the patient first gives his informed consent.

(2) If a patient has the capacity to give informed consent but refuses to give it, the procedure may not be administered.

(3) Anticipated failure to obtain informed consent does not excuse failure to comply with the informed consent requirements of this subtitle.

(b) (1) Except as prohibited in subsection (c) of this section, if the patient has a guardian appointed by a court of competent jurisdiction, the guardian may give informed consent to procedures for the patient.

(2) Except as prohibited in subsection (c) of this Section and Section 7(a) of this Act, if the patient is a minor, a parent may give informed consent to procedures for the minor.

(3) Except as prohibited in subsection (c) of this Section, Section 7(a) of this Act [and], if the patient is a minor and lacks a

---

133 70 C.J.S. *Physicians and Surgeons* § 48 (1951).

134 *See, e.g.,* Cache Valley Gen. Hosp. v. Cache County, 92 Utah 279, 67 P.2d 639, 643 (1937); Mansfield Gen. Hosp. v. Board of County Commissioners, 170 Ohio St. 486, 488-89, 166 N.E.2d 224, 226-27 (1960).

135 *See* W. PROSSER, LAW OF TORTS 103 (4th ed. 1971).

136 *See, e.g.,* Kennedy v. Parrott, 243 N.C. 355, 90 S.E.2d 754 (1956).

parent or legal guardian, a substitute decision maker appointed for him under this subtitle may give informed consent to procedures for the minor.

(c) (1) In this subsection the following words have the meanings indicated:

(A) "Psychosurgery" means any removal or destruction of brain tissue for the primary purpose of affecting behavioral or emotional disturbance;

(B) "Sterilization" means any procedure that results in the termination of a patient's ability to procreate.

(2) A substitute decision maker, parent, or guardian may not give substitute consent for psychosurgery or sterilization. A court shall determine whether or not psychosurgery or sterilization may be performed on a patient who does not have the capacity to give informed consent.

(d) Consistent with Section 2(c) of this Act, if an emergency situation exists and informed consent cannot be obtained within the time available, a health facility may perform a procedure without informed consent.

COMMENT: Following the clear judicial and legislative trend,[137] subsection (a) makes the right to refuse a treatment pro-

---

137 Some states have codified the right to refuse. Georgia and Louisiana each have a general "Medical Consent Law" which affords all citizens the right to refuse all treatment. GA. CODE ANN. § 88-2907 (1975); LA. REV. STAT. ANN. § 40:1299.56 (Supp. 1977). Rhode Island has a similar provision in a "bill of rights" for the patients in all hospitals. R.I. GEN. LAWS § 23.16-19.1 (Supp. 1976). Moreover, most right-to-refuse statutes afford protection to institutionalized populations against unconsented administration of certain treatment such as "psychosurgery" or "lobotomy" without consent. KY. REV. STAT. §§ 202A.180, 202B.060 (1977); MASS. GEN. LAWS ANN. ch. 123 § 23 (West Supp. 1977); OHIO REV. CODE ANN. §§ 5122.271, 5123.86 (Page Supp. 1976); S.D. COMPILED LAWS ANN. §§ 27A-12-2, 27B-8-20 (1976); N.J. STAT. ANN. § 30:4-24.2 (d) (Supp. 1977); "electro-convulsive therapy," "insulin shock," "convulsive therapy," or "shock treatment." N.Y. MENTAL HYG. LAW, § 15.03(b) (McKinney 1976); OHIO REV. CODE ANN. §§ 5122.271, 5123.86 (Page Supp. 1976); S.D. COMPILED LAWS ANN. §§ 27A-12-2, 27B-8-20 (1976); KY. REV. STAT. §§ 202A.180, 202B.060 (1976); IOWA CODE ANN. § 229.23 (West Supp. 1977); MASS. GEN. LAWS ANN. ch. 123 § 23 (West Supp. 1977); N.J. STAT. ANN. § 30:4-24-2d (Supp. 1976); "chemotherapy," "medication" or "drugs," IOWA CODE ANN. § 229.23 (West Supp. 1977); N.J. STAT. ANN. § 30:4-24-2d (Supp. 1976); S.D. COMPILED LAWS ANN. §§ 27A-12-2, 27B-8-20 (1976); "experiments," "experimental research," "experimental treatment," or "experimental drugs or procedures," MINN. STAT. ANN. § 144.651 (West Supp. 1977); N.J. STAT. ANN. § 30:4-24.2d (West Supp. 1977); S.D. COMPILED LAWS §§ 27A-12-2, 27B-8-20 (1976); "sterilization," N.J. STAT. ANN. § 30:4-24.2d (West Supp. 1977); OHIO REV. CODE ANN. §§ 5122.271, 5123.86 (Page Supp. 1976); and "aversive stimuli," OHIO REV. CODE ANN. §§ 5122.271, 5123.86 (Page Supp. 1976).

cedure an absolute right of persons capable of giving informed consent.

Subsection (b) does not attempt to change significantly the rights of a parent to consent to medical treatment for his or her child,[138] or the power that a guardian possesses under state law to make medical decisions for his ward.[139] However, subsection (c) clearly leaves the determination of administration of psychosurgery or sterilization of a person incapable of informed consent to the courts. It is doubtful whether, under existing law, a guardian has the right to consent to these procedures for his ward.[140] Parents similarly appear to lack

138 As drafted, this Act would not affect that class of medical decisions by guardians or parents which concern proposed procedures of questionable benefit to the child, but do not involve life termination. The now classic case of Strunk v. Strunk, 445 S.W.2d 145 (Ky. 1969), is a good example of judicial practices in this area. In *Strunk* the court examined whether it was in the best interests of a mentally retarded person to donate one of his kidneys to his normal sibling. The possible abuse in organ and bone marrow transplants of incompetent persons is evident. *See also* Hart v. Brown, 29 Conn. Supp. 368, 289 A.2d 386 (Super. Ct. 1972); *In re* Richardson, 284 So.2d 185 (La. Ct. App.), *cert. denied,* 284 So.2d 338 (La. 1973); *In re* Guardianship of Pescinski, 67 Wis.2d 4, 226 N.W.2d 180 (1975). *See generally* Robertson, *Organ Donations By Incompetents and the Substituted Judgment Doctrine,* 76 COLUM. L. REV. 48 (1976); Baron, Botsoford & Cole, *Live Organ and Tissue from Minor Donors in Massachusetts,* 55 B.U.L. REV. 159 (1975).

While the drafters did not address this problematic situation in this Act, they believed that this conflict problem could be addressed on a case-by-case basis in the courts notwithstanding the statute.

139 Under the Adult Protective Services Act, ch. 768 (July 1, 1977), enacted this year, a guardian's latitude as to medical decisions for his ward are significantly limited. A guardian must receive judicial approval of his proposed consent to a medical procedure involving "substantial risk." MD. EST. & TRUSTS CODE ANN. § 13-708(b)(8). No other state places such a restriction on a guardian's powers *vis-a-vis* his ward's medical treatment.

140 Absent a specific statutory grant of authority, courts have found that guardians do not have the authority to consent to sterilization under general equity powers. Frazier v. Levi, 440 S.W.2d 393 (Tex. Ct. App. 1969); Holmes v. Powers, 439 S.W.2d 579 (Ky. Ct. App. 1968). *See also* Sparkman v. McFarlin, 552 F.2d 172 (7th Cir. 1977), *rev'd and remanded sub nom.* Stump v. Sparkman, 98 S.Ct. 1099 (1978) (judge held to possess immunity from liability for damages to involuntary sterilization patient).

Sterilization has received significant attention in the legal literature. Commentators appear to be in general agreement that a parent or guardian lacks the authority to consent to a sterilization on behalf of his child or ward, particularly in the absence of a specific sterilization statute. *See* Annot., 74 A.L.R.3d 1210, 1224 (1976); Comment, *Eugenic Sterilization Statutes: A Constitutional Re-evaluation,* 14 J. FAM. L. 280 (1975); Murdock, *Sterilization of the Retarded: A Problem or a Solution?* 62 CAL. L. REV. 917 (1974); Comment, *Sterilization of Mental Defectives: Compulsion and Consent,* 27 BAYLOR L. REV. 174 (1975); Comment, *Sexual Sterilization-Constitutional Validity of Involuntary Sterilization, and Consent Determinative of Voluntariness,* 40 MO. L. REV. 509 (1975).

authority under the common law to consent to sterilization of their children.[141]

As discussed above, the Act permits the performance of psychosurgery and sterilization without personal informed consent only on court authorization because of the highly invasive and irreversible nature of the procedures and their impact on the fundamental constitutional rights of procreation and freedom of mentation. For the same reason, sterilization and psychosurgery are broadly defined by subsection (c). Thus the definition of sterilization includes any operation or procedure resulting in sterility even if the sole purpose of the operation or procedure was to remove a cancerous tumor, for example, and sterility was an unavoidable and undesirable by-product.[142] The definition of psychosurgery is similarly

---

While some state statutes permit the next of kin or legal guardian to consent to sterilization of his relative or ward, Comment, *Eugenic Sterilization Statutes: A Constitutional Re-evaluation,* 14 J. FAM. L. 280, 291-92 (1975), no decision has yet been rendered on these statutes. *See* Annot., 74 A.L.R.3d 1224, 1227 (1976).

While there is no similar law as to psychosurgery, it is dubious that a guardian's general equity authority would extend to consent to psychosurgery. *See* Kaimowitz v. Department of Mental Health, No. 73-19434 (Cir. Ct. Wayne Co., Mich. July 10, 1973), *reported in* 2 PRISON L. REP. 433 (1975) (the court refused to accept the consent of the parents of the patient as valid on the unexplained basis that the guardian may not consent to psychosurgery to which the patient may not consent). *See also* Psychosurgery Report, *supra* note 65. The Commission recommended, *inter alia,* that psychosurgery be performed on persons adjudicated incompetent only after the approval of a National Psychosurgery Board and a court order are obtained to supplement the guardian's informed consent. *Id.* at 26,330.

141 A.L. v. G.R.H., 325 N.E.2d 501 (Ind. Ct. App. 1975), *cert. denied,* 425 U.S. 936 (1976). There is no similar case law as to psychosurgery, but parental authority probably would not extend to psychosurgery. While the National Commission's Psychosurgery Report would permit the performance of psychosurgery on minors, the approval of both a National Psychosurgery Advisory Board and a court of competent jurisdiction, in addition to parental consent, would be required. Psychosurgery Report, *supra* note 65 at 26,331.

The statute limits parental authority over medical decisions which could be anticipated to result directly in the termination of life; those decisions are made by the Board. State interference in this area of parental decision-making has significant precedents. Courts are often asked to review parental decisions that could affect their children's lives, and they have consistently overruled parental rejection of life-saving treatment for their children. *See, e.g., In re* Sampson, 65 Misc.2d 658, 317 N.Y.S.2d 641 (Ulster Co. Fam. Ct. 1970).

142 Compare the definition of "nontherapeutic sterilization" in the federal regulations governing sterilizations performed with federal monies, 42 C.F.R. 50.202(b) (1977):

> any procedure or operation, the purpose of which is to render an individual permanently incapable of reproducing and which is not either (1) a necessary part of the treatment of an existing illness or injury, or (2) medically indicated as an accompaniment of an operation on the female

broad.[143] Because the results of psychosurgery are still unpredictable,[144] the Act could not rely on the results of the operation in defining psychosurgery. Psychosurgery is instead defined by its "primary" purpose.

Subsection 3(d), exempting treatment in emergency situations from the informed consent requirement, is discussed in the comments to Section 2(c).

Section 4. *The Substitute Consent Review Board: Structure, Composition and Independence*

(a) The Secretary shall designate at least one Substitute Consent Review Board for each county and may assign a Board to hear petitions from one or more health facilities as caseloads require.

(b) The Secretary shall appoint to each Board the following:

(1) A physician who is licensed in this state, has practiced at least five years and shall be selected from a list compiled by the county medical society;

(2) A lawyer who is admitted to practice in this state, has practiced at least five years and shall be selected from a list compiled by the county bar association and who shall chair the board to which he is appointed; and

(3) A member who is not a lawyer or a physician.

(c) The Secretary shall appoint alternate members with the requisite qualifications to replace members who are absent or are engaged in the care of or are related to the patient.

(d) A member of the Board who is engaged in the care of or is related to the patient may not participate in the Board's considera-

---

genitourinary tract. For purposes of this paragraph mental incapacity is not considered an illness or injury.

This definition is similarly broad to prevent the administration of involuntary sterilization with federal monies in contravention of federal law. *See* Relf v. Weinberger, 372 F. Supp. 1196 (D.D.C. 1974), *modification denied sub nom.* Relf v. Matthews, 403 F. Supp. 1235 (D.D.C. 1975).

143 This definition is similar to the definition adopted by the National Commission with one notable exception. The Commission specified that psychosurgery included the implantation of electrodes or the destruction or stimulation of brain tissue by any means. The drafters, on the advice of the physician members of the Committee, believed that such implantation or stimulation ought to be considered "experimentation," and as such would be regulated pursuant to 45 C.F.R. § 46.101 to .301 (1977) (Protection of Human Subjects).

144 Psychosurgery Report, *supra* note 65, at 26,323-26.

tion of that patient. The members of the Board may not be employees of, and the lawyer may not have an attorney-client relationship with, the health facility or facilities in which the patient is to be treated or resides.

(e) Each member shall serve at the pleasure of the Secretary and shall be paid by the State at a rate to be fixed in the State budget.

COMMENT: This section provides for a review board, rather than a court, to decide the patient's capacity and to appoint a substitute decision maker if required, because such a board can sit at a location and in a setting more convenient and less disruptive to the patient, the patient's family, and to personnel administering treatment than can a court. Moreover, utilization of a specialized administrative board should reduce the often substantial delays now occasioned by guardianship proceedings.

An interdisciplinary review board is mandated to insure that the issues of capacity and the appointment of a substitute decision maker will be examined thoroughly from all relevant perspectives. The Board's decisions should reflect legal and medical opinions, as well as community values, without biasing the result toward the viewpoint of any one member.

The requirement of subsection (d) that the members of the Board not be employees of the health facility is included to insure the Board's independence.[145] Where there is no qualified substitute decision maker, the Board will assume this function, deciding whether treatment will be provided and, if so, what type of treatment. The independence of the Board is essential, for it might be difficult for an "in-house" board to make decisions contrary to those of treating personnel at the

---

145 As originally drafted, this legislation specified that two of the Board's members were to be employees of the health facility and appointed by the chief administrator of the facility. The lawyer member of the panel was to be independent and appointed by the Secretary of the Department of Health and Mental Hygiene. The arguments against a completely independent Board focused on the potentially prohibitive costs of such independence. The compromise adopted in the original draft would have prevented the Committee from being completely "in house," while reducing costs by only paying the salary of one member. Sponsors of the legislation felt, however, that the independence of the Board was so important that the extra costs were justified.

facility with which the members of such a board are affiliated.

Section 5. *The Substitute Consent Review Board: Its Operation*

(a) If there is a question as to the capacity of the patient to give, deny, or withdraw informed consent, the person responsible for administering the proposed procedure at a health facility shall refer the case to the Board designated for the health facility in which the patient is to be treated or resides for determination of capacity and, if indicated, appointment of a substitute decision maker.

COMMENT: Subsection (a) is intended to conform to existing law, which requires a physician or other person administering treatment to obtain informed consent before administering any procedure. The person administering treatment is the person most likely to have doubts about a patient's capacity to consent to treatment, and therefore the responsibility to voice those doubts by referring the case to the Board is delegated to him.[146]

(b) Until the Board makes its determination, any necessary interim standard medical care may be delivered with the consent of a family member or interested person, or if a family member or interested person is not reasonably available, without consent. However, if any interim standard medical care is delivered before a determination by the Board, the person responsible for administering the proposed procedures shall document in the patient's medical

---

146 In most states there is a statutory privilege concerning communications between patients and physicians. *See, e.g.,* MD. CTS. & JUD. PROC. CODE ANN. § 9-109 (1974). The statutory privilege would have to be amended to enable a physician to file with the Board a petition setting forth his reasons for believing that his patient lacks capacity to consent. The following example is an illustration of a possible amendment: There is no privilege if a disclosure is necessary for the determination of the capacity to consent to health care procedures and for the obtaining of substitute consent to health care procedures.

Some state statutes already contain an exception to the privilege, which would allow a physician to file a petition with the Substitute Consent Review Board. For example, Michigan's law provides:

> (3) Privileged communications shall be disclosed upon request:
>
> (c) When the privileged communication is relevant to a matter under consideration in a proceeding to determine the legal competence of the patient or his need for a guardian but only if the patient was informed that any communications made could be used in such a proceeding. MICH. COMP. LAWS ANN. § 330.1750(3)(C) (1975).

record the reasons for questioning the capacity of the patient to give informed consent and the need for administering the procedures before a Board determination can be made.

COMMENT: Subsection (b) recognizes that serious practical problems would result from a prohibition of any treatment without a Board determination. The statute permits family members or interested persons to consent to interim standard medical care. In defining the term "interested persons," the drafters chose those persons most likely to make decisions in the patient's best interest. The subsection (b) requirement of documentation of interim standard medical care is designed to encourage provision of adequate treatment and discourage the performance of non-essential treatment prior to determination of the patient's capacity by the Board.

(c) (1) A person responsible for administering a procedure who refers a case to the Board shall submit a petition to the Board and inform the patient that a petition has been submitted.

(2) Each petition shall contain the following information:

(A) the patient's name, address, age, and case number, if available;

(B) the reason that the petitioner believes the patient lacks the capacity to give, deny, or withdraw informed consent;

(C) the procedure proposed; and

(D) the petitioner's name and position.

COMMENT: The limited amount of information required in the petition reflects the concern that treating personnel not be overburdened with unnecessary paperwork.

(d) On receipt of a petition, the Board shall:

(1) schedule a hearing within five days after the date on which the petition is received; and

(2) provide written and oral notification of the hearing to the patient, including:

(A) a copy of the petition;

(B) a statement that the patient has a right to counsel and that if he does not intend to obtain counsel, a patient advocate will be appointed under subsection (e) of this Section; and

(C) a place in the statement for the patient to indicate whether or not he has obtained counsel and, if so, the name and

address of counsel and any other person that the patient wishes to be notified of his hearing.

COMMENT: The requirement that a hearing be held within five days after a petition is filed is the result of a careful balancing of several factors: (1) the desirability of prompt consideration to minimize unnecessary medical costs and to prevent undue delays in treatment; (2) the need for notice and preparation of the case; and (3) the practical difficulties of more frequent meetings.

Subsection (d)(2)(A) provides that the Board's notice to the patient, in addition to stating the location, date, and time of the hearing, must also include a copy of the petition, which contains the reasons why the petitioner believes the patient lacks capacity to give informed consent. This requirement is in accordance with recent court decisions in the area of commitment. These decisions require that patients be given notice designed both to inform them of their rights under the commitment statute and to facilitate the preparation of their defense.[147]

(e) Each patient is entitled to representation by counsel of his choice. The health facility shall inform the patient of the availability of the legal aid bureau, judicare, lawyer referral service, and other agencies that may exist for persons needing legal counsel. If the patient does not obtain counsel, the Board shall appoint a patient advocate for him. The Secretary shall develop a program to train patient advocates.

COMMENT: Subsection (e) reflects a difficult compromise on the nature of the representation provided the patient. Ideally, each patient should be represented by an attorney because a determination of incapacity would deprive the patient of the right to make his own health care decision. However, subsection (e) acknowledges that a properly trained non-attorney

147 Lessard v. Schmidt, 349 F. Supp. 1078 (E.D. Wis. 1972), *vacated and remanded for a more specific injunctive order,* 414 U.S. 473 (1974), *amended opinion,* 379 F. Supp. 1376 (E.D. Wis. 1974), *vacated and remanded,* 421 U.S. 957 (1975); Bell v. Wayne County Gen. Hosp., 384 F. Supp. 1085 (E.D. Mich. 1974).

can provide adequate representation at a non-judicial hearing.[148] Among the pragmatic considerations which support this view are the scarcity of available attorneys knowledgeable in the law of consent and the inadequacy of state financial resources to meet the cost of attorney representation of the indigent population, particularly those patients in state facilities for the mentally ill and retarded.

Subsection (e) directs the Board to appoint a patient advocate for patients lacking other legal counsel. It also requires the Secretary of the relevant state agency to develop a program to train the patient advocates.[149]

---

148 An additional safeguard is § 11(e) of the Model Act which allows any patient who feels that inadequate representation resulted in an improper decision by the Board to take a *de novo* appeal to court.

149 Two advocacy models currently in operation suggested this alternative as a way to provide quality representation. The first is the nationwide Citizen Advocacy Program developed from the Wolfensberger concept. *See generally* W. WOLFENSBERGER, TOWARD CITIZEN ADVOCACY FOR THE HANDICAPPED (1970). The core of this system is a one-to-one relationship between a capable volunteer (advocate) and a mentally retarded person (protege) in which the advocate defends the rights and interests of the protege within the framework of the structured advocacy system. *See* NATIONAL ASSOCIATION FOR RETARDED CITIZENS, ADVOCACY FOR MENTALLY RETARDED CHILDREN: AN INTRODUCTION (1974). Local citizen advocacy offices provide training for the advocate through workshops where new advocates discuss the literature on citizen advocacy and handicapping conditions, participate in panel discussions involving actual advocates and proteges, and familiarize themselves with community resources which the protege might need. After completing his training, an advocate may intervene for a protege in various ways, including assisting him to apply for government benefits, to secure an attorney if needed, to plan a budget, or to offer him emotional reinforcement.

The second model is the Mental Patient's Advocacy Project, located at Northampton State Hospital, Northampton, Massachusetts. This is a joint project of Western Massachusetts Legal Services, Inc., the University of Massachusetts Legal Studies Program, and the Hampshire College Law Program. It is designed to provide legal assistance to hospitalized patients. Advocates assist attorneys in individual and class action litigation and represent clients in their fiscal competency evaluations.

Non-lawyer advocates play a key role in providing this assistance on the theory that, unlike lawyers, they can present a more balanced and human approach to patients, are less likely to limit their focus to narrow legal problems, and often are more effective negotiators because they are perceived by hospital personnel as less threatening than attorneys. Attorneys and a psychiatrist train advocates through: (1) formal academic instruction at local colleges, (2) a clinical program at mental hospital facilctie train advocates through: (1) formal academic instruction at local colleges, (2) a clinical program at mental hospital facilities, (3) weekly work in a mental health facility, and (4) participation in weekly case review and legal strategy sessions. *See* Mental Patient Advocacy Project Brochure (on file at Developmental Disabilities Law Project, University of Maryland Law School, Baltimore, Maryland 21201).

(f) The patient shall return to the Board the portion of the petition set forth in subsection (d)(2)(C) of this Section and the Board shall give notice of the nature, location, date, and time of hearing by registered mail to each person specified by the patient and to all interested persons, as defined in this Act.

COMMENT: The provisions of this subsection should be considered in light of the complementary notice requirements contained in preceding sections of the Act. Subsection (c)(1) requires that whenever treating personnel submit petitions to the Board alleging that the patient lacks the capacity to give informed consent, they shall also inform the patient that a petition has been submitted. Subsection (b)(2) of the legislation further provides for notice by requiring that the patient be given written and oral notification of the hearing. Written notification must also be given to each person specified by the patient, the patient's parents, spouse, custodian, or other adult responsible for his care, according to the provisions of this subsection.

To accommodate the concern that written notice will traumatize the patient and reduce the likelihood of effective treatment, subsections (c) and (d) require both written and oral notification of the petition and its contents.[150]

Because individuals alleged to be unable to consent to medical treatment may not be fully able to understand what will take place at the hearing, this subsection provides that notification of the hearing must also be given to each person specified by the patient and to all interested persons.

(g) (1) The hearing shall be conducted at the health facility in a place accessible to the patient.

(2) A patient is entitled to be present in person during the

Both programs could be adapted to the context of the Model Act. A curriculum modeled on the Citizen Advocacy Program would be utilized to train an advocate to act aggressively to further the total needs of his protege, while a program based on the Mental Patient's Advocacy Project could teach advocates to act as forcefully in a more limited capacity.

150 One proposal which was advanced to reconcile the danger of trauma with the requirement of notice is that medically-trained personnel, such as members of the hospital staff, inform the individuals. *See* F. LINDMAN, THE MENTALLY DISABLED AND THE LAW 51 (rev. ed. 1971).

hearing, and, except on a showing of good cause for proceeding in his absence, the Board may not proceed in the absence of the patient.

(3) The patient and the petitioner may introduce evidence and cross-examine all witnesses.

(4) The Board may call witnesses.

(5) On request of the patient's counsel, the Board may order tests and evaluations.

(6) The Board, on its own motion, may order experts to present written or oral testimony.

(7) A stenographic or mechanical recording of the proceeding shall be made and retained for at least five years after the date of the hearing.

COMMENT: Although the vast majority of states require the alleged incompetent to be present at the guardianship hearing unless contrary to his best interests, in few cases is the alleged incompetent actually present.[151] This subsection gives the patient the right to be present at the Board's hearing at the health facility for the following reasons. First, the Board has the ultimate responsibility of determining the patient's capacity to make decisions. An opportunity to speak to the patient and observe his behavior is critical to its evaluation of his capacity. Second, if the patient is present, he can insure that his interests are being protected. For example, the patient may point out errors in the testimony about his actions, which otherwise may go unnoticed. Finally, because the patient's right to make his own health care decisions is in jeopardy, reasons of basic fairness compel his participation in the process. Therefore the subsection provides that the Board may proceed without the patient's presence, but only upon a showing of good cause.

---

151 Although most jurisdictions require that the alleged incompetent be present for the hearing, forty-five states and the District of Columbia allow the court to dispense with that requirement if the "best interest" of the alleged incompetent would be served thereby. F. LINDMAN, *supra* note 150, at 280-92. Alexander and Lewin conducted a two-year study of New York incompetency hearings in which they found that the alleged incompetent was seldom present for the hearing which determined his competency. G. ALEXANDER & T. LEWIN, THE AGED AND THE NEED FOR SURROGATE MANAGEMENT 25 (1972).

Section 6. *The Substitute Consent Review Board: Its Decision-Making Responsibility*

(a) At the close of the hearing, the Board shall state its findings of facts and conclusions of law and immediately issue a written order that sets forth:

(1) its determination as to capacity;

(2) its designation of a substitute decision maker, if applicable;

(3) the scope of the substitute decision maker's powers as to procedures;

(4) the duration of the order;

(5) the appeal procedure as set forth in Section 11 of this Act;

(6) a description of the redetermination procedures set forth in Section 9 of this Act; and

(7) the designation of a person to serve as a continuing patient advocate after expiration of the initial appeal period if:

(A) a substitute decision maker is appointed; or

(B) the patient is represented at the hearing by counsel who is unable or unwilling to serve.

(b) (1) If a majority of the Board finds that clear and convincing evidence does not exist to show that the patient lacks capacity to give informed consent, the written order shall state that the patient has the capacity to give, deny, or withdraw informed consent to the proposed procedure.

(2) If a majority of the Board finds that clear and convincing evidence exists to show that the patient lacks capacity to give informed consent, the written order shall state that the patient does not have the capacity to give, deny, or withdraw informed consent to the proposed procedure, and shall appoint a qualified individual, if available, as substitute decision maker.

(3) If a majority of the Board finds that the incapacity to consent does not apply to all procedures, the Board may limit the scope of the order to apply to certain procedures only.

(c) (1) Each substitute decision maker is required to have the capacity to give informed consent. The Board shall consider at least the following factors in appointing a substitute decision maker:

(A) familial relationship;

(B) availability for the duration of the order; and

(C) the extent to which the person has evinced interest in and assumed responsibility for the patient's welfare.

(2) An employee of the health facility in which the patient is to

be treated or resides may not be appointed as an individual substitute decision maker unless he is a relative of the patient.

(3) If the Board finds that a qualified substitute decision maker is not available, the Board shall be the substitute decision maker and, by majority decision, shall determine whether to give, deny, or withdraw informed consent for the proposed procedure.

(d) An order is effective only for procedures administered in health facilities and for the time specified in the order. An order may not be effective for longer than six months.

(e) The Board shall send a copy of this order to the patient, his counsel, and the substitute decision maker and shall place a copy in its permanent files and in the patient's medical record.

(f) Within three working days after the close of the hearing, the Board shall issue written findings of facts and conclusions of law, which shall be sent to the patient and his counsel and be placed in the Board's permanent files.

COMMENT: It is imperative that the Board not base its determination of the patient's capacity on the reasonableness, or lack thereof, of the patient's decision, rather than the patient's ability to decide. To guard against the possibility that the Board will impose its moral or medical viewpoint on the patient, subsection (b) merely requires that the individual have the ability to understand and knowingly, rationally, and voluntarily act on the information required for informed consent. As a further check on arbitrary decision making, subsection (b) merely requires that a majority of the Board determine that clear and convincing evidence exists to show that the patient lacks the capability to give consent.

The preponderance of the evidence standard used in civil actions is an insufficient protection, in light of the serious potential consequence of the Board's determination — loss of ability to make one's own decisions concerning treatment.[152] Federal and state courts have overwhelmingly required a standard of proof stricter than preponderance of the evidence

---

152 In most civil proceedings, and especially those in which the stakes are economic, the preponderance of the evidence standard is seen to be appropriate. Justice Harlan's concurring opinion in *In re* Winship, 397 U.S. 358, 371 (1970) stated one reason for this belief: "We view it as no more serious in general for there to be an

Federal and state courts have overwhelmingly required a standard of proof stricter than preponderance of the evidence in various types of involuntary commitment proceedings;[153] a similar standard is appropriate for the Board's proceedings, since the risks involved in its cases are similar to — and given that withdrawal of life support systems is a possible outcome, sometimes higher than — the risks involved in civil commitment proceedings.

In drafting the Act, the authors considered two alternative solutions to the problem of who should make decisions for the patient found to lack capacity. First, the Board could be empowered to make treatment decisions in all cases. Second, the Board could be required to appoint a substitute decision maker whenever such a substitute was available. The latter course was chosen because it is preferable that a family member or other qualified and interested person, rather than the Board, make decisions in this difficult and highly personal area. Furthermore, the approach adopted in subsection (c) conserves the financial resources of the Board. Only where

---

erroneous verdict in the defendant's favor than for there to be an erroneous verdict in the plaintiff's favor."

On the other hand, in situations where the various interests of society are pitted against restrictions on the liberty of the individual, a more demanding standard is frequently imposed, such as proof by clear, unequivocal and convincing evidence. *See, e.g.,* Woodby v. Immigration and Naturalization Service, 385 U.S. 276 (1966).

153 *See, e.g.,* United States *ex rel.* Stachulak v. Coughlin, 520 F.2d 931 (7th Cir. 1975) (beyond a reasonable doubt); *In re* Ballay, 482 F.2d 648 (D.C. Cir. 1973) (beyond a reasonable doubt); Lynch v. Baxley, 386 F. Supp. 378 (M.D. Ala. 1974) (clear and convincing evidence); Davis v. Watkins, 384 F. Supp. 1196 (N.D. Ohio 1974) (beyond a reasonable doubt); Lessard v. Schmidt, 349 F. Supp. 1078 (E.D. Wis. 1972) (beyond a reasonable doubt); People v. Burnick, 14 Cal.3d 306, 535 P.2d 352, 121 Cal. Rptr. 488 (1975) (beyond a reasonable doubt); *In re* Andrews, 75 Mass. Adv. Sh. 2550, 334 N.E.2d 15 (1975) (beyond a reasonable doubt); State v. Valdez, 88 N.M. 338, 540 P.2d 818 (1975) (clear and convincing evidence); *In re* Hodges, 325 A.2d 605 (D.C. App. 1974) (beyond a reasonable doubt); People v. Sansone, 18 Ill. App.3d 315, 309 N.E.2d 733 (1974) (clear and convincing evidence); *In re* Levias, 83 Wash.2d 253, 517 P.2d 588 (1973) (clear and convincing evidence).

Commentators have approved of the trend of this case law. *See, e.g., Developments in the Law-Civil Commitment of the Mentally Ill,* 87 HARV. L. REV. 1190, 1295-1303 (1974); Note, *Commitment and Release Standards and Procedures: Uniform Treatment for the Mentally Ill,* 41 U. CHI. L. REV. 825, 829 (1974); Ennis and Litwack, *Psychiatry and the Presumption of Expertise; Flipping Coins in the Courtroom,* 62 CALIF. L. REV. 693, 750-51 (1974); Combs, *Burden of Proof and Vagueness in Civil Commitment Proceedings,* 2 AM. J. CRIM. LAW 47, 59-63 (1973).

no appropriate persons are available to assume the responsibility need the Board act as substitute decision maker.

The maximum six-month duration of the Board's order, established by subsection (d), recognizes the impracticality of determining capacity and appointing a substitute decision maker for every medical procedure. At the same time, the six-month maximum also insures periodic review of the patient's capacity. Furthermore, by limiting the Board's order to specified procedures, subsection (d) does not deprive the patient of his ability to make health care decisions concerning those procedures to which he is capable of giving his informed consent.

Section 7. *The Substitute Decision Maker's Powers*

(a) During the period that the order is effective, the substitute decision maker may give, deny, or withdraw informed consent to all procedures except those where substitute consent is prohibited under Section 3(c) of this Act or where it is anticipated that the denial or withdrawal of consent would directly cause the termination of life.

(b) The substitute decision maker, in deciding whether to give, deny or withdraw informed consent for the proposed procedure shall:

(1) determine its necessity and reasonableness;

(2) consider the factors set forth in Sections 1(a)(7)(B)(i)-(iv) of this Act; and

(3) consider whether or not the proposed procedure is in the best interest of the patient.

COMMENT: In making his decision to give, deny, or withdraw informed consent for the proposed procedure, the substitute decision maker must, under subsection (b)(1), evaluate the "necessity and reasonableness" of the procedure. This is the standard used by the Minnesota Supreme Court in *Price v. Sheppard*[154] in determining whether to authorize treatment for an incompetent or objecting patient. *Price* also sets out the criteria to be followed in making this determination,

154 307 Minn. 250, 239 N.W.2d 905 (1976).

balancing the patient's need for treatment against the intrusiveness of the prescribed treatment.[155]

Subsection (b)(3) requires that the substitute decision maker consider the proposed procedure in light of the best interests of the patient. This standard was adopted in lieu of the "substitute judgment" standard set forth by Chief Justice Hughes in *In re Quinlan*.[156] There, the New Jersey Supreme Court empowered the guardian, the family, and the physician, following specified procedures, to use their best judgment in making health care decisions as Karen Quinlan would have made them had she been competent to do so. The Act does not adopt this standard, because requiring a substitute decision maker to act based upon his prediction of how another individual would have acted in the same situation would be an onerous burden on the substitute decision maker. The "best interest" tests has been employed by the more persuasive statutes and cases.[157]

Section 8. *Denial or Withdrawal of Consent by the Board If Termination of Life is the Anticipated Result*

(a) If he anticipates that denial or withdrawal of consent by the substitute decision maker, parent of a minor, or guardian will result directly in the termination of life, the person responsible for administering the procedure shall refer the case to the Board.

(b) The Board shall decide whether to deny or withdraw the procedure. In making the decision, the Board shall consider and be bound by the wishes of the patient made when he as legally competent.

---

155 Factors which should be considered are:
(1) the extent and duration of changes in behavior patterns and mental activity affected by the treatment, (2) the risks of adverse side effects, (3) the experimental nature of the treatment, (4) its acceptance by the medical community of this state, (5) the extent of intrusion into the patient's body and the pain connected with the treatment, and (6) the patient's ability competently to determine for himself whether the treatment is desirable. 239 N.W.2d at 913. These factors are in many instances similar to the factors the substitute decision maker would consider under subsection (b)(1) of the proposed of the Act.

156 70 N.J. 10, 355 A.2d 647 (1976).

157 N.M. Mental Health and Disab. Code, ch. 279, § 14(B), 1977 N.M. Laws 2177, 2195-97; *In re* Guardianship of Pescinski, 67 Wis.2d 4, 226 N.W.2d 180 (1975); *In re* Richardson, 284 So.2d 185 (La. Ct. App.), *cert. denied*, 284 So.2d 338 (La. 1973).

(c) If the Board cannot ascertain such wishes, it shall make a decision after:

(1) consulting with the substitute decision maker, if appointed, interested persons, the Life Preservation Advisory Committee and other people whom the Board considers necessary; and

(2) considering the factors set forth in Section 7(b) (1)-(3) of this Act. Any decision of the Board to deny or withdraw consent is required to be unanimous. If the Board is unable to reach a unanimous decision, it shall refer the case to the [ ] court for a determination.

COMMENT: The first major problem addressed by this section is who shall decide whether to deny or withdraw the life-sustaining procedure. Subsections (a) and (c) give the Board the power to make this decision after consulting with the substitute decision maker, interested persons, a "Life Preservation Advisory Committee,"[158] and any other parties the Board deems necessary.

By requiring the Board to make the decision, the Act creates a mechanism whereby the decision maker will be assured of hearing the diverse viewpoints of all parties before making a decision. The Board, and not family members, are given the ultimate responsibility because the family's financial difficulties or emotional ties might make it difficult for family members to render a decision in the patient's best interest.

The second problem addressed by this section is the standard to be employed in deciding whether to withdraw life-support procedures. Two recent court decisions have wrestled with the problem of when to withdraw life support procedures from terminally ill incompetent patients. In the well-publicized case of *In re Quinlan*,[159] the New Jersey Supreme Court empowered the guardian, family, and physicians,

158 Maryland House Joint Resolution No. 158, 1976 Md. Laws 2720, urges hospitals and related institutions in the State to create Life Preservation Advisory Committees. These committees are counseling committees whose purpose is to aid, counsel, and advise physicians, hospital personnel, and family members in dealing with difficult circumstances arising in cases of terminal illness. They are composed of a medical adviser who is not a medical director of any nursing home or hospital, a lay person who is not a member of any hospital's administrative staff, an ethicist, a religious counselor, and a lawyer.

159 70 N.J. 10, 355 A.2d 647 (1976).

following specified procedures, to use their best judgment to make health care decisions as the patient would have made them if she had been competent to do so.[160]

In a similar case in Tennessee, *Dockery v. Dockery*,[161] the court, once a determination had been made that there was no possibility that the patient would return to a cognitive state, issued an order which allowed the family to make the decision to withdraw the use of a life-sustaining respirator once the doctor made certain medical determinations.[162]

While these two cases concern the more unusual situation of withdrawal of life support apparatus, a third recent case, *Superintendent of Belchertown State School v. Saikewicz*,[163] presents the more common problem: whether treatment which cannot cure the patient, but can only prolong his life, should be initiated. Since the desires of Mr. Saikewicz could not be ascertained,[164] the probate court appointed a guardian *ad litem* who, after considering the risks associated with the proposed treatment, the intensity of pain of the proposed treatment, and the length of prolongation of life likely to be gained by the proposed treatment, refused to give consent to this treatment. His decision was accepted by the probate court, whose order was affirmed by the Massachusetts Supreme Judicial Court.[165]

---

160 *See* note 3 *supra*.

161 No. 51439 (Ch. Ct., Hamilton Cty. Feb. 11, 1977).

162 The court held that if the treating physician of Della Dockery, in accordance with professional standards of care in the community, makes the determination that: (1) there is no reasonable possibility of the patient's ever emerging from the comatose condition; and (2) there is no reasonable possibility that the medical treatment that requires the invasion of the incompetent's body will cure the patient, who is otherwise terminally ill, then the physician cannot continue the use of the respirator without the family's consent. *Id.* at 14.

163 1977 Mass. Adv. Sh. 2461, 370 N.E.2d 417 (1977).

164 Mr. Saikewicz was a 67-year-old profoundly retarded man who had been a resident of Belchertown State School, a public facility for retarded persons for nearly fifty years. He was functioning on a developmental level of less than three years and had an I.Q. of 10. *Id.* at 2464, 370 N.E.2d at 420. In the words of the Supreme Judicial Court, he was "unable to respond intelligibly to inquiries such as whether he was experiencing pain." *Id.*

165 In 1976 it was discovered that Mr. Saikewicz was suffering from acute leukemia. Belchertown State School petitioned the probate court pursuant to Massachusetts law, seeking the appointment of a guardian to give informed consent

In affirming the probate court's order, the Supreme Judicial Court expressed disagreement with the *Quinlan* court's view that it was inappropriate for courts to make a substitute decision as to whether potentially life-prolonging treatment should be withheld from a patient incapable of making his own decision, stating that "such questions of life and death seem to us to require the process of detached but passionate investigation and decision that forms the ideal on which the judicial branch of government was created."[166] Such a decision, said the court, is "not to be entrusted to any other group purporting to represent the 'morality and conscience of our society,' no matter how highly motivated or impressively constituted."[167] Nonetheless, in *Saikewicz*, the probate court, in exercising its authority to make the decision as to treatment, relied in large part upon the recommendation of a guardian *ad litem*, who applied the test of whether the proposed treatment was in the best interest of the patient.[168]

Section 8(c)(2) adopts the "best interest" test — which is to be applied in the usual case by a substitute decision maker

---

to the medical treatment for leukemia — in this case, chemotherapy. The probate court appointed a guardian *ad litem*, who was to have the authority to consent to the chemotherapy treatment. The guardian *ad litem* visited the patient and interviewed medical personnel, who informed him that the chemotherapy treatment was painful and often had severe side effects, and that its administration required cooperation from the patient. Medical personnel also stated that if Mr. Saikewicz did not receive the treatment, the prognosis was that he would suffer a painless death in two months. If he did receive the treatment, he would have a forty percent chance of remission that could last for six months to six years. He was also informed that every person in Mr. Saikewicz's age group faced with his prognosis, had decided to receive the chemotherapy treatments. *See* Superintendent of Belchertown State School v. Saikewicz, 1977 Mass. Adv. Sh. 2461, 2467-69, 370 N.E.2d 420, 421-22 (1977).

The guardian *ad litem*, after considering all these factors, refused to give consent for the treatment. The probate court accepted the guardian *ad litem's* refusal of consent and ordered, on May 13, 1976, that the chemotherapy not be administered. The Massachusetts Supreme Judicial Court accepted the case for review on direct appeal. On July 9, 1976, the Supreme Judicial Court unanimously upheld the lower court's order, but did not release its opinion in support to the decision until November 29, 1977. Mr. Saikewicz died on September 4, 1976, as a result of bronchial pneumonia, which was a complication of the leukemia. *Id.* at 2463, 2469, 370 N.E.2d at 419, 422.

166 *Id.* at 2501, 370 N.E.2d at 435.

167 *Id.*

168 *Id.* at 2462, 370 N.E.2d at 419.

under section 7(b)(3) — for cases involving withdrawal of life support procedures from terminally ill patients lacking capacity to give informed consent. This test is preferable to the "substitute judgment" test, for the latter could give no guidance in situations where the patient had never expressed his wishes prior to becoming incompetent. Furthermore, the "substitute judgment" test fails to take into account factors, such as the associated risks of the proposed procedure, the expected intensity of pain caused by the proposed procedure, and the length of prolongation of life likely to be gained by the proposed procedure, which are relevant to the decision of the Board under this section.[169]

The patient is protected by the requirement that the Board's decision be unanimous. In cases where all Board members cannot agree, the issue must be referred to the trial level court of general jurisdiction[170] for a determination.

Section 9. *Redetermination of the Patient's Capacity*

(a) (1) If the Board has determined that the patient lacks capacity, any member of the health facility treatment staff, the substitute decision maker, the patient advocate who believes the patient has regained capacity, or the patient may petition the Board for a redetermination of the capacity of the patient to give, deny, or withdraw an informed consent.

(2) The Board shall meet within three working days after this petition is filed.

(3) If a redetermination petition is filed by one person in each category set forth in Section 9(a)(1) above, procedures may be performed before the Board's redetermination of the patient's capacity to consent if the substitute decision maker and the patient co-sign an informed consent statement.

(4) If a redetermination petition is not unanimous, procedures

---

169 *See* Superintendent of Belchertown State School v. Saikewicz, 1977 Mass. Adv. Sh. 2484-85, 2488-91 370 N.E.2d at 428-29, 430 ("best interest" test takes into account, to the greatest possible extent, the individual circumstances of each case, while allowing the substitute decision maker to rely on "objective criteria" where it is not possible to ascertain what the patient might have decided if capable of making the decision for himself).

170 *See* Comment to section 11(a) *infra*.

set forth in Section 1(a)(9) of this Act may not be performed while the redetermination petition is pending.

(b) A substitute decision maker may resubmit the case to the Board for consultation or may request that the Board terminate his responsibilities and appoint a new substitute decision maker.

(c) A majority of the Board may remove a substitute decision maker for good cause.

COMMENT: Mental disabilities are not static conditions. Individuals who at one time may not be able to make lucid decisions may at another time be quite stable and competent to make decisions concerning their own health care. In recognition of this fact, this section authorizes any member of the hospital facility treatment staff, substitute decision maker, or patient to petition the Board for a redetermination of the patient's capacity.

Section 10. *Confidentiality of Proceedings and Records*

(a) The proceedings under this Act shall be confidential and shall be closed to the public unless the patient or his counsel waives this protection.

(b) The record of the hearing, including findings and supporting documentation, are confidential and, except with the permission of the patient, may not be disclosed to any person other than authorized representatives of the Federal or State governments monitoring compliance with Federal and State laws or regulations or for purposes of research. Disclosure for research purposes may not characterize the patient in any way which reveals his identity.

COMMENT: In providing for the confidentiality of the records of substitute consent proceedings, the proposed statute differs from former guardianship laws.[171] However, its provisions are consistent with statutory provisions in most states, as well as federal law providing for confidentiality of records involving mental disability.[172]

---

171 Most guardianship proceedings are treated like any civil matter and thus the court records in such cases are open to the public.

172 *E.g.*, 5 U.S.C. § 552(b)(6) (1976) (personnel and medical files constitute clearly unwarranted invasion of privacy). MD. ANN. CODE art. 59, § 19, art. 59A, § 17 (Supp.

Section 11. *Appellate Review*

(a) Within two working days after the close of the hearing, the patient and the petitioner may appeal to the [ ] Court for review of the findings of facts and conclusions of law.

(b) The issues that may be raised on appeal are:

(1) whether or not the patient has the capacity to give informed consent to the procedure; and

(2) whether the appointed substitute decision maker is appropriate.

(c) Notice of the appeal shall be served on the petitioner and the patient.

(d) Implementation of an order is stayed automatically until the period for the appeal lapses without an appeal being filed or, if an appeal is filed, until court review is completed, except that any necessary interim standard medical care may be delivered as provided in Section 5(b) of this Act. The patient, with agreement of his counsel, may waive his right to appeal, in which case the order of the Board may be implemented immediately.

(e) Court review shall consist of a hearing de novo.

(f) Notwithstanding any other provision of law, rule, or regulation to the contrary, no decision or appeal under this Act is subject to review under the [ ] or by the Board of Review of the Department.

COMMENT: The title of the State Administrative Procedure Act should be inserted in the brackets. The proposed statute provides for a *de novo* court appeal. The appeal is to be heard in the trial court of general jurisdiction (*e.g.,* Circuit Court in Maryland; Superior Court in California; Supreme Court in New York), and the name of the relevant court should be inserted in subsection (a), as well as sections 8(c)(2), 12(a), and 12(c). Because of the important rights involved, the patient

---

1977) (prohibiting institutions for the mentally ill and retarded from disclosing patient records except where such disclosure would be in accordance with the provisions of the statute establishing psychiatrist-psychologist privilege or to persons designated by the directors of the Mental Hygiene and Mental Retardation Administration).

States substantially in accord with the Maryland approach include New Jersey, N.J. STAT. ANN. § 30:4-24.31 (West Supp. 1977); Virginia, VA. CODE § 37.1-84.1 (1976); Michigan, MICH. COMP. LAWS ANN. § 330.1748 (1975); Tennessee, TENN. CODE ANN. § 33-306 (1977); and Delaware, DEL. CODE, art. 29, § 1002 (Cum. Supp. 1976).

should have the right to a full court hearing on the matter on appeal. In a *de novo* appeal, as opposed to an appeal on the record, the appellant would have the right to introduce evidence and to have the court make its own independent evaluation of the facts.

Subsection (b) provides that two issues be appealable — whether or not the patient has the capacity to give informed consent to the procedure, and whether the appointed substitute decision maker is appropriate. A third issue — whether the decision of the substitute decision maker is clearly contrary to the patient's interest — may be appealed pursuant to section 12 of the Act. Originally, the drafters of the Act felt that the substantive decision of the substitute decision maker should not be appealable because if his decisions were always subject to question, the substitute decision maker might be placed in an untenable position. However, some protection from a possible decision contrary to the patient's best interest is necessary. The provision for court review of this issue gives such protection while limiting the decision maker's uncertainty by restricting appeals to one forum. To insure that proper weight be given to the substitute decision maker's decision, and more importantly, in order to prevent the patient advocate from feeling a responsibility to appeal routinely, the patient advocate may appeal on that issue only if the substitute decision maker's decision is clearly contrary to the patient's best interest.

Section 12. *The Role of the Patient Advocate*

(a) After the order of the Board becomes effective and the substitute decision maker has signed the consent form for a procedure listed in Section (1)(a)(9) of this Act, he shall communicate his decision to the patient advocate. If the procedure does not appear clearly contrary to the patient's best interest, the patient advocate shall sign the consent form unless a basis for an appeal exists under this Act. The consent is effective only upon signature of the patient advocate or an order of the [ ] Court after appeal upholding the decision of the substitute decision maker.

(b) The patient advocate may not sign the consent form if:

(1) the procedure appers clearly contrary to the best interest of the patient; or

(2) the patient or an interested person denies consent to the procedure prior to the hearing and Board appointment of the substitute decision maker; or

(3) the patient or an interested person continues to object to the procedure.

(c) If one of the situations listed in subsection (b) precludes the signing of the consent form, the patient advocate shall secure an attorney to file an appeal in the [ ] Court for review of the substitute decision maker's consent. The attorney shall be selected from the list referred to in Section 4(b)(2) of this Act unless he is the patient's private attorney. Reasonable attorney fees, if any, and court costs shall be paid by the state.

COMMENT: When the substitute decision maker has signed a consent form for a procedure listed in section 1(a)(9), such as a surgical procedure, and has communicated that fact to the person serving as continuing patient advocate, the continuing patient advocate must decide whether to sign the consent form, which is only effective upon his signature. His decision to sign or not will be based on two factors: the objective determination of whether the procedure is clearly contrary to the best interest of the patient and the subjective decision of the patient or an interested person to object to the procedure. In either of these situations, the patient advocate may not sign the consent form, and it is his responsibility to see that an appeal is filed immediately.

Section 13. *The Effect of a Finding of Incapacity on Other Proceedings*

A Board's finding that a patient lacks the capacity to give informed consent to procedures shall not constitute evidence of incompetency in any other proceeding.

COMMENT: The drafters felt that the determination of incapacity should have no effect on any other proceeding because the determination is made solely for the specific purpose of determining the patient's capacity to consent to health care services.

Section 14. *Protection from Liability*

Except for willful, malicious, or grossly negligent acts or omissions, the substitute decision maker, the members of the Board, the petitioner or his agent, and any other person participating in implementation of this subtitle, may not be held civilly or criminally liable for actions necessary to comply with the provisions of this Act or for the performance or authorization of procedures in accordance with this Act.

COMMENT: The committee recognized that physicians and health facilities are increasingly subject to malpractice suits. Consequently, this section relieves all persons who act in conformance with this Act from civil and criminal liability except in the following circumstances: (1) when the petitioner or his agent are negligent in actually performing medical procedures; or (2) when willful, malicious or grossly negligent acts or omissions are committed by anyone who is a party to the proceedings or a participant in the procedures required by this Act. These exceptions are consistent with existing professional practices.

Section 15. *Severability*

The provisions of this Act are severable. The finding by a court that some provision this Act statute is unconstitutional and void does not affect the validity of the remaining portions of this Act, unless the court finds that the remaining valid provisions alone are incomplete and incapable of being executed in accordance with the legislative intent.

COMMENT: In some states such a provision may be unnecessary because there is a general severability clause applicable to all statutes enacted after a certain date.[173]

Section 16. *Effective Date*

This Act shall be effective on the date of its enactment.

173 *See, e.g.*, MD. CODE ANN. art. 1, § 23 (1976).

NOTE

REGULATING MEDICAL SERVICES AND THE PROSPECTS FOR MEDICAL GOODS

DAVID B. HINGSTMAN*

The Carter Administration's proposal for national health insurance has focused renewed attention upon the condition of American medical care. Recognizing the escalating costs of health care and the inadequate provision of medical care to the poor, advocates of reform have attacked the "fee-for-service" system of medical assistance. They recommend rationalizing the health care system through the increased use of Health Maintenance Organizations (HMOs) and Professional Standards Review Organizations (PSROs).

In this Note, Mr. Hingstman examines the underlying problems of health care provision and asserts that the current services-oriented system, which emphasizes the role of the individual physician as the provider of services, is incapable of meeting the nation's health care needs. He rejects the contention that reform through greater use of HMOs and PSROs will remedy the current problems in the provision of medical assistance. Instead, Mr. Hingstman proposes an alternative to the service mode of delivering medical care. Through a system of selling "medical goods," medical consumers would have access to routinized patterns of diagnosis and treatment by low-cost technical personnel. The medical goods strategy would encourage both innovation and the honest evaluation of medical treatment. At the same time it would make the providers of medical care more responsive to market forces. Establishing a medical goods strategy, Mr. Hingstman argues, would go far toward eliminating the artificial scarcity of medical care produced by the medical services system.

---

* A.B., Princeton University, 1975; member of the class of 1978, Harvard Law School.

Introduction

Interest groups have resurrected the concept of national health insurance for the United States after receiving serious criticism from academic and social commentators.[1] Congress recently has begun to consider two major health insurance bills that propose to tax or subsidize Americans to cover part or all of their medical expenses.[2] Evaluations of the potential for congressional approval have risen once again to the level of "inevitability."[3] This sudden re-emergence of a dispirited principle may be the result of a perception that the objections of previous critics can be answered. In the process of responding to past questions, nevertheless, the advocates of national health insurance have altered its original justification subtly into a new set of health goals that seek to establish a system of regulated medical service. These individuals prefer to deemphasize measurement of the extent to which recent proposals will promote the nation's health.

In a sense, the disadvantages of the old national health insurance have become the advantages of the new. Some writers complained that national health insurance would raise medical costs until they absorbed an intolerable portion of the national budget.[4] Now advocates suggest that a fixed health budget will stabilize or even reduce these costs when it is combined with reorganization of medical care providers.[5]

---

1 *See, e.g.*, K. DAVIS, NATIONAL HEALTH INSURANCE: BENEFITS, COSTS, AND CONSEQUENCES (1975); V. FUCHS, WHO SHALL LIVE? HEALTH, ECONOMICS, AND SOCIAL CHOICE (1974); R. KEINTZ, NATIONAL HEALTH INSURANCE AND INCOME DISTRIBUTION (1976); Brecher, Brudney & Ostow, *The Implementation of National Health Insurance for Ambulatory Care Services in New York City*, 53 BULL. N.Y. ACAD. MED. 179 (1977); Newhouse, Phelps & Schwartz, *Policy Options and the Impact of National Health Insurance*, 290 NEW ENG. J. MED. 1345 (1974) [hereinafter cited as Newhouse].

2 *See Carter Moving on National Health Insurance*, MED. WORLD NEWS, May 1, 1978, at 8.

3 *Id.*

4 One study projects that medical care could absorb 11 percent of GNP in the near future. *See* Newhouse, *supra* note 1, at 1354.

5 For a recent proposal, *see* Enthoven, *Consumer Choice Health Plan, Part II*, 298 NEW ENG. J. MED. 709, 716 (1978). Senator Edward Kennedy (D. Mass.) sponsored a Health Security Program in 1975 that would have instituted fixed-budget allocations. *See* Havighurst & Blumstein, *Coping With Quality/Cost Tradeoffs in Medical Care: The Role of PSROs*, 70 NW. L. REV. 6, 35 (1975). *See generally* Mead *Health Policy: The Need for Governance*, 434 ANNALS 55-56 (1977).

Other critics have argued that the quality of medical care would suffer because cost control would cut unnecessary services.[6] Proponents of national health insurance presently claim, however, that unified federal health care financing will improve the quality of services by strengthening peer review and other assessment procedures.[7] Thus the new national health insurance promises lower overall costs for health care with no general loss in its quality.

By contrast, the original allure of national health insurance had at least two different elements. First, many Americans believed that national health insurance would free them from worry about medical costs while it maintained their access to a personal physician.[8] Second, some supported it in the liberal (or paternalistic) expectation that it would guarantee a right of access to medical care for all Americans, regardless of their income.[9] Underlying both of these faiths was the more fundamental assumption that more medical services would improve the health of the population.[10]

Examination of recent proposals reveals that these goals have been forsaken. Complete subsidization of medical services and unlimited access would encourage overutilization, thus lowering the quality of care and bankrupting the health fund.[11] Federal regulatory efforts have been marshalled to balance medical cost with access to services. The new national health insurance requires physicians and patients to ration medical services according to need and expense by limiting total expenditures and the level of subsidy.[12] It

---

6 *E.g.*, Roberts & Bogue, *The American Health Care System: Where Have All the Dollars Gone?* 13 HARV. J. LEGIS. 635, 684 (1976).

7 Advocates draw on the Canadian experience for support. *See* Marmor, *Rethinking National Health Insurance*, PUB. INTEREST, Winter 1977, at 73, 85.

8 *See* Wildavsky, *Doing Better and Feeling Worse*, in DOING BETTER AND FEELING WORSE 109 (J. Knowles ed. 1977) [hereinafter cited as DOING BETTER].

9 *See* Ginzberg, *Power Centers and Decision-Making Mechanisms*, in *id.* at 206; Starr, *Medicine and Professional Sovereignty*, DAEDALUS, Winter 1978, at 187.

10 Wildavsky calls this perception the "Great Equation." Wildavsky, *supra* note 8, at 105.

11 Newhouse, *supra* note 1, at 1346. *See also* Seminar, *National Surgical Work Patterns as a Basis for Residency Training Plans*, 57 ARCHIV. SURG. 125, 140 (Feb. 1977).

12 *See, e.g.*, Enthoven, *supra* note 5, at 714, 716.

would also rely on the newly-organized health planning programs, such as the Professional Standards Review Organizations (PSROs), and the concentration of physicians and administrative personnel in Health Maintenance Organizations (HMOs) to review these allocative decisions, eliminate unnecessary services, and promote improved performance at lower cost.[13] Advocates of national health insurance have also incorporated the recent critiques of medical care that question the assumption that more services produce better national health.[14] New provider organizations should deliver effective preventive health education,[15] and if health is not affected by traditional medical services, then national health insurance will be no more detrimental than present practices, even if the total quantity of services is cut back.[16]

The current conviction that the medical care market must be rationed, regulated, and rationalized to give all Americans a maximum opportunity to achieve a healthy life differs markedly from traditional methods of promoting social justice. In many other instances, the failure of an industry to provide for the needs of significant portions of the population at a price they can afford has been met by attempts to increase supply and lower costs through internal restructuring of the market.[17] One important method has been the investment of capital to change the composition of an industry

---

13 *See* Roberts & Bogue, *supra* note 6, at 667-81.

14 *See, e.g.*, R. CARLSON, THE END OF MEDICINE (1975); I. ILLICH, LIMITS TO MEDICINE (1976); Knowles, *The Responsibility of the Individual*, in DOING BETTER, *supra* note 8, at 57.

15 Some commentators argue that HMOs have a financial incentive to give preventive care to improve their return on the fixed prepayment. Havighurst & Blumstein, *supra* note 5, at 36; Recent Developments, *Health Maintenance Organization Act of 1973*, 27 VAND. L. REV. 1043, 1045 (1974). One survey that incorporated data from the Kaiser-Permanente Health Plan in California computed a preventive service advantage of 12 to 20 percent over Blue Cross and other commercial insurance plans. Roemer & Shonick, *HMO Performance: The Recent Evidence*, 51 MILBANK MEM. FUND Q. 271, 293 (1973). *But see* Heyssel & Seidel, *The Johns Hopkins Experience in Columbia, Maryland*, 295 NEW ENG. J. MED. 1225, 1231 (1976).

16 *See* Crawford, *You Are Dangerous to Your Health*, 8 SOC. POL'Y 11, 19-20 (Jan./Feb. 1978).

17 *See generally* J. GALBRAITH, THE AFFLUENT SOCIETY 93-94 (2d ed. 1971). High costs of skilled services provide impetus for mass production of goods. *See* L. SUSSKIND, UNDERSTANDING TECHNOLOGY 27 (1973).

from the provision of services to the sale of goods.[18] Once the supply was increased, the trickledown effect and social subsidies brought the new goods within the reach of the poor. The continued prevalence of a service organization in the medical care industry suggests both that there are qualities of medical practice that resist translation into goods and that physicians have some power to direct the course of change in the delivery of health care.

This Note will first analyze the service nature of present medical care and its implications for providers, consumers, and costs. The past contribution of the legal system to the perpetuation of the service economy will be discussed. Section Two will then examine the new techniques for allocating and reviewing medical care and explain how the service nature will render these methods ineffective in improving the access of the poor. Finally, Section Three will explore the opportunities for encouraging the development of medical goods to lower costs, improve effectiveness, and increase access.

I. MEDICAL SERVICES AND THE DELIVERY OF MEDICAL CARE

The identifying characteristic of health care in the United States is the existence of a large medical profession. Potential physicians must meet certain state educational requirements to receive a license to practice medicine.[19] Upon entry into the medical profession, the physician must assume certain responsibilities of care loosely defined by the law of malpractice and hospital rules.[20] In exchange, the physician receives the discretion to accept or reject patients, diagnose their ailments, and define a course of treatment. He decides what medical services will be delivered to his patients and whether

---

18 *See generally* Kaempffert, *The Past Century — and the Next — in Science,* in TECHNOLOGY AND SOCIAL CHANGE 117 (W. Moore ed. 1972). The composition of required skills changes from specific knowledge of a trade to general education useful for handling machinery. *See* T. VEBLEN, THE INSTINCT OF WORKMANSHIP 303-09 (1914).

19 Strict supervision of medical education began after the Flexner Report of 1910 sharply criticized the quality of the existing medical school structure. *See* Ebert, *Medical Education in the United States,* in DOING BETTER, *supra* note 8, at 171-73.

20 *See* Roberts & Bogue, *supra* note 6, at 639.

those services are to be provided in his office or in the hospital.[21] Physicians rely on professional organizations to coordinate relations among doctors[22] and between doctors and hospitals.[23] These organizations also protect the interest of doctors against serious encroachment by government in the form of undesired changes in financing or regulation.[24]

The professionalization of American medical care has stabilized the role of the physician in the provision of health care services. Innovations in medical technology and practice have been designed to improve the ability of the physician to deliver his service.[25] Personnel who can perform medical services without extensive education and licensing have been relegated to the duties of "physician assistants," carefully supervised and circumscribed to avoid intrusions upon the practice of medicine.[26] Most effective drugs must be prescribed by a physician before a licensed pharmacist can dispense them to a patient.[27] The physician must volunteer to join an organized group practice and will seldom be compelled to do so by the pressure of competition.[28] These restrictions

---

21 This discretion severely limits the ability of hospitals to exercise control over medical costs. *Id.* at 662.

22 Organization of doctors in local medical societies and the American Medical Association gives them significant market power, even though individual providers might be thought to compete with each other. During the price control period of the early 1970s, the A.M.A. persuaded doctors to avoid raising fees too precipitously to meet higher costs because it might alienate Congress. S. KLAW, THE GREAT AMERICAN MEDICAL SHOW 16 (1975).

23 The medical profession exercises substantial control over hospital management and the American Hospital Association. *See* Saward, *Institutional Organization,* in DOING BETTER, *supra* note 8, at 195.

24 The A.M.A. has been the most influential national political organization for physicians in recent years, but its power to resist changes in the structure of the profession has waned. *See* Starr, *supra* note 9, at 178.

25 Recently developed medical instrumentation for use by physicians in hospitals is costly, uncertain in effect, and inflationary for hospital charges. *See* Russell, *The Diffusion of New Hospital Technologies in the United States,* 6 INT'L J. HEALTH SERV. 557 (1976).

26 *See* Kissam & Johnson, *Physician's Assistant and Nurse Practitioner Laws: A Study of Health Law Reform,* 24 U. KAN. L. REV. 1, 31 (1975) [hereinafter cited as Kissam I].

27 Only the individual doctor can evaluate the appropriateness of a particular prescription for a patient and his illness. *See Drug Safety Amendments of 1976: Hearings Before the Senate Select Comm. on Small Business,* 94th Cong., 2d Sess. 191 (1976) (statement of Herb Huffington).

28 *See* Garfield, *Prevention of Dissipation of Health Services Resources,* 61 AM. J. PUB. HEALTH 1499, 1501 (1971).

on the replacement or modification of the physician's services remain because the physician's special skills or knowledge seem to be necessary to organize these medical resources in a way that improves the patient's health.[29]

Professionalization also creates substantial incentives for providers and consumers to support a costly regime of medical services. The section will first discuss the effect of professional service upon the expectations of physicians and patients about medical care and their relationship to medical care costs.

A. *Medical Services and their Providers*

The special character of physician training for the provision of medical services affects the depth of the doctor's job aspirations and his ability to attain them. Physicians share with other service workers the goals of job security, income, and prestige.[30] But the physician must learn far more to perform his functions than does the average laborer. Medical diagnosis and treatment are non-routinized and require substantial exercise of judgment.[31] Moreover, the physician must keep himself aware of many developments in clinical practice and research to make a valid decision about the probability of success from a particular course of treatment. Little effort is made to synthesize the results of this research.[32]

As a result of these procedural uncertainties, the future physician must make a substantial capital investment in education to obtain the license to practice medicine.[33] This

---

29 *See* Yarmolinsky, *The Professional in American Society,* DAEDALUS, Winter 1978, at 159, 160-62.

30 McKinlay, *The Limits of Human Services,* 8 SOC. POL'Y 29, 31 (Jan./Feb. 1978).

31 D. MECHANIC, THE GROWTH OF BUREAUCRATIC MEDICINE 41 (1976). For a discussion of the factors that affect the physician's therapeutic decisions, *see* R. GREENE, ASSURING QUALITY IN MEDICAL CARE 137-72 (1976). This element of discretion makes external assessment of physician performance difficult. *See* text accompanying notes 281 to 288 *infra.* But some objective criteria have begun to emerge. Yarmolinsky, *supra* note 29, at 163.

32 *See* McKinlay, *supra* note 30, at 30-31.

33 *See* Burghardt, *Medical Malpractice and the Supply of Physicians,* in THE ECONOMICS OF MEDICAL MALPRACTICE 106-07 (S. Rottenberg ed. 1978) [hereinafter cited as ECONOMICS OF MALPRACTICE].

education now includes a long period of internship and residency in a hospital to obtain instruction in the "real world" aspects of medical care.[34]

Moreover, medical schools have tightened their standards of admission in response to the tremendous growth in applications.[35] Medical students thus must demonstrate a high level of previous achievement and mental competence to reach the profession.[36] These specialized educational requirements for medical services have had a number of consequences for the physician's practice. The literature on health care has observed some of these outcomes, but tends to treat them as isolated phenomena or as the result of perverse monopoly behavior by the medical profession.[37] This discussion will attempt a more analytical interpretation of physician behavior and expectations about practice.

1. Service Orientation and Paramedicals

The first effect of physician training concerns physician treatment of paramedical personnel. Many commentators have noted the traditional reluctance of physicians to delegate substantial tasks to nurses and other allied health personnel.[38] Until recently, states imposed serious legal barriers to the employment of paramedicals.[39] The persistence of these laws has been attributed to the power of the medical profession to draw a tight line around the profession and maintain monopoly profits.[40] Yet a number of states have recently enacted special laws to promote delegation to physi-

---

34 *See* Ebert, *supra* note 19, at 178.

35 *Id.* at 181; Yarmolinsky, *supra* note 29, at 163.

36 *See* S. KLAW, *supra* note 22, at 264. The scope of acceptable prior achievement has also narrowed to success in technical sciences. *Id.* at 263.

37 *See, e.g.*, Bailey, *An Economist's View of the Health Service Industry*, 6 INQUIRY 12 (1969); Schneider, *Model Consumer Health Maintenance Organization Act and Commentary*, 6 RUT.-CAM. L. J. 265, 275 (1974).

38 Newhouse, *supra* note 1, at 1352.

39 Kissam I, *supra* note 26, at 13.

40 *See, e.g.*, Alford, *The Political Economy of Health Care: Dynamics Without Change*, 2 POL. & SOC'Y 127 (1972).

41 Kissam I, *supra* note 26, at 1.

cian assistants.[41] But the responsibilities of paramedical personnel, even in the most advanced group practices, remain substantially limited and the subject of much dispute.[42]

Closer consideration reveals that physician attitudes about medical service and corresponding legal notions of responsibility will continue to hinder effective use of paramedicals in any treatment setting. First, the diffuse quality of diagnosis and choice of treatment convinces doctors that they must supervise closely the work of paramedicals.[43] They presume that the stringent educational requirements for medical practice must have been imposed because the doctor should ultimately decide all issues of treatment and perform all needed services. Thus it is not surprising that many studies of physician assistants conclude that they contribute little to a reduction in medical care costs.[44] An added layer of physician review may well absorb the savings in physician time. Even large prepaid group practices staffed by hospital administrators with special training in manpower utilization tend to limit paramedical roles to the initial screening of the worried well who do not require more than a placebo or simple reassurance.[45]

Second, legal doctrines have adopted the notion of physician discretion as the basis for malpractice actions against paramedicals. The law assumes that the doctors are fully aware of all of the actions of their paramedicals and exercise tight control.[46] Thus the physician is liable for the errors of the paramedical that result in injury to the patient if the injury occurs in the course of his services.[47] This principle of

---

42 *See* Roberts & Bogue, *supra* note 6, at 682.

43 *See* Ginzberg, *supra* note 9, at 210.

44 *Id. See also Panel Discussions on National Health Insurance: Hearings Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare,* 94th Cong., 1st Sess. 50 (1975) (statement of Uwe Reinhardt) [hereinafter cited as *1975 Panel Discussions*].

45 *See* Kissam & Johnson, *Health Maintenance Organizations and Federal Law: Toward a Theory of Limited Reformmongering,* 29 VAND. L. REV. 1163, 1172 (1976) [hereinafter cited as Kissam II].

46 This reflects the tort principle of respondeat superior. *See* Hoppe, *Liability for Negligence of Office Assistants and Hospital Employees,* 238 J.A.M.A. 1485 (1977).

47 *Id.*

medical malpractice represents a serious obstacle to the widespread delegation of diagnosis and treatment functions to paramedical personnel.[48] As long as the physician perceives that he must captain a service delivery team, no amount of restructuring of the form of delivery will reap the full efficiencies of paramedical labor.[49]

2. Service Orientation and Level of Care Provision

A second outcome of physician service training is the intensity of physician labor and overprovision of medical services. Many critics rightly observe that physicians work hard to build up their incomes as much as possible.[50] Others have noted that physicians tend to specialize and that incomes increase with specialization.[51] Still others have documented that much unnecessary provision of services, such as surgery, occurs among physicians.[52]

Although many commentators discuss these results and possible solutions individually, a few attribute them to physician greed that is artificially stimulated by the fee-for-service structure of payment. The fee-for-service system appears to give the physician every incentive to increase his income through long hours of piecework with a large number of patients.[53] Furthermore, it seems to encourage specialization because higher fees and referrals can support a larger number of physicians on the same population base.[54] Finally, it impresses some critics as a source of overprovision of services

---

48 *See* Kissam I, *supra* note 26, at 34.

49 *See* notes 44 *supra* and 102 *infra*.

50 *See, e.g.*, INSTITUTE OF MEDICINE, NATIONAL ACADEMY SCIENCES, CONTROLS ON HEALTH CARE 167 (1975).

51 Specialization increases costs by encouraging the provision of costly but marginally useful services. *See id.* at 64, 144.

52 Many studies estimate a nationwide rate of unnecessary surgery of 20 percent. *See* N.Y. Times, Jan. 27, 1976, at 21, col. 6.

53 *See* W. GLASER, SOCIAL SETTINGS AND MEDICAL ORGANIZATION: A CROSS-NATIONAL STUDY OF THE HOSPITAL 136-40 (1970).

54 *See* S. KLAW, *supra* note 22, at 68-69.

because unnecessary care is reimbursed as readily as any other form.[55]

There is probably considerable truth to the claim that the level of a physician's labor is related to the desire for a large income. This attitude reflects in part a natural urge to recoup the large capital investment in education that is required by state licensing.[56] But there is little evidence to link the various forms of overprovision to the fee-for-service system. High rates of elective surgery, for example, exist in countries that retain physicians on salary.[57] Salaried practice has also had little impact upon specialization.[58] Factors more closely related to physician service training may be involved.

One element may be the physician's tendency to trade off intellectual stimulation, income, and leisure. Biological and chemical research in medical school often represents the apex of intellectual challenge for future physicians.[59] Medical schools do not prepare students for the mundane aspects of general practice.[60] Students must maintain their own methods of sustaining interest in their work while they move through the final steps of internship and residency.[61]

Specialization represents one way of heightening challenge

---

55 *See Cost and Quality of Health Care: Unnecessary Surgery, Hearings Before the House Comm. on Interstate and Foreign Commerce,* 94th Cong., 2d Sess. 14 (1976) (statement of Dr. Edward Hughes); Crile, *Kicking the Fee-for-Service Habit,* 11 HOSP. PHYS. 34 (1975).

56 *See* note 33 *supra.*

57 Cross-national comparisons of surgery rates show that they depend more on medical philosophies within individual countries. *See* Lichtner & Pflans, *Appendectomy in the Federal Republic of Germany: Epidemiology and Medical Care Patterns,* 9 MED. CARE 311, 326 (1971); Neutra, *Implications for the Surgical Treatment of Acute Appendicitis: A Cost-Effectiveness Approach,* in COSTS, RISKS, AND BENEFITS OF SURGERY 277, 277-78, 299-300 (J. Bunker, B. Barnes & F. Mosteller eds. 1977) [hereinafter cited as J. BUNKER].

58 Salaried practice in England and Wales, for example, has not discouraged specialization within the National Health Service. J. BLANPAIN, NATIONAL HEALTH INSURANCE AND HEALTH RESOURCES: THE EUROPEAN EXPERIENCE 76 (1978).

59 *See* Ebert, *supra* note 19, at 174.

60 Rogers, *The Challenge of Primary Care,* in DOING BETTER, *supra* note 8, at 84.

61 Clinical patients who receive treatment in teaching hospitals have complex diagnostic and medical management problems that make them far different from what the great majority of doctors sees in private practice. *See* Jason, *The Relevance of Medical Education to Medical Practice,* 212 J.A.M.A. 2092 (1970).

because the physician can master most of the techniques in the field, keep up with the literature, and perhaps even contribute to medical knowledge through observation of and experimentation on his patients.[62] Moreover, specialization brings more patients with unusual ailments whose treatment tends to be more exciting.[63] The intellectual attraction of specialization helps to explain the continued antipathy of medical students to family practice in spite of some recent successes in establishing it as a specialty in itself.[64]

Another means of maximizing challenge for the doctor is to concentrate on those aspects of medical practice within a particular area that are most interesting. For some doctors, unnecessary surgery may be a more rewarding use of time than the consolation of patients with colds or unspecifiable illnesses.[65] There is also considerable evidence that physicians tend to neglect education of patients about effective preventive health measures because it is more tedious than curative or ameliorative efforts.[66] Finally, doctors exhibit a bias toward hospital care as opposed to ambulatory or home care in part because hospital practice offers greater stimulation.[67]

Failing in these methods, the physician will substitute income for the lack of challenge. He will often accept teaching or research positions in medicine at a substantial cut in salary.[68] But hard work among many primary physicians

---

62 *See* Rogers, *supra* note 60, at 83.

63 The search for interesting work may help to explain high rates of elective surgery. *See* R. GREENE, *supra* note 31, at 145.

64 The number of first-year family practice residents in 1973-74 was far below the replacement level for retiring general practitioners. Edwards & Morrow, *U.S. Health Manpower Policy: Will the Benefits Justify the Cost?* 51 J. MED. ED. 791, 798 (1976). Student polls also indicate a high degree of antipathy toward general practice. *See* Bloom, *The Medical School as a Social System,* 49 MILBANK MEM. FUND Q. 100, 190-91 (1971). Recent projections foresee a continuing shortage of primary care physicians through 1990. *See* Scheffler, Weisfeld, Ruby & Estes, *A Manpower Policy for Primary Health Care,* 298 NEW ENG. J. MED. 1058, 1059 (1978).

65 *See* D. MECHANIC, *supra* note 31, at 94.

66 *See* Wildavsky, *supra* note 8, at 118.

67 *See* D. MECHANIC, *supra* note 31, at 240.

68 In a 1968 survey, 50 percent of the participating physicians were willing to accept a training or research position in place of their practice. Fredericks, Kosa,

often is directed at maximizing income, with some of the highest fees charged as penalties for unchallenging care of patients who can afford to pay.[69] The consequences of the tradeoff for health care systems that place controls on physician incomes can be easily predicted. Upon joining prepaid group practices, doctors tend to substitute leisure for income at a high rate.[70] There is also the potential for physician strikes if conditions within the group practice do not satisfy them.[71] Highly educated and intelligent physicians cannot be expected to settle for a life of medical drudgery without significant compensation in some other form. Changes in payment and the delivery system will have little impact upon this behavior.

The structure of medical education that arises from service orientation suggests a second explanation for overprovision of services and specialization. As part of the service ethic, the physician assumes the responsibility of trying all remedies that have a reasonable chance of improving the health of the patient.[72] A normal medical education exposes a physician to a variety of procedures that an observer might consider to be "unnecessary," but which would offer relief to some patients.[73] The widespread coverage of hospitalization insurance[74] combines with the absence of cost-benefit training in medical education[75] to encourage the physicians to deliver these services where there is some indication of possible

---

Roberts & Alpert, *Physicians and Poverty Programs: A Study of Physicians' Expressed Willingness to Change Positions,* 52 HOSP. PROG. 57 (1971).

69 This policy permits the physician to give "Robin Hood" care to the poor. *See* H. SCHWARTZ, THE CASE FOR AMERICAN MEDICINE 117 (1972).

70 The total number of hours worked may decrease by 20 percent or more. Ginzberg, *supra* note 9, at 211.

71 The recent malpractice crisis has increased the militancy of some leaders of physician associations. *See* Sanford Marcus, *cited in* Coyne, *The A.M.A., Doctors' Voices, and the Ultimate Trauma,* PRIVATE PRACTICE, March 1976, at 14, 25.

72 *See* Havighurst & Blumstein, *supra* note 5, at 27.

73 For discussion of controversial forms of surgery, *see* J. BUNKER, *supra* note 57, at 91-105, 212-371.

74 Neuhauser, *Cost-Effective Clinical Decision-Making: Implications for the Delivery of Health Services,* in *id.* at 28.

75 *See* Bunker, *et al., Summary, Conclusions, and Recommendations,* in *id.* at 393.

benefit.[76] Attempts to control such overprovision have been frustrated by the absence of an adequate definition of unnecessary services.[77]

The service nature of medical care and medical education has also affected specialization. Doctors are trained to view it as a means of providing a higher quality of service at lower costs.[78] Referrals can direct patients among specialists while individual autonomy of the specialist can be maintained.[79] Medical educators often regard specialization as the only way to accommodate the recent proliferation of medical knowledge.[80] The strong trend toward specialization in post-war America matches that of other professions.[81] Family practice specialties were reestablished only after patients and congressmen exerted serious fiscal pressure and dangled incentives before medical school administrators.[82] Liberalization of entrance requirements for foreign medical graduates has provided additional room for specialization by American graduates.[83] Specialization thus fits well with the conception of the physician as a service provider. The patient must find his way to the serviceman with the assistance of any available general physicians as a reference.[84]

---

76 *See* Havighurst & Blumstein, *supra* note 5, at 26.

77 For one continuing dispute over unnecessary service in the form of surgery, *see Quality of Surgical Care, Volume II: Hearings Before the Subcomm. on Oversight and Investigations of the House Comm. on Interstate and Foreign Commerce*, 95th Cong., 1st Sess. 3-39, 108-23 (1977) (testimony of Dr. Ralph Emerson and Dr. C. Rollins Hanlon) [hereinafter cited as *Quality of Surgical Care Hearings*].

78 Ebert, *supra* note 19, at 179.

79 *See* D. MECHANIC, *supra* note 31, at 93.

80 Rogers, *supra* note 60, at 82-83.

81 Lawyers and architects, among other service providers, have engaged in extensive specialization. *See* Yarmolinsky, *supra* note 29, at 162.

82 These efforts were part of the general interest of the federal government in relieving maldistribution of physicians. *See* Starr, *supra* note 9, at 190.

83 *See* S. KLAW, *supra* note 22, at 252. But this liberality has been reversed by a new law that forbids recruiting of foreign interns and residents after 1980. 8 U.S.C.A. § 1182(j)(1) (West Supp. 1977). *See* N.Y. Times, Feb. 2, 1977, § II, at 1, col. 3.

84 There is sufficient demand for physicians to allow them to locate where they want within a region and require the patients to come to them. *See* Elesh & Schollaert, *Race and Urban Medicine: Factors Affecting the Distribution of Physicians in Chicago*, 13 J. HEALTH & SOC. BEHAV. 236 (1972).

3. Service Orientation and Geographical Maldistribution

Physician maldistribution has been widely recognized as a serious shortcoming in the present structure of medical care delivery.[85] Rural families suffer from inadequate health care because they cannot obtain access to a physician.[86] The federal government has made efforts to alleviate geographical maldistribution through various incentive and compulsory programs, but the problem persists.[87]

Some of the inadequacies of the redistribution programs may be the result of their simplistic analysis of the motives underlying physician location. The subsidy programs assume that financial considerations predominate in the physician's residential choice and that tuition loans and scholarships can provide the initial capital incentive to get doctors into underserved areas.[88] But the high default rate on these loans suggests that doctors do not just grumble politely and settle down to serve new rural clients.[89] The attitude of physicians about practice in rural settings is far more deeply rooted in the value structure of professional service.

One of the most important expectations of a service provider is the acquisition of considerable geographic mobility upon the completion of his professional training and licensure.[90] The rigors and expense of medical education both en-

---

85 *See, e.g.*, Edwards & Morrow, *supra* note 64, at 798; Navarro, *The Political and Economic Determinants of Health and Health Care in Rural America*, 13 INQUIRY 111, 112 (1976); Ross, *Rural Health Care: Is Prepayment a Solution?* 90 PUB. HEALTH REP. 298, 301 (1975).

86 *Rural Health Care — Problems and Prospects, 1977: Hearings Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources*, 95th Cong., 1st Sess. 3-4 (1977) (testimony of Karen Davis).

87 Income-related mechanisms appear to have little effect. Eisenberg & Cantrell, *Policies to Influence the Spacial Distribution of Physicians: A Conceptual Review of Selected Program and Empirical Evidence*, 14 MED. CARE 455, 464 (1976). In 1974, only 360 doctors actually went to underserved areas under the National Health Service Corps program. Rosenberg, *Government Controls: Where and Whether You Can Practice*, MED. ECON., Sept. 29, 1975, at 37.

88 This was the premise of the National Health Service Corps incentive structure. *See* 34 CONG. Q. WEEKLY REP. 2688 (1976).

89 Eisenberg & Cantrell, *supra* note 87, at 464.

90 Physicians can move far in advance of general population shifts. *See* Mattera, *Will More Doctors Mean That You'll Earn Less?* MED. ECON., May 15, 1978, at 183, 188.

courage this view and make mobility possible by screening out large numbers of potential competitors.[91] No area of the country has such an oversupply of physicians that incomes are depressed to a noticeable degree.[92]

Once physicians obtain their freedom, two subsidiary desires that derive from professional service training direct their location in cities and their suburbs. First, highly educated professionals feel a need to live in areas that offer a prodigious amount of cultural stimulation.[93] Rural towns cannot hope to compete with urban centers in intellectual attraction. A related concern of professionals is that their municipalities provide a high level of public services.[94] This, too, is difficult for rural towns to achieve.

Second, medical schools teach physicians to integrate their practices with large health institutions, primarily hospitals.[95] Doctors come to consider medical practice without these institutions to be virtually impossible.[96] Thus the isolation of rural areas from the mainstream of hospital-based practice becomes a highly undesirable aspect of exurban location.[97]

The strength of these sentiments does not bode well for the progress of laws that try to manipulate the financial calculations of physicians. Even a generous expansion in the number of physicians is unlikely to alleviate geographical maldistribution. One countervailing influence would be the ability of physicians to increase the supply of unnecessary ser-

---

91 The liberalization of admissions policies and the consequent expansion of the supply of physicians is expected to constrain the locational decisions of physicians in favor of smaller metropolitan areas and rural towns. *Id.* at 88-89.

92 Martin, *The Federal Initiative in Rural Health,* 90 PUB. HEALTH REP. 291, 295 (1975).

93 *See* studies cited in U.S. DEP'T OF HEALTH, EDUCATION, WELFARE, PUBLIC HEALTH SERVICE, FACTORS INFLUENCING PRACTICE LOCATION OF PROFESSIONAL HEALTH MANPOWER: A REVIEW OF THE LITERATURE 30 (1974).

94 *Id.* at 31.

95 *Field Delivery of Home Health Services: Hearings Before the Senate Select Comm. on Aging,* 94th Cong., 2d Sess. 70 (1976) (testimony of Albert Wagner).

96 *Id.*

97 The perception of isolation may be sufficient to deter some physicians from leaving urban areas, even if doctors are not actually distributed according to distance from teaching hospitals. *See* Bauer, *An Economist Looks at Rural Health Care,* 71 ROCKY MTN. MED. J. 623, 624 (1974).

vices to buffer their incomes.[98] Another important obstacle would be medical school admissions policies. New students would still be subject to the vigorous admissions standards of test scores and academic achievement. Applicants who have garnered the academic records that fall just below current standards tend to live in urban and suburban areas.[99] Because those students who grew up in rural areas are the most likely to return to them, only a conscious decision to lower standards in favor of small-town applicants will be effective.[100] Medical schools can be expected to resist this dilution in the perceived quality of their students.[101]

Service providers who require extensive professional training cannot be expected to distribute themselves in a manner that brings medical services within reasonable distance of all potential patients. National finance of medical care, even with sophisticated incentive plans, cannot cure physician maldistribution. Experiments with rural health clinics have shown the potential for delivery of care by paramedicals.[102] But the general provision of care through such institutions must somehow eliminate the need for constant supervision by physicians.[103] The professional service nature of present medical care delivery precludes such a development.[104]

---

98 *See* note 50 *supra.*

99 *See* U.S. DEP'T OF HEALTH, EDUCATION, AND WELFARE, *supra* note 93, at 27.

100 *See* Evashwick, *The Role of Group Practice in the Distribution of Physicians in Nonmetropolitan Areas,* 10 MED. CARE 808, 809 (1976).

101 The reaction of American medical schools to the proposed clause to a new aid bill requiring admission of United States students in foreign medical schools to a third year of school in America to participate in internship and residency here is instructive. *See* Scalia, *Guadalajara! A Case Study in Regulation by Munificence,* REGULATION, Feb./Mar. 1978, at 23.

102 *See* Hill, *The Physician's Assistant in a Rural Satellite Clinic: Report on an Evaluative Case Study of Utilization, Acceptance and Economics,* THE PHYS. ASS'T J., Fall 1975, at 165-77; Lewis, Resnik, Schmidt & Waxman, *Activities, Events, and Outcomes in Ambulatory Patient Care,* 280 NEW ENG. J. MED. 645 (1969); Miles & Rushing, *A Study of Physician's Assistants in a Rural Setting,* 14 MED. CARE 987, 994 (1976); Runyan, *The Memphis Chronic Disease Program: Comparisons in Outcome and the Nurse's Extended Role,* 231 J.A.M.A. 264 (1975); Sackett & Spitzer, *et al., The Burlington Randomized Trial of the Nurse Practitioner: Health Outcomes of Patients,* 90 ANNALS INTERNAL MED. 137 (1974).

103 *See* note 44 *supra.*

104 *See 1975 Panel Discussions, supra* note 44, at 50 (testimony of Dr. Rashi Fein).

4. Service Orientation and Medical Malpractice

Widespread fears of a malpractice crisis three years ago led to a deluge of articles and books on the problem and its possible solutions.[105] The growing number of malpractice claims was blamed for medical inflation,[106] a decreasing supply of physicians,[107] and an expansion in the use of unproductive procedures as defenses against claims.[108] Since mid-1977, the perception of crisis has diminished considerably as insurance premiums have stabilized and juries have become more favorable to physicians in close cases.[109] But the expense of defending against malpractice actions still constitutes a significant portion of medical care costs.[110]

The service character of the medical profession provides a different perspective on the malpractice problem and allows a prediction that medical malpractice insurance rates will continue to rise. Lying at the core of legal philosophy of malpractice is the belief that physicians should be held to a standard of care equal to the customary degree of skill or ability of others within the medical profession.[111] This general principle of liability responds to the ability of a service group to define its own product. It gave a tremendous advantage to the pro-

---

105 *See, e.g.*, materials collected in *Continuing Medical Malpractice Crisis, 1975: Hearings Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 94th Cong., 1st Sess. 60-655 (1975).

106 SENATE COMM. ON GOVERNMENT OPERATIONS, SUBCOMM. ON EXECUTIVE REORGANIZATION, 91ST CONG., 1ST SESS., MEDICAL MALPRACTICE: THE PATIENT VERSUS THE PHYSICIAN 22 (Comm. Print 1969) (response of Eli Bernzweig) [hereinafter cited as 1969 MALPRACTICE STUDY]; *Hospital Costs: Biggest Piece of the Health Care Bill*, MED. WORLD NEWS, May 2, 1977, at 49, 50.

107 TEXAS MEDICAL ASS'N, TMA UPDATE ON THE MEDICAL MALPRACTICE INSURANCE CRISIS 6 (1977); Blackman, *How the Malpractice Squeeze is Redistributing Doctors*, MED. ECON., Apr. 5, 1976, at 71, 72.

108 Surveys report that 50 to 70 percent of all physicians admit some defensive practices. These studies produce cost estimates of $3 to $7 billion per year. ASS'N OF THE BAR OF THE CITY OF NEW YORK, REPORT ON THE MEDICAL MALPRACTICE INSURANCE CRISIS 4 (1975).

109 ECONOMICS OF MALPRACTICE, *supra* note 33, at Preface.

110 *See* Congressional Research Service, Medical Malpractice Issue Brief 1 (Apr. 15, 1977).

111 *See* Epstein, *Medical Malpractice, Its Cause and Cure*, in ECONOMICS OF MALPRACTICE, *supra* note 33, at 251.

fession in the past, but its inherent disadvantages have contributed to the recent "crisis."

The advantage of the customary practice standard was that the profession could control its own liability by defining acceptable practice.[112] Thus the standard subsidized the mistakes of the physician and the resulting iatrogenesis in a way that would not be tolerated in the field of product liability.[113] The informed code of physician silence on the practices of other physicians once prevented many injured patients from recovering compensation for malpractice.[114] Yet the standard left considerable room for expanding liability as the medical profession explored new frontiers in the provision of care and implemented riskier procedures.[115] One consequence of the larger procedural repertoire of physicians is that the possibility for error in selecting one procedure over another increases. The new physician inherits a difficult responsibility of keeping up with burgeoning developments in his field as these are added to the profession's "custom."[116] Moreover, new developments put a premium on accuracy in diagnosis because new modes of treatment become specialized for particular patterns of illness. The observed rise in "defensive" medicine, which usually takes the form of more diagnostic testing, responds to this pressure for specificity.[117]

A second consequence of new procedures was that the public gained false confidence in the ability of physicians to

---

112 *See* Kendall, *Expectations, Imperfect Markets, and Malpractice Insurance,* in *id.* at 173.

113 Product liability law adopts an outcome position in holding a manufacturer strictly liable for a product that does not meet the reasonable expectation of the ordinary consumer about its safety. The question of negligence becomes less relevant. Courts sometimes use the service/good distinction that now comes between medical malpractice and product liability to cover certain intermediate products that they wish to protect from liability. *See* W. PROSSER, THE LAW OF TORTS 659-62 (4th ed. 1971).

114 *See* Kendall, *supra* note 112, at 173.

115 Physicians working on the frontier of medical practice are often the defendants of malpractice suits. ASS'N OF THE BAR OF THE CITY OF NEW YORK, *supra* note 108, at 53.

116 *See* Quayle, *In Defense of Defensive Medicine,* MED. ECON., Sept. 1, 1975, at 61, 63.

117 SENATE COMM. ON LABOR AND PUBLIC WELFARE, DOCTORS ORDER MORE TESTS FOR MALPRACTICE FEARS, H. R. REP. NO. 978, 92d Cong., 1st Sess. 50 (1972).

cure their illnesses without introducing new iatrogenic injuries.[118] The sense of physician "control" over the events transpiring during the course of treatment convinced courts that the res ipsa loquitur doctrine of negligence could be applied to make physicians more careful.[119] Plaintiffs need only prove the existence of a condition that developed after an operation and would not ordinarily occur in the absence of negligence.[120] This rule shifts the physician's burden more toward defending the outcome of his treatment rather than the procedures employed and greatly improves the plaintiff's chances for recovery.[121]

New obligations for the solicitation of informed consent to medical treatment have been a third effect of new procedures upon malpractice liability. More complex and risky methods require patient approval because the outcome may be much more harmful as well as beneficial.[122] But the requirement of intelligibility and completeness places a burden on the physician that can be difficult to meet.[123] In addition, patients may react irrationally and refuse necessary treatment that seems too risky.[124]

These elements of medical malpractice add impetus to the effects of inflation and recessions on insurance premiums.[125] Physicians presently pass these costs on to the consumer in the form of higher fees and hospital expenses.[126] But the rise in malpractice judgments serves as a signal to physicians that present delivery of medical services exacts either a politically unacceptable cost upon the injured or an economically unacceptable cost upon the patients who must pay the increased costs. Under normal market conditions, this signal would force structural changes in the industry

---

118 *See* Kendall, *supra* note 112, at 173. For a discussion of various types of hospital iatrogenesis, *see* I. ILLICH, *supra* note 14, at 35-41.

119 Kendall, *supra* note 112, at 78.

120 *Id.*

121 *Id.*

122 *See* D. MECHANIC, *supra* note 31, at 257.

123 *Id.* at 259.

124 *Id.* at 259, 260.

125 *See* Kendall, *supra* note 112, at 180-81.

126 *Id.* at 191-92; Rubsamen, *Medical Malpractice,* SCI. AM., Aug. 1976, at 18.

that would encourage modes of treatment that minimized the contribution of malpractice to medical costs if doctors could not become careful enough to lower the rates.[127] Resistance to altered conditions of practice, however, increases interest in statutes that would adapt the liability structure to the physician instead. One plan advocates a no-fault system of compensation for medical malpractice.[128] But it has not been able to overcome fears that it will remove some incentives for physicians to avoid careless mistakes.[129] Furthermore, the cost of malpractice may not decrease because the no-fault structure removes the deterrent of legal expenses for suit.[130] Another method would be to use standards developed by PSROs as the basis for physician liability.[131] Yet this technique would reduce only those injuries that could be prevented by the exercise of caution, not those which result from imperfect information or inherently risky procedures.[132] In sum, alternatives that try to manipulate the liability system may not affect the underlying political and economic forces that increase malpractice insurance rates. Changes in the service structure of medical care may be the only alternative to drastic weakening of the standard of negligence.

B. *Medical Services and their Consumers*

The special training and licensing requirements of medical practice place physicians in a unique position of high status and responsibility within American society. Doctors are admired for their ability to command substantial incomes, but they are expected to show altruism toward patients who cannot pay their fees. Many people believe that doctors are

---

127 *See* Bovbjerg, *Medical Malpractice Standard of Care: HMOs and Customary Practice,* 1975 DUKE L. J. 1375, 1376.

128 *See* O'Connell, *An Elective No-Fault Liability Statute,* 628 INS. L. J. 261-93 (1975).

129 *See* Statement of Dr. William B. Schwartz, in THE MEDICAL MALPRACTICE DILEMMA 19 (AEI Forum No. 2, 1977).

130 *See* D. MECHANIC, *supra* note 31, at 272.

131 *See* J. BLUM, P. GERTMAN & J. RABINOW, PSROs AND THE LAW 106-67 (1977) [hereinafter cited as J. BLUM].

132 *See* Rottenberg, *Introduction,* in ECONOMICS OF MALPRACTICE, *supra* note 33, at 4-5.

almost omnipotent in their control over illness, yet the physician's very powers can arouse feelings of fear and resentment.

Because consumers hold these unrealistic expectations, they tend to hold a number of ambivalent attitudes about doctors that affect the delivery of medical care. First, they may refuse to seek treatment of disorders that do not seem important. Second, once they decide to see a doctor, they may demand a large amount of psychological support from him by becoming overly dependent upon his services. Third, patients who resent their dependence upon the physician during serious illness may register their dissatisfaction by a desire to litigate for a malpractice judgment. Finally, successful interaction with a physician may discourage individuals from undertaking effective preventive measures to preserve their own health.

By maintaining the illusion of physician omnipotence and altruism, the medical services industry may detract from the general health of the patient and contribute to the inflation in medical care costs. This section will analyze the adverse effects of service orientation upon patient behavior and the provision of care.

1. Attitudes Toward Service and Utilization

Critics of medical care delivery in the United States have long been concerned about the access of low-income individuals to medical care. They have focused their attention on financial barriers that preclude adequate treatment.[133] Although the failure to obtain needed medical care because of inability to pay has been difficult to document statistically,[134]

---

133 *See, e.g.*, Blackstone, *On Health Care as a Legal Right: An Exploration of Legal and Moral Grounds*, 10 GA. L. REV. 391, 417-18 (1976).

134 Few studies have been done that correlate increases in morbidity or mortality to inability to obtain medical care because of financial want. One attempt, which has serious methodological shortcomings, is the extrapolation from a New York Commissioner's estimate of 15,000 deaths of this type in the City in 1968 to 500,000 deaths per year throughout the nation. *See* R. KUNNES, YOUR MONEY OR YOUR LIFE 135 (1971).

advocates of national health insurance have urged that it could remove whatever financial constraints deter the poor from seeking care.[135]

These arguments fall short of explaining some recent results of the experience in large-scale medical subsidy programs, such as Medicaid and Medicare, and free-care facilities such as Neighborhood Health Centers (NHCs). These efforts have increased the utilization of services by the poor,[136] but when the rate of use is adjusted for health status, the poor still lag behind higher-income groups.[137] Moreover, experiments that remove all financial barriers to health care observe that a hard-core group of potential patients takes no advantage of the opportunity to receive services.[138] Therefore, financial subsidies do not necessarily ensure that those who need medical care the most will be served. Increased spending for health care under a comprehensive health insurance system may simply finance other clients who overutilize services or doctors who seek to increase their incomes.[139]

Barriers related to the nature of medical services available to lower-income patients may be a more important deterrent to effective use. First, medical service providers do little to overcome the lack of knowledge about the proper time to seek assistance. Potential patients whose cultural background prizes independence and the toleration of illness as a sign of strength may avoid seeking care when it would be most effective.[140] Moreover, poorly educated people may not recognize

---

135 *See* Boaz, *Equity in Paying for Health Care Services Under a National Health Insurance System*, 53 MILBANK MEM. FUND Q. 337, 344 (1975).

136 *See* K. DAVIS, *supra* note 1, at 3.

137 *See* Aday, *Economic and Non-Economic Barriers to the Use of Needed Medical Services*, 13 MED. CARE 447, 451 (1975); Davis, *The Impact of Inflation and Unemployment on Health Care and Low-Income Families*, in HEALTH: A VICTIM OR CAUSE OF INFLATION? 58 (M. Zubkoff ed. 1976).

138 *See* Brook & Williams, *Quality of Health Care for the Disadvantaged*, 1 J. COMM. HEALTH 132, 137 (1975); Leveson, *The Economics of Health Services for the Poor*, 399 ANNALS 227 (1972).

139 This phenomenon may have been the result of the Canadian national health insurance program. *See 1975 Panel Discussions*, *supra* note 44, at 392 (statement of Dr. Bette Stephenson).

140 C. LEWIS, R. FEIN & D. MECHANIC, THE RIGHT TO HEALTH 17 (1976).

illness by its specific symptoms in a way that would convince them that a doctor could help.[141] General medical ignorance might explain nonuse of services as much as financial inability does, but statistical verification is difficult because low-income people also tend to be poorly educated.[142] Medical outreach programs could solve some of these problems, but few professionals have considered such efforts to be part of their responsibility, even under public subsidy programs.[143]

Second, the structure of welfare medical care services encourages retreat. On the one hand, the reluctance of ordinary physicians to treat Medicaid or other low-income individuals[144] may compel these potential patients to visit welfare-mill inner-city doctors and clinics, who provide low-quality care and often stigmatize their customers.[145] On the other hand, the patient may be allowed to participate in high-quality urban hospital clinics or foundation plans.[146] Under ideal circumstances, this alternative could encourage traditionally-resistant people to seek care earlier. Ironically, though, the structure of medical education and clinical training brings in young, middle-class doctors who are least likely to understand or tolerate the idiosyncrasies of poor patients.[147] These young physicians feel entitled to treat patients who are articulate, obedient, interesting, and grateful for their services. Instead, they are confronted with uneducated and suspicious clients who often present trivial complaints and seem to take the doctor's services for granted.[148] Even if new practitioners come into the clinics without prejudices about the poor, they either succumb to

---

141 *See* D. MECHANIC, *supra* note 31, at 100-01.

142 *See* Wakefield, *Studies of Response to Cervical Cancer*, 62 TUMORI 315 (1976).

143 *See* Rose, *Federal Regulation of Services to the Poor Under the Hill-Burton Act*, 70 NW. L. REV. 168, 193 (1975).

144 Roghmann, Haggerty & Lorenz, *Anticipated and Actual Effects of Medicaid on the Medical-Care Patterns of Children*, in MEDICAID — LESSONS FOR NATIONAL HEALTH INSURANCE (A. Spiegel & S. Podair eds. 1975).

145 Davis, *supra* note 137, at 59; Zarefsky, *Book Review*, 53 TEXAS L. REV. 636, 638 (1975).

146 *See* S. KLAW, *supra* note 22, at 57.

147 *Id.* at 61.

148 *Id.* at 60.

the weight of their patients' troubles or assume a cynical veneer.[149] Furthermore, the continuing education nature of hospital practice and the research orientation of many hospitals lead physicians to regard poor patients as mere instructional or research tools.[150] These hostile motives engendered by service training hamper the provision of useful care in clinic settings and discourage patients from returning or complying with medical advice.

As long as the medical care system continues to function with the physician, who delivers general services to all those seeking care, at its center, people who are poor, uneducated, or fearful of the physician will avoid treatment or be shunted into second-class facilities.[151] Those who provide medical care must have the cultural understanding or the incentive to reach these medical outcasts. Decentralization of medical care may be the only effective way to match the patient to the provider.[152]

2. The Psychology of Health and Medical Costs

Health is a condition of life that is extremely difficult to define.[153] Most people recognize specific examples of the absence of health in illness,[154] but the presence of good health requires a subjective evaluation of physical and social well-being that varies according to an individual's emotional structure.[155] Strategies to delimit the field to some objective measures of medical service availability are inevitably met by the objection of arbitrariness.[156]

The diffuse conception of health has at least two important

---

149 *Id.* at 65.
150 *Id.* at 59.
151 *See* discussion of the failure of rationing systems within HMOs to avoid discouraging lower-income individual utilization in text accompanying notes 262 to 270 *infra.*
152 *See* text accompanying notes 328 to 332 *infra* for a description of decentralized paramedical provision of medical care.
153 Callahan, *Health and Society: Some Ethical Imperatives,* in DOING BETTER, *supra* note 8, at 24.
154 *Id.*
155 *Id.* at 25.
156 *Id.* at 26.

implications for delivery of medical care services. One effect has been to encourage doctors to expand their influence into areas once thought to be related only tangentially to the practice of medicine. For example, true health may not be attainable unless the individual conquers psychological and personality disorders that could lead to organic dysfunctions.[157] Thus some doctors have felt obliged to attempt a cure for deviant behaviors once thought to be caused by man's sinful nature or by innate criminality.[158] Psychologists become the close working partners of the physician in treating these new disease entities. Of course, as doctors link psychological services closer to the mainstream of medical practice, these services seem to become more "essential" to the comprehensive care of the individual.[159] Expensive services proliferate as doctors take over larger chunks of social policy.[160] Once these bulwarks are completed, moreover, they are extremely difficult to dislodge.[161]

A second consequence of ambiguity in health is that doctors must now bear the burden of satisfying psychological needs that were once mediated by other segments of society. At one time, most Americans purchased services from a wide variety of sellers. The majority of household amenities at the beginning of this century could not be obtained without interaction with a service provider.[162] These services involved significant intangible psychological benefits in the relief of loneliness and the reduction of social tensions.[163] But these

---

157 D. MECHANIC, *supra* note 31, at 13; Fox, *The Medicalization and Demedicalization of American Society*, in DOING BETTER, *supra* note 8, at 11.

158 Fox, *supra* note 157, at 11.

159 Some government officials, for example, have suggested that full mental health services should be offered in Neighborhood Health Centers. *See, e.g., Department of Labor and Health, Education, and Welfare Appropriations for FY 1977: Hearings Before the House Comm. on Appropriations*, 94th Cong., 2d Sess. 426 (1976) (statement of Rep. Roybal (D. Cal.)).

160 *See* I. ILLICH, *supra* note 14, at 55.

161 *Id.* at 56.

162 *See* N. SMELSER, THE SOCIOLOGY OF ECONOMIC LIFE 92 (1963).

163 The process of social distancing and differentiation induced by goods production in many industries created some social tensions. *Id.* at 102. Service producers themselves face a loss of status, and consumers experience disturbances of established routines. *See* A. Stafford, Trends of Invention in Material Culture 43 (1950) (unpublished Ph.D. dissertation, U. of Chicago).

services became too expensive as labor costs increased and competition from self-service merchandisers drove them out of business.[164] Each time a service would be replaced by the sale of goods, the public would expect services to replace the supply of emotional support.[165] Eventually, the sources of psychological comfort narrowed to the few remaining professions that serve the public.

Medicine represents one of these professions.[166] Doctors have always been concerned about the preservation of a good doctor-patient relationship because they perceive that it improves the prospects for successful treatment.[167] Moreover, environmental stress and life problems are often the reasons people undertake the effort to seek a medical service provider.[168] Therefore, the physician must add a large psychological component to his tangible regimen of treatment to meet his responsibility to patients assuming the "sick role."[169]

But the lesson of the recent rampant inflation in medical care costs is that the intangible benefits of a personal physician's services are a luxury that the system can no longer afford. A constant stream of worried-well individuals whose visits and hospitalization are covered by medical insurance has monopolized much physician time with simple prescription and psychological sustenance.[170] Physicians have been increasingly vocal about the trivial character of many patients' complaints.[171] These relatively wealthy patients also bid medical resources away from those who cannot afford private insurance or do not qualify for government assistance.[172] Moreover, hospital costs rise as the demand for

---

164 *See* note 18 *supra.*

165 *See* D. MECHANIC, *supra* note 31, at 12.

166 Mead, *supra* note 5, at 47.

167 *See* Campbell, *We Need a New Approach,* 49 DEL. MED. J. 18, 24 (1977).

168 D. MECHANIC, *supra* note 31, at 10-11.

169 Parsons, *The Sick Role and the Role of the Physician Reconsidered,* 53 MILBANK MEM. FUND Q. 257 (1975).

170 One survey indicated that nearly 70 percent of the patients in a prepaid group practice could be classified as worried-well. Garfield, *Evaluation of an Ambulatory Medical Care Delivery System,* 294 NEW ENG. J. MED. 426, 427 (1976).

171 *See* D. MECHANIC, *supra* note 31, at 11.

172 *See* Garfield, *The Delivery of Medical Care,* SCI. AM., Apr. 1970, at 15, 19.

unnecessary surgery that is performed to relieve psychological problems requires more expensive in-patient facilities.[173] Finally, the emotional dependence of the hypochondriac patient upon the physician reduces both the capacity of these people to cope with the problems and the social pressure to do so.[174] These forms of overutilization encourage private insurers and national health insurance advocates to consider steep co-insurance and deductible provisions to insurance plans in an effort to restrain unnecessary expenditures.[175] But such provisions raise financial barriers to the purchase of medical care by the poor.[176]

Excessive respect for a doctor's services attracts many patients who waste expensive physician time on minor, incurable maladies. To reduce medical care costs and prevent overutilization when care is insured, the methods of delivering medical care must reduce the infatuation of the psychologically-dependent patient with the doctor. Expanding the role of non-physicians and medical goods in the system could produce these effects. Psychologists and the family must be the ultimate repositories of emotional sustenance for the individual, for only they can provide it at relatively low cost to society as a whole.

3. Dissatisfaction and Malpractice Suits

Patients now suppose that doctors have the ability to ameliorate all of their major complaints. When the physician fails, or induces a concomitant injury, disillusionment sets in much more quickly than in previous times.[177] Disappointment with physician services has manifested itself in a greatly increased propensity on the part of patients to litigate malpractice actions.[178] Dissatisfaction that leads to

---

173 *See* Paulshock, *"Unnecessary" Surgery: Who'll Have the Final Say?* MED. ECON., March 7, 1977, at 75, 80.

174 *See* I. ILLICH, *supra* note 14, at 48.

175 D. MECHANIC, *supra* note 31, at 319.

176 *See* Scitovsky & Snyder, *Effect of Coinsurance on Use of Physician Services,* 35 SOC. SEC. BULL. 3 (1972).

177 1969 MALPRACTICE STUDY, *supra* note 106, at 33.

178 *Id.* at 21.

malpractice claims also stems from the perception that the physician is not delivering a full complement of emotional support.[179] As noted above, growth in malpractice claims contributes to medical care inflation by increasing insurance premiums and inducing defensive testing procedures.[180]

Many of these complaints may involve legitimate grievances of the patient who genuinely has been hurt through his physician's carelessness. In these situations, fault-based tort recovery may serve as an acceptable, if not finely honed, tool for influencing the quality of physician performance by forcing the doctor to take precautions against an adverse legal judgment.[181] Nevertheless, the disillusionment that succeeds the overconfidence in medical abilities engenders many vindictive, frivolous suits. Just under fifty percent of all claims filed in 1974 received no award.[182] These suits do not improve the quality of the physician's services, but they do cost money to screen out or settle.[183]

Changes within the law of malpractice by themselves will do little to reduce the number of frivolous claims. No-fault plans would curtail the patient's entry into the compensation system. Moreover, disillusionment with doctors makes potential litigants susceptible to the persuasion of contingency-fee lawyers who promise a quick and lucrative recovery.[184] Only a new realization of the limits of medical practice and physician competence through alterations in medical structure will have any chance of reducing these malpractice costs.

4. Perception of Medical Competence and Preventive Action

Perhaps the most significant contribution of recent critics to the literature on medical care has been the recognition that an individual's lifestyle and environment engender many of

179 *Id.* at 20-21.
180 *See* notes 106 to 108 *supra.*
181 *See* Green, *Medical Malpractice and the Propensity to Litigate,* in ECONOMICS OF MALPRACTICE, *supra* note 33, at 193.
182 *Id.* at 195.
183 1969 MALPRACTICE STUDY, *supra* note 106, at 8-9.
184 *Id.* at 16.

his afflictions.[185] Present medical techniques can do little to reverse the progress of illnesses resulting from these factors.[186] But the commentators who observe this phenomenon differ among themselves on the implications of human-induced disease for medical care. Some believe that medical care should be curtailed because it does not help and may discourage individual self-help.[187] Others see this doctrine of individual responsibility as an attempt by dominant social groups to exercise greater control over the lives of the labor force and to deny the poor an expanded share in medical resources.[188] These critics believe that ordinary citizens should use environmental causation as a rallying point for further political confrontation and bargaining with polluters.[189] In between these two positions lies the theory that the physician should take the lead in delivering preventive services that require professional skills and the government should invest in massive health education efforts to change individual lifestyles.[190]

It may be unrealistic to expect anything more than small incremental changes in the effort to promote preventive methods within the present structure of medical services. Physicians often show little interest in delivering preventive care because it does not present the intellectual challenge of curative or ameliorative practice, and they thus label prevention as "trivial" and unworthy of a serious physician's attention.[191] Furthermore, patients seldom comply with the preventive instructions and admonitions that they do receive from their doctors.[192] And public education efforts in the past

---

185 *See, e.g.,* Knowles, *supra* note 14, at 57; Weisburger, CHEMTECH, Dec. 1977, at 734.

186 Thomas, *On the Science and Technology of Medicine,* in DOING BETTER, *supra* note 8, at 45.

187 I. ILLICH, *supra* note 14, at 272-73.

188 Crawford, *supra* note 16, at 15-16.

189 *Id.* at 12-13.

190 Knowles, *supra* note 14, at 66.

191 *See* note 66 *supra.*

192 *See* Svarstad, *Physician-Patient Communication and Patient Conformity with Medical Advice,* in D. MECHANIC, *supra* note 31, at 220-35.

have demonstrated few permanent changes in the public antipathy toward individual prevention.[193]

The slow progress of preventive care may be attributable in part to the primitive state of knowledge in this field,[194] but resistance to the diffusion of proven strategies among medical consumers appears to be more deeply rooted in their attitudes toward life and the abilities of service providers. Most current techniques for individual protection rub against the grain of American life and comfort. Giving up alcohol and tobacco, for example, may mean a considerable loss of pleasure for many patients. Other recommendations for a healthier life may exact inconvenience costs or expose adherents to ridicule in social situations.[195]

When individuals weigh these costs against the uncertain benefits of an abstinent life,[196] they will often choose to ignore prevention. Occasionally general changes in social outlook, such as those which occurred in the late 1960s, will tip the balance in favor of good practices, like more exercise through jogging.[197] But the service structure of medical care often tips the scale in the other direction. Public overconfidence in the ability of professional physicians to undo the effects of an unhealthy lifestyle and environment leads to an unwarranted discount in the costs of avoiding uncomfortable preventive activities.[198] The wide variety of physicians and hospital services lent credence to the exaggerated claims of the profession and the media in the post-war period.[199] Therefore, many people believed that a mere expansion in the national resources devoted to health care could cure the overindulgence and conformity to social pressures.[200] Their unsuc-

193 Consider the example of anti-heart disease education. Aranow, Allen & De Cristofaro, *Response of Patients and Physicians to Mass Screening for Coronary Risk Factors,* 52 CIRCULATION 586, 587 (1975). Campaigns against alcohol and tobacco have been equally unsuccessful. N.Y. Times, Oct. 14, 1976, § 1, at 37, col. 1.

194 Knowles, *supra* note 14, at 65.

195 *Id.* at 60.

196 *Id.* at 59.

197 Recent estimates suggest that millions of Americans now jog and 30 million play tennis. *See* Yeager, *The Self-Care Surge,* MED. WORLD NEWS, Oct. 3, 1977, at 43, 50.

198 Knowles, *supra* note 14, at 59.

199 *See* Thomas, *supra* note 186, at 45.

200 *See* Knowles, *supra* note 14, at 59-60.

cessful efforts to seek a cure for these conditions continue to clog the service delivery system and raise costs.[201]

The difficulty of implementing preventive action in medical care does not compel the conclusion of some critics that society should "demedicalize" and reduce its commitment to health care.[202] Rather, the element of service orientation within medical care that maintains the myth of professional omnipotence must be removed by changes in the structure of the industry. When non-professionals take over large portions of the physician's practice under controlled standards of performance, the better-defined limits of care will encourage people to undertake preventive measures to match their requirements to the medical product.[203] Moreover, new competitive forces will give medical merchandisers the incentive to offer a higher guarantee of health through distribution of preventive care packages of treatment and information.[204] A service-based profession, by contrast, will continue in the belief that its costly intervention can render prevention irrelevant. It will also perpetuate the waste of scarce medical resources on unnecessary services and deny needed care to the victims of medical cost inflation.

II. RATIONALIZED MEDICAL CARE AND THE PROSPECTS FOR SALVATION

The consensus of the "enlightened" elements of the profession — health planners, hospital administrators, and medical school faculty, among others — has chosen to fix the blame for medical care inflation and inadequate service of the poor

---

201 Well-conceived preventive efforts, for example, can reduce hospital admissions for complications by as much as 50 percent. *Id.* at 67.

202 *See* I. ILLICH, *supra* note 14, at 224-62.

203 The use of paramedicals for delivery of primary care encourages prevention because they can better muster the individualized caring that is necessary to obtain the patient's compliance with instructions. *See* Eisenberg, *The Search for Care,* in DOING BETTER, *supra* note 8, at 239-42.

204 HMOs with a strong preventive orientation could offer these packages as part of their general informational strategy. *See* Kissam & Johnson, *State HMO Laws and the Theory of Limited Reformmongering,* 25 U. KAN. L. REV. 21, 24 (1976) [hereinafter cited as Kissam III].

upon the fee-for-service method of payment for medical care.[205] Most of these critics appear to agree with the hypothesis that the fragmented free market provision of care by private physicians causes inflation in two ways. First, the fee-for-service structure gives the physician no incentive to control costs. When patients pay for services individually, physicians will want to provide services of the highest quality, particularly if it increases profits.[206] They will resolve doubts on treatment in favor of hospitalization.[207] Hospitals will provide costly services because their cost-based fee-for-service system encourages cost-maximization.[208] Medical insurance plans exercise little constraint over these practices because they are controlled by physicians and use cost-plus reimbursement procedures.[209] Second, the fee-for-service system makes it difficult to control the provision of unnecessary services. Doctors have an incentive to deliver too much care because it increases their incomes.[210] General practitioners seem to perform much unnecessary surgery rather than risk referral to a specialist who might advise against an operation.[211] Informed peer review mechanisms fail to restrain physicians because they lack legal sanctions to deter them from performing operations found unjustified by retrospective evaluations.[212] In sum, the critics of the medical care system argue that fee payment must be supplanted by salaries and strict quality control review must be established if medical costs are to be contained.[213]

These health planners and advocates of reform believe that larger professional units and direct regulation of physician activity can best restrain the chaotic, inflationary ways of the

---

205 *See* notes 53 to 55 and accompanying text *supra.*

206 *See* Kissam II, *supra* note 45, at 1171.

207 *See* Chao, *Cost and Quality Control in the Medicare/Medicaid Program: Concurrent Review,* 11 HARV. C.R.-C.L. L. REV. 664, 669 (1976).

208 *See* Roberts & Bogue, *supra* note 6, at 657.

209 *See* MED. WORLD NEWS, *supra* note 106, at 51.

210 *See* note 50 *supra.*

211 *See* D. MECHANIC, *supra* note 31, at 94.

212 *Federal Medical Malpractice Insurance Act of 1975: Hearings Before the Subcomm. on Health of the Senate Labor and Public Welfare,* 94th Cong., 1st Sess. 806 (1975) (statement of Sen. Inouye (D. Hawaii)).

213 *See, e.g.,* Roberts & Bogue, *supra* note 6, at 684-86.

fee-for-service structure. They have mustered two important concepts to realize these goals. One suggestion is that prepaid group practice through Health Maintenance Organizations (HMOs) be given a "fair market" test against the fee-for-service system to see which structure proves to be more popular with the public over the long run. Some of the preliminary conditions for "fairness" in the test are removal of restrictive state laws against HMOs and liberal initial operating requirements (implicit subsidies).[214] HMOs rely on capitation payments rather than fees and promise to meet the health needs of an individual within a specified period of time in exchange for the yearly payment.[215] As institutions of care, they integrate specialists with a base of general practitioners in an effort to construct an optimal mix of medical resources.[216] HMO advocates claim reductions in medical costs from economies of scale,[217] greater use of preventive care,[218] increased control over hospitalization,[219] and more thorough cost-benefit analysis of all procedures.[220]

Health planners have also recommended the expansion of Professional Standards Review Organizations (PSROs) from physicians delivering hospital services reimbursed by Medicare or Medicaid to the entire medical profession.[221] PSROs add the necessary legal sanction of denied reimbursement to make peer review effective as a deterrent to the provision of unwarranted services or poor quality care.[222] The organizations are expected to use at least three techniques to

---

214 *See* Enthoven, *supra* note 5, at 717.

215 Kirkland, *Labor's Point of View on HMOs,* 90 PUB. HEALTH REP. 104 (1975).

216 Ellwood & Herbert, *Health Care: Should Industry Buy It or Sell It?* HARV. BUS. REV., July-Aug. 1973, at 99, 102.

217 Kissam II, *supra* note 45, at 1173-74.

218 Havighurst & Blumstein, *supra* note 5, at 36.

219 Kissam II, *supra* note 45, at 1171-72.

220 Weil, *Comparative Costs to the Medicare Program of Seven Prepaid Group Practices and Controls,* 54 MILBANK MEM. FUND Q. 339 (1976).

221 Roemer, *The Expanding Scope of Governmental Regulation of Health Care Delivery,* 6 U. TOL. L. REV. 591, 606 (1975).

222 *National Health Insurance, Major Issues, Vol. III: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce,* 94th Cong., 2d Sess. 846 (1976) (statement of Dr. Goran) [hereinafter cited as *1976 NHI Hearings*].

review the physician's practice. Concurrent utilization review of hospital admissions, length of stay, and use of ancillary services should determine whether hospitalization is necessary and whether the physician allocates medical care resources in a manner that appropriately minimizes costs.[223] Profile review of the physician's practices for certain disease categories should provide a general check on overutilization of hospitals and the quality of care. Medical care evaluations through medical audits are permitted to measure the physician's performance against a set of explicit criteria for the management of particular ailments to promote better quality and curtailment of unnecessary surgery.[224] PSRO supporters believe that institutional evaluation from within the profession itself will reduce the costs of providing care enough to finance national health needs out of a fixed government budget while maintaining a high standard of quality.[225]

The weakness of the planning philosophy of organized medical care is that it overemphasizes the fee and ignores the service. Physicians may deliver the highest quality services not because they want to raise costs, but because they are trained that exploring every alternative is in the patient's best interest.[226] They do not have a systemic view of which procedures represent an efficient allocation of medical resources because the high cost is exchanged for a low probability of benefit.[227] Moreover, the complexity of the medical repertoire and the diffuse character of practitioner choice ensures that quality controls will have little authority over the individual physician. Doctors will be the only ones knowledgeable enough to run the review process, but they will be reluctant to enforce the requirements vigorously against the matters that seem to be within the discretion of their colleagues.[228] The implicit constraint on all cost-control mechanisms for physician services will be the feeling that

223 *See* J. BLUM, *supra* note 131, at 27; R. GREENE, *supra* note 31, at 62.
224 R. GREENE, *supra* note 31, at 64-67, 76.
225 *Id.* at 76-77.
226 *See* note 72 *supra.*
227 *See* Warner, *Treatment Decision Making in Catastrophic Illness,* 15 MED. CARE 19, 21 (1977).
228 *See* N.Y. Times, Jan. 27, 1976, at 1, col. 6.

levels of quality will be endangered by stiff enforcement, even when the evidence is unclear.[229]

HMOs and PSROs in combination represent a policy of care intermediate in position between pure provision of medical services and the sale of medical goods. Each concept seeks in its own way to regularize the provision of services and guarantee to medical consumers a "package of health."[230] This section will analyze the potential effectiveness of these structures in promoting access to services, reducing medical costs, and maintaining quality. It will suggest reasons to believe that the residual influence of professional service philosophy will interfere with their operation and diminish their beneficial impact.

A. *HMOs and their Physicians*

The term "health maintenance organization" technically includes a wide variety of organizational arrangements of physicians, among them prepaid group practices and medical foundations, which contract with individuals or groups for all necessary medical services within a definite period of time.[231] Nevertheless, prepaid group practice (PGP), which uses centralized management to regulate access to physicians and hospital beds, stands out as the flagship model for HMOs and represents the concept upon which advocates would want evaluation to be based.[232] PGPs ration a relatively fixed supply of medical resources among its participants in an effort to minimize medical costs. Ultimately, however, it relies upon individual physicians to decide what care is delivered to patients who succeed in passing through the initial screening mechanisms, subject to whatever administrative review and

---

229 *See* Havighurst & Blumstein, *supra* note 5, at 34-35.

230 These institutions attempt to enforce minimum guarantees of quality care to all participants in the plan or in Medicaid and Medicare hospital services. *See* Roberts & Bogue, *supra* note 6, at 646-48.

231 D. MECHANIC, *supra* note 31, at 83-84.

232 Medical care foundations, which retain fee-for-service reimbursement, have not achieved the same efficiencies as have been claimed for HMOs. *See* Gaus, Cooper & Hirschman, *Contrasts in HMO and Fee-for-Service Performance*, 39 SOC. SEC. BULL. (no. 5) 3-14 (1976).

sanctions exist within the organization.[233] The combination of dependence upon physician decisions and management review may ultimately undermine the benefits of organization and add serious bureaucratic problems in any major implementation plan for HMOs.

Advocates of prepaid group practice presumably would prefer to document cost reduction within the organization from what might be termed "justifiable" sources. If PGPs can cut costs by eliminating unnecessary surgery, unnecessary hospitalization, unnecessary use of specialists, and unnecessary use of prescription drugs, it can claim to achieve savings without exerting any adverse influence on quality or access to care. But little evidence has been offered that bases its evaluation of PGPs on criteria of necessity in comparing them to the prevailing fee-for-service structure.[234] Instead, researchers present general statistics quantifying the lower total costs of PGPs and the comparable health status of the two case populations.[235] These figures may obscure hidden tradeoffs among access, quality, and expense.

The accuracy of the broad comparative statistics in themselves must be subject to serious reservation. First, several studies have found that many PGP clients seek care outside the plan in numbers ranging from ten to fifty percent of the enrollment.[236] This effect is difficult to neutralize because the composition, and therefore the cost, of the services cannot be determined with precision.[237] If these outside costs were adequately accounted for in the plan's calculation, most of the savings in resource costs and hospital utilization might be dissolved. Second, PGPs suffer from various forms of selection bias in their care populations. One aspect of PGP development that skews representation is the propensity to

---

233 D. MECHANIC, *supra* note 31, at 87.

234 *See id.*

235 *See* Kissam III, *supra* note 204, at 23.

236 *See* Chavkin & Treseder, *California's Prepaid Health Plan Program: Can the Patient Be Saved?* 28 HASTINGS L. J. 685, 753-4 (1977); Roemer & Shonick, *supra* note 15, at 308.

237 Roemer and Shonick estimate that it would amount to less than 10 percent of total services, but they employ no weighting system. *See* Roemer & Shonick, *supra* note 15, at 308.

contract with middle-class employee groups and exclude Medicaid and Medicare recipients.[238] This socioeconomic bias may produce a care population that is significantly healthier than the fee-for-service control group.[239] Attempts to control for this factor may not adequately define the fee-for-service population.[240] If Medicaid and Medicare patients were permitted to join PGPs, the rate of hospitalization and costs of care could rise to match that of traditional health care providers. Another possible form of selection bias may be that people with an interest in personal preventive activities are overrepresented in the PGP population because they are more likely to show interest in the health maintenance principle that these organizations promote.[241] Personal prevention through more austere life-styles could reduce the need for physician intervention in present PGPs. In short, there is little reason to conclude from the general figures that PGPs attain their savings through pure economies of scale and elimination of medical "waste" without affecting access or quality.

The operating record of PGPs also supports the judgment that they employ hidden trade-offs, common in rationing strategy, that implement what could be socially "unjustifiable" cuts in service. Most of the cost savings in hospitalization appear to come from tight bed supply, which may not be distributed according to an evaluation of need.[242] Furthermore, some PGP studies show reduced ambulatory care as well as reduced hospitalization, suggesting that some patients are denied access to allegedly low-cost outpatient services.[243] There is no reason to believe that this lower

238 *See* Angermeier, *Impact of Community Rating and Open Enrollment on a Prepaid Group Practice,* 13 INQUIRY 48 (1976); Berki, Asheraff, Penchansky & Fortus, *Enrollment Choice in a Multi-HMO Setting, The Role of Health Risk, Financial Vulnerability, and Access to Care,* 15 MED. CARE 95, 104 (1977).

239 *See* Rosoff, *The Federal HMO Assistance Act,* 13 AM. BUS. L. J. 137, 158 (1975).

240 Interstate comparisons can lead to invalid conclusions because of selectivity in HMO location. *See* NATIONAL ACADEMY OF SCIENCES, *supra* note 50, at 56.

241 Wolinsky, *Health Service Utilization and Attitudes Toward Health Maintenance Organizations: A Theoretical and Methodological Discussion,* 17 J. HEALTH & SOC. BEHAV. 221 (1976).

242 Chavkin & Treseder, *supra* note 236, at 754.

243 D. MECHANIC, *supra* note 31, at 89.

number of physician visits represents more concentrated efforts within individual visits by PGP physicians. Prepaid doctors give less time to each patient and are under no pressure comparable to that facing fee-paid doctors to avoid raising the patient's suspicions by suggesting extra visits.[244] Moreover, physicians in PGPs tend to reduce their work effort generally.[245] A more convincing explanation is that some patients are kept away from the physician by various initial bureaucratic hurdles.

What explains the apparent inability of PGPs to effect pure economies in the delivery of medical care? The answer may lie in the deeper attitudes of physicians as service providers. There is little in the PGP structure that changes the context of decisions doctors make.[246] The concept of health maintenance constitutes an extremely vague mandate that does not outweigh the clinical judgments that correspond to the physician's needs and training.[247] The physician is likely to continue giving full service to those patients that reach him and hope that others will economize.[248] Expansion of PGPs to include the average physician will magnify this effect by forcing groups to hire doctors who are not specially screened for attitudinal conformity with the presumption-against-service ideology of some PGP pioneers.[249] Finally, vague incentives for PGP physicians are unlikely to change their patterns of practice.[250]

The response of plan administrators to the reluctance of PGP physicians to change their style of service provision is to reap economies through other techniques, such as rationing the physicians themselves. There are a number of variations on this theme. First, managers can put a general ceiling on the number of physicians and associated facilities. This process could result in a rational queueing procedure for

244 *Id.* at 90.
245 *See* Wildavsky, *supra* note 8, at 118.
246 *See* Kissam III, *supra* note 204, at 23-24.
247 D. MECHANIC, *supra* note 31, at 87.
248 *See* Weil, *supra* note 220, at 363.
249 *See* Kissam II, *supra* note 45, at 1169; Roemer & Shonick, *supra* note 15, at 278; Roberts & Bogue, *supra* note 5, at 672.
250 D. MECHANIC, *supra* note 31, at 94.

various services according to relative need if physicians assembled the list without interference, but pressure from certain clients can be brought to bear to disrupt the schedule.[251] Second, managers can structure a pyramid of general practitioner referrals to specialists to maximize use of low-cost primary services. Evidence from abroad, however, indicates that the desire of generalists to maintain an interesting practice will lead to under-referral of unusual cases and over-referral of mundane cases.[252] Third, administrators can erect non-economic barriers to utilization by interposing layers of bureaucracy between the potential patient and the doctor.[253] This technique has been the most notable feature of PGPs from the perspective of participants.[254] Appointments are difficult to obtain, and members find it nearly impossible to retain a single physician within the group for more than a few of their medical needs.[255]

It would be difficult to know whether the rationing procedures that PGP management uses lead to a deterioration in quality of care that is delivered. As noted earlier, wide variations in medical care may have little effect on statistical measures of health because experts have yet to be confident of the value of many practices.[256] Furthermore, the unrepresentative nature of PGP populations could cancel the effect of decreased access in existing PGPs.[257]

Nor will client satisfaction surveys allow conclusions about the absence of underservice. First, many consumers cannot judge whether appropriate, high-quality care has been given to them.[258] Second, many subscribers will go for long periods of time without attempting to make use of the plan's ser-

---

251 *Id.* at 92.
252 *Id.* at 93-94.
253 Carnoy & Koo, *Kaiser-Permanente: A Model American Health Maintenance Organization,* 4 INT'L J. HEALTH SERV. 597, 614 (1974).
254 *See* Campbell, *Comments on "Demand for Health Care Among the Urban Poor, with Special Emphasis on the Role of Time,"* in THE ROLE OF HEALTH INSURANCE IN THE HEALTH SERVICES SECTOR 211 (R. Rosett ed. 1976).
255 *See* Wildavsky, *supra* note 8, at 113.
256 *See* note 30 *supra.*
257 *See* notes 238 to 241 and accompanying text *supra.*
258 *See* Schneider, *supra* note 37, at 273.

vices.[259] At any one time, then, most individuals will be satisfied with the medical care. Contrived problems of access, nonetheless, seem to engender more complaints.[260]

Malpractice is often claimed to operate as a check on the PGP's temptation to reduce quality by underservice.[261] But this argument assumes that the patient gets to the doctor in the first place. The law of malpractice does not yet comprehend failure to give services, only the infliction of injury,[262] and it seems unlikely that Congress would want to cripple PGPs by imposing new burdens of liability on them. Consumers might have an action for breach of the service contract, but their ignorance of the quality, the cost of suits, and the difficulty of proving the efficacy of care mitigate against widespread use. The poor malpractice record of PGPs up to now suggests that administrators are willing to trade relatively heavy malpractice settlements for a reduction in cost through lower quality care.[263]

Even if quality could be assured, however, the effects of PGPs on access to care would render them undesirable candidates for expansion through public subsidy. The bureaucratic controls on physician appointments discriminates against clients who do not have the communication skills necessary to negotiate their way around stubborn clerks and receptionists.[264] As a result, unskilled laborers tend to see physicians less often than other members of PGP plans.[265] If Congress were to assist PGPs to engage in a fair market test, it would surely require that the poor be allowed to join. But the poor would be as handicapped as the unskilled worker in

259 This low probability of use also precludes the effectiveness of departure from the plan as a check on bad services. *See* Starr, *The Undelivered Health System,* PUB. INTEREST, Winter 1976, at 66, 81-82.

260 *See* note 254 *supra.*

261 *See* Roberts & Bogue, *supra* note 6, at 669.

262 *See* Rottenberg, *supra* note 132, at 4-5. But a few cases have based a finding of liability upon a breach of a "cure" guarantee. *See* Curran & Moseley, *The Malpractice Experience of Health Maintenance Organizations,* 70 NW. L. REV. 69, 71 n.11.

263 *See* Curran & Moseley, *supra* note 262, at 81.

264 Wildavsky, *supra* note 8, at 113.

265 M. ROEMER, ET AL., HEALTH INSURANCE EFFECTS: SERVICES, EXPENDITURES, AND ATTITUDES UNDER THREE TYPES OF PLAN 29-31 (Univ. of Mich. Sch. of Pub. Health, Bureau of Pub. Health Econ., Research Series No. 16, 1972).

overcoming bureaucratic obstacles to the physician visit.[266] Moreover, the cultural hesitation to visit physicians would cripple them further, because outreach would raise operating costs.[267] Therefore, PGPs may well reduce the ability of the poor to receive adequate medical care because they would replace the amenable financial barriers of the fee-for-service practice with educational obstacles that Medicaid subsidies cannot hope to touch. The Medicaid dollars that once brought some care would be used by PGPs to subsidize the physician visits of the more affluent client.[268] Moreover, the Medic-Cal experience with PGPs in California warns that what little care the poor receive will be low quality.[269] Finally, if regulations force PGPs to make special provision for the access difficulties of the poor, the resulting double bureaucracy may eliminate any remaining financial advantage.[270]

Thus HMOs should not be considered the vehicle for reducing costs and utilization of care enough to justify a national health insurance scheme. The rationing of care inherent in such systems grants, at best, a one-time reduction in costs[271] at the expense of impaired access, particularly for those who cannot manage its intricacies. But, in addition, the construction of a "fair market" test for HMOs through capital subsidies and liberal operating requirements, if done within a national health insurance system, might eventually have perverse effects upon the competitive environment. If Congress were to provide generous loans to HMOs and remove the other obstacles, HMOs might succeed, beyond their advocates' best expectations, in reducing costs while maintaining quality. Congress would interpret these results as a signal to allocate its health expenditures into HMOs because they "won" the test. This direction of funds would make it

---

266 *See* Heyssel & Seidel, *supra* note 15, at 1231.

267 *See* D. MECHANIC, *supra* note 31, at 93.

268 R. HETHERINGTON, C. HOPKINS & M. ROEMER, HEALTH INSURANCE PLANS: PROMISE AND PERFORMANCE (1975); *see* Carnoy & Koo, *supra* note 253, at 609.

269 *See* Chavkin & Treseder, *supra* note 236, at 754-55.

270 *See* Heyssel & Seidel, *supra* note 15, at 1231.

271 *See* Health Policy Advisory Council, *HMOs,* in PROGNOSIS NEGATIVE: CRISIS IN THE HEALTH CARE SYSTEM 353, 361 (D. Kotelchuck ed. 1976).

difficult for private physicians to survive, and as HMOs expanded, physicians would be compelled by economic forces to join. Once large HMOs began to cover whole regions, they would gain significant political and market power. They could allow cost and service levels to rise by claiming that their populations required more care to increase their revenue.[272] Long-term contracts for medical care and the threat of economic disruption within centralized delivery systems would be a substantial barrier to market reentry by individual physicians.

These objections do not mean that the federal government should abandon its efforts to encourage diverse configurations of medical service provision, including HMOs. Competition among providers may be an important step toward reducing the number of unnecessary services and improving the quality of care. But rationalization of the health care system through centralized delivery systems will not solve the problems of medical inflation and inadequate access for the poor.

B. *PSROs and their Evaluators*

Many health planners have heralded the implementation of Professional Standards Review Organizations within the authorizing provisions of the 1972 Medicare and Medicaid Amendments[273] as an important new opportunity for introducing some external regulation into the physician's decision to deliver medical services.[274] PSROs appear to strengthen professional peer review programs in hospitals by threatening to impose credible sanctions for failure to meet well-established criteria for utilization.[275] They establish audits to monitor the quality of individual physicians' work

---

272 Roberts & Bogue, *supra* note 6, at 675.

273 P.L. 92-603, 86 Stat. 1329 (1972).

274 *See, e.g.*, Egdahl & Taft, *On Measuring Quality Health Care: Beyond the Hospital*, 294 NEW ENG. J. MED. 161 (1976); Nestler, *Effect of Quality Control Programs on the Organizational Structure of the Hospitals*, 52 BULL. N.Y. ACAD. MED. 157, 159 (1976); Schlicke, *Doctor, Is This Operation Necessary?* 134 AM. J. SURG. 3, 9 (1977).

275 *See* R. GREENE, *supra* note 31, at 38-46.

as well as expanding concurrent utilization review for the appropriateness of continued institutional care and the use of ancillary services.[276] Hospital administrators expect PSROs to set norms for all hospital practice by physicians and reduce hospitalization through the elimination of unnecessary surgery and stays of excessive length.[277] Once the efficacy of PSROs as indirect regulators of the cost and quality of hospital services has been demonstrated, many advocates believe that the concept will be extended to ambulatory care delivered by physicians outside the hospital setting.[278]

Congress set forth two major goals for PSROs in the authorizing legislation, reduction in the cost of medical care and improvement in the quality of medical care.[279] It assumed that the major quality concerns of providers would be congruent with the goal of economy in that both would aim for the elimination of unnecessary services.[280] Such an assumption, however, fails to find support in the broader attitudes of professional medical service providers about the relative insignificance of cost and the paramount concern for quality. Consideration of these motivations will suggest that the PSRO program could actually increase medical costs without having any measurable impact on quality.

The primitive state of medical quality assessment constitutes the fundamental flaw in present peer review mechanisms.[281] Little has been done to develop outcome criteria (treatment effectiveness, length of stay, cost, unanticipated side effects, and ancillary services) by which to judge physician performance or to link outcome criteria that have been developed to measures of process (use of acceptable procedures).[282] The responsibility for this reluctance to test and regularize medical procedures in part may lie with

276 *See* Egdahl & Taft, *supra* note 274, at 161.
277 *See 1976 NHI Hearings, supra* note 222, at 832.
278 *See* Roemer, *supra* note 221, at 606.
279 *See* 42 U.S.C. 1320(c) (Supp. II 1972).
280 *See* J. BLUM, *supra* note 131, at 20.
281 *See* McDermott, *Evaluating the Physician and His Technology,* in DOING BETTER, *supra* note 8, at 135.
282 *See* J. BUNKER, *supra* note 57, at 390.

the role perceptions of the doctor. Physicians as professional service providers tend to believe that the complexity of medical care requires that individual doctors be given substantial discretion to try every procedure that might produce a beneficial result and has some basis in the best judgment of some medical expert.[283] Therefore they will not always evaluate the desirability of using certain techniques according to the available empirical evidence, even if such evidence takes the form of carefully-controlled random clinical trials.[284] Moreover, doctors make implicit cost-benefit analyses of the necessity for services that vary significantly from one doctor to another.[285] They consider efforts to alter their assessment a threat to their professional autonomy.[286] The results of these attitudes and the deference paid to them[287] by the physicians who staff review boards is that PSROs, like other types of peer review, can do nothing more than check the grossest forms of technical incompetence and urge physicians to perform procedures that they may have rejected before.[288] This half-hearted enforcement may have a perverse effect upon medical costs and little influence over quality.

Utilization review and medical audits in themselves are not inexpensive, because they require a layer of managing bureaucracy, and their costs must be weighed against the presumed savings from the elimination of unnecessary services.[289] But contributions by PSROs to medical costs can also arrive through indirect routes. The emphasis on quality of care may convince reviewing physicians to recommend more elaborate and expensive procedures that may be unjustified by outcome analysis but fit the interest of these physicians in new techniques.[290] Whatever influence can be

283 *See* R. GREENE, *supra* note 31, at 6.
284 *Id.*
285 *See Quality of Surgical Care Hearings, supra* note 77, at 123 (testimony of Dr. C. Rollins Hanlon).
286 R. GREENE, *supra* note 31, at 173.
287 *See Quality of Surgical Care Hearings, supra* note 77, at 115 (testimony of Dr. Ralph Emerson).
288 *See* N.Y. Times, Jan. 29, 1976, at 1, col. 6.
289 *See* J. BLUM, *supra* note 131, at 60-65.
290 *Id.* at 14.

brought to bear on uncertain individual physicians will have the effect of encouraging clinically untested diagnosis and treatment.[291] PSROs themselves, moreover, have no resource constraints to guide their decisions of medical necessity or cost-beneficial adjustments in quality.[292] These conditions will help to ensure that PSROs will abandon the statutory goal of controlling costs.[293]

The prospects for significant improvements in quality regulation are equally doubtful. Curbing what planners consider to be costly overuse of medical resources and substandard performance will require a good faith effort on the part of the profession to report honestly, investigate thoroughly, and levy punitive sanctions against the violator. But past experience with peer review assessment gives little reason to expect that kind of compliance. First, physicians can circumvent the review process by manipulating their criteria for decisions.[294] Second, peer review is notorious for lax enforcement and investigation because physicians will close ranks to protect their colleagues.[295] Liberal weight will probably be given to physician excuses that explain away violations of the standards.[296] There is little in the PSRO statutory structure that would prevent such nonfeasance other than the chance that HEW will terminate its contract with the PSRO upon substantial evidence that the PSRO falls short of complying with the statutory mandate, and possible organizational liability for injuries that could have been prevented by PSRO intervention.[297] Third, hospitals will shelter physicians from the cost of any denials of reimbursement for unacceptable treatment under the statute because they need to maintain good will with physicians, who provide their financial

---

291 Lipkin, *Quality of Care Assessment in Light of the Relation Between the Doctor and the Patient*, 52 BULL. N.Y. ACAD. MED. 9, 14 (1976).

292 Havighurst & Bovbjerg, *Professional Standards Review Organizations and Health Maintenance Organizations*, 1975 UTAH L. REV. 381, 405.

293 *See* Kissam II, *supra* note 45, at 1201.

294 *See* Havighurst & Blumstein, *supra* note 5, at 54-55.

295 *Federal Medical Malpractice Insurance Act of 1975: Hearings Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 94th Cong., 1st Sess. 697 (1975) (statement of Sen. Inouye (D-Hawaii)).

296 *See* J. BLUM, *supra* note 131, at 39.

297 *See id.* at 197.

support through patient admissions.[298] The combination of the elements helps to explain recent preliminary findings that PSROs produce few positive results in preventing unnecessary service.[299] Professionals appear to be responsible only to their individual and collective self-discipline and consciences.[300]

But skepticism about the potential short-term benefits in medical costs and quality from PSROs should not be permitted to stifle the development of process and outcome criteria by which the effectiveness of medical practices may be evaluated. Random clinical trials can weed out expensive procedures that make little or no contribution to the patient's health.[301] Moreover, process criteria can establish simpler analytical paths for treatment that reduce the training necessary to diagnose and treat.[302] Physicians' objections that process standards will produce cookbook medicine are based upon the perception that they may lose the service provider's prerogative to tailor their treatment to fit all of the special characteristics of each patient.[303] The next section of this article will discuss the possibility that the forces of the medical care market may compel that conclusion in the future.

III. Medical Goods and the Future of Medicine

Despite the criticisms of monopolistic elements within the medical profession,[304] the profession has not been able to maintain a static structure for a very significant portion of American history. Before the early twentieth century, many different types of care providers competed with each other for the patient's dollars and exercised varying degrees of self-restraint in their claims for the efficacy of their treatments.[305]

298 *Id.* at 71.
299 Med. World News, *supra* note 106, at 57.
300 *See* Ginzberg, *supra* note 9, at 207.
301 *See* J. Bunker, *supra* note 57, at 390.
302 *See* J. Blum, *supra* note 131, at 78.
303 *Id.* at 77-78.
304 *See, e.g.*, Alford, *supra* note 40, at 127; Enthoven, *Consumer Choice Health Plan, Part I*, 298 New Eng. J. Med. 650, 652 (1978).
305 *See* Starr, *supra* note 9, at 179-80.

American society was willing to accept the Flexnerian formula for limiting entry into the medical profession and raising physician compensation in exchange for more rigorous training because contemporary medical advances gave hope that more extensive preparation of physicians could produce a clear improvement in the quality of medical care.[306] The gains in technical competence of the average physician seemed to be worth the costs of denying some parts of the population access to medical care.[307]

Recent experience has demonstrated that a uniform structure of physician services with substantial provider discretion in their delivery is no longer practical either economically or politically. The proliferation of new methods and machinery to assist the physician in diagnosis and treatment continues to raise medical costs faster than the general cost of living.[308] Middle-class Americans complain because the high cost of hospital treatment for many serious, acute, and chronic illnesses puts more of these services out of reach.[309] Moreover, the poor have exercised their growing political power to demand that the old agreement to limit their access be abrogated without sacrificing quality.[310] And many now realize that an increase in expenditures alone will be insufficient to give everyone access to quality care.[311]

The profession itself has recognized the weaknesses of the current medical structure and continues to fight a holding action by acquiescing to changes in the market that do not seem to threaten the general service orientation. One attempt to satisfy public demand for greater access has been to increase the number of physicians in the population by expanding medical school classes and allowing more graduates of foreign medical schools to practice in the United States.[312]

---

306 *See* Roberts & Bogue, *supra* note 6, at 638.

307 *Id.* at 639.

308 *See* Eisenberg, *supra* note 203, at 235.

309 *See* Knowles, *Introduction,* in DOING BETTER, *supra* note 8, at 5.

310 *See* Anderson, *Are National Health Services Systems Converging? Predictions for the United States,* 434 ANNALS 24, 28 (1978).

311 *See* Anderson & Smedby, *Changes in Response to Symptoms of Illness in the United States and Sweden,* 13 INQUIRY (Supp.) 116, 127 (1976).

312 *See* Scheffler, Weisfeld, Ruby & Estes, *supra* note 64, at 1059; note 83 *supra.*

Although the effect on quality of these changes remains unknown, the ability of individual physicians to create demand for their services may simply increase the volume of services, thus increasing costs without affecting access.[313] Another response has been to encourage physicians to enter the field of primary care in the expectation that more generalists will be able to screen out those patients whose needs are largely psychological or episodic from the specialty practice of most physicians.[314] But in spite of the growing surplus of physicians and medical school incentive programs, there remains a serious shortage of primary care physicians and those that do pratice are geographically maldistributed in favor of wealthier urban and suburban areas.[315] Furthermore, the ability of primary physicians to reduce costs and improve the utilization of medical professionals has yet to be demonstrated persuasively.[316] Their attitudes as service providers would seem to point in the opposite direction of over-service.[317] A third direction of change has been the recent experimentation with new forms of physician organization. As discussed earlier, however, this area of development has uncertain implications for costs and access and promises new bureaucratic problems of internal communication that may lead to deterioration of care rather than improvement.[318]

Current difficulties within the medical care system and widespread dissatisfaction teach a broader lesson that unlimited provision of medical services is ultimately incompatible with minimum cost and maximum access. If national health insurance without strict budget limits is enacted within this structure, it will guarantee huge demand increases, overutilization, and consequent skyrocketing in the share of national fiscal resources that must be devoted to medical care.[319] Moreover, a fixed budget form of health care

313 *See* Starr, *supra* note 9, at 191.
314 *See* Rogers, *supra* note 60, at 84.
315 *See* Scheffler, Weisfeld, Ruby & Estes, *supra* note 64, at 1059.
316 *See* D. MECHANIC, *supra* note 31, at 93-95.
317 *See* text accompanying notes 59 to 84 *supra*.
318 D. MECHANIC, *supra* note 31, at 87.
319 *See* Mead, *supra* note 5, at 47-48.

planning may put an absolute lid on financing for medical services in a given year, but it will have little effect on the cost of particular services and may make it more difficult for the poor to achieve access when the budget constraints are implemented within local delivery systems.[320] Political pressure will be great to devote more government resources to medical care each year and reduce funding for other desirable social programs.[321] As long as the medical care industry cannot produce enforceable criteria to distinguish necessary and effective services from unnecessary and ineffective varieties, it will be unable to restrain cost increases and the consequent loss in access. Rationing care by nonmarket structures is not worth the effort within the present limited value and high cost of medical intervention.[322]

The alternative to the service mode of delivering all assistance, including intangible psychological benefits, that might be helpful to those who can reach the physician and afford any redundancy is the strategy of selling medical "goods" of demonstrated efficacy to medical consumers within routinized patterns of diagnosis and treatment by low-cost technical personnel. Its essential characteristics would be clear definition of medical outcomes, cost reduction through regularized methods of paramedical training and utilization, testing and implementation of advances in biomedical research, and outreach to potential consumers through "advertising" that would emphasize low-cost "service packages" for disease prevention and treatment. The medical goods strategy would reject the service ethic that all feasible techniques must be utilized regardless of their effects on cost and access. But the provision of medical goods could be fine-tuned to provide levels of quality consistent with future developments in medical research. Moreover, different "service packages" could be made available to the public in a way that guarantees at least some minimum access to all citizens. Public subsidies would then become more effective

320 *See* note 6 *supra.*
321 *See* D. MECHANIC, *supra* note 31, at 315.
322 *See* Thomas, *supra* note 186, at 37, 46.

in improving access by giving poor people the ability to buy better packages as the state of the art in medical care improves over the next few decades.

The advantages of implementing a goods strategy come from its removal of the attitudinal traits that inhibit innovation and honest evaluation of treatment and its providers. Routinized training for diagnosis and treatment leaves less discretion for providers to undertake treatment because it interests them or increases their income. Moreover, medical technicians would have to be more responsive to market forces in their choice of location and organization of care provision. In addition, consumers would become more realistic about the efficacy of medical intervention and more concerned about undertaking personal preventive action. Providers would have a much greater economic incentive to engage in outreach to overcome the cultural inhibitions of lower-income individuals because their ability to over-serve some individuals would be more limited.

In some ways, the goods strategy resembles the original concept of health maintenance promoted by the early advocates of HMOs.[323] These critics expected that HMO consumers would buy a "package" of health, including preventive as well as therapeutic care, through a yearly capitation payment. But the HMO concept was lost in the institutional translation into prepaid group practices that are dominated by the service philosophies of plan managers who determine the distribution of responsibilities and the physicians who join them. This section will explore some of the future conditions under which the goods strategy could restructure the medical care industry. Two general developments will be examined: first, the competition to physicians from paramedical personnel and the prospects for a more diverse labor force performing regularized patterns of diagnosis and treatment; second, the capital investment in biomedical research that will yield simplified curative techniques. The analysis will also suggest appropriate government policies to encourage the transition to the provision of medical goods.

---

323 *See* Ellwood, *et al., Health Maintenance Strategy,* 9 MED. CARE 291 (1971).

A. *Manpower for the Production of Medical Goods*

The state of personnel licensure laws has always been most important in determining the composition of the labor force in the medical care industry.[324] These laws are designed to exclude practitioners who could be expected to deliver medical services of inadequate quality.[325] Thus physicians have defended the legal structure against external challenges by invoking the nightmare of poor quality service from quacks.[326] This solemn warning has usually been sufficient to convince the public to support strong licensure laws, although it has not prevented osteopaths and chiropractors from delivering what some critics believe to be useless or harmful services.[327]

Licensure laws also limit the ability of paramedicals to provide care independent of direct supervision by physicians.[328] Doctors themselves are restrained from delegating tasks to assistants unless they fall within the provisions of a special statutory exemption for allied health personnel.[329] But recent experiments and physician maldistribution have put pressure on state legislatures to revise their licensing practices. Rural health clinics have begun to use paramedical nurse practitioners and physician assistants as their only medical personnel.[330] Moreover, studies of these operations are yielding results that prove these workers capable of providing high quality care on their own.[331] The success of these programs in delivering low-cost routine care should create pressure for more widespread implementation of the paramedical clinic. The federal government can encourage

---

324 *See* Kissam I, *supra* note 26, at 15.

325 *See* Starr, *supra* note 9, at 180-81.

326 *See* Kissam I, *supra* note 26, at 15.

327 *See* Kessler, *The A.M.A. and the Supply of Physicians*, 35 L. & CONTEMP. PROB. 267, 271 (1970).

328 *See* Kissam I, *supra* note 26, at 13.

329 *Id.*

330 *See* Joseph, *Health Manpower for Rural Primary Care*, 91 PUB. HEALTH REP. 159, 160 (1976).

331 *See* Flight & Schussler, *A Post-Hire Evaluation of Nurse-Conducted Preplacement Health Assessments*, 18 J. OCCUP. MED. 231, 233-34 (1976); note 102 *supra*.

this trend by permitting Medicare and Medicaid reimbursement for care purchased from these clinics.[332]

Revision of licensure laws to accommodate paramedicals would likely take the initial form of permitting them to perform specific medical acts.[333] These types of amendments would slow the pace of change because medical entrepreneurs would have to match groups of paramedicals trained to perform specific acts with diagnosis and prohibited treatments done by physicians. But other forces within the medical care market should help to promote the employment of paramedicals who occupy a position intermediate between the physician and the simple assistant.

One force would come from the development of process and outcome criteria from research done for PSRO medical audit reviews of hospital and ambulatory care. Although this research probably will not be used successfully to control the physician's discretion,[334] it could be employed to establish routine patterns of practice that paramedicals could undertake after a shorter period of training.[335] Physicians could begin to serve much more specialized roles for the treatment of conditions that fall outside routine procedural guidelines, which would become more comprehensive as research progressed. HMOs with much more extensive use of paramedicals and a defined medical care product would offer a serious challenge to present PGPs and individual providers.[336] Growth in the employment of paramedicals would also break down the dependence of medical consumers on service professionals and encourage price consciousness and better evaluation of medical care quality.[337]

---

332 *See* 123 CONG. REC. E2,796 (daily ed. May 5, 1977)(remarks of Rep. Richardson Preyer (D.-N.C.)). For a discussion of the issues involved, *see Reimbursement of Rural Clinics Under Medicare and Medicaid: Hearings on H.R. 8543, H.R. 791, H.R. 8459, H.R. 6259, H.R. 2504, and H.R. 842 Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce,* 95th Cong., 1st Sess. (1977).

333 *See* Kissam I, *supra* note 26, at 65.

334 *See* notes 284 to 288 and accompanying text *supra.*

335 *See* Wildavsky, *supra* note 8, at 113.

336 D. MECHANIC, *supra* note 31, at 113.

337 Kissam I, *supra* note 26, at 17-18.

To maintain the momentum of quality assessment in removing barriers to the labor of non-comprehensive medical technicians, the federal government must be willing to fund the research aspects of the PSRO program generously. The results of random clinical testing of treatment methods and the development of standards for the performance of medical tasks will be critical in responding to the objections of self-interested service providers that quality will suffer if state statutes liberalize entry into the medical labor force.[338] Congress must resist the pressure to cut back on PSRO research even if the enforcement provisions against doctors fail to achieve any results.[339] Moreover, the federal government should assist the states in developing malpractice standards that use the PSRO criteria as a basis for liability if the actions of a paramedical deviate from the criteria in a way that injures the patient.[340] This kind of modification would help merge malpractice law with product liability by rendering the medical entrepreneur liable for injury that results from a medical product not within defined tolerances or for quality below the industry standard.[341] Furthermore, the standards for liability could be tightened over time to enforce a desired level of quality as the sophistication of quality assessment and medicine itself progresses.

A second source of market pressure favoring the paramedical will be the development of computer diagnostics.[342] These machines can absorb the medical history of a patient, compare symptoms to disease with programmed case histories, and reach probable diagnoses.[343] The importance of this device for the diversification of the health manpower pool is similar to that of improved quality assessment. Centralized computer diagnosis would rely on the iterative process and wider scope of the whole industry's patient experience to prescribe treatment for other medical consumers

338 Such testing has already begun. *See* Sackett & Spitzer, *et al., supra* note 102.

339 *See* J. BLUM, *supra* note 131, at 204-06.

340 Some commentators advocate the use of PSRO guidelines as a standard of due care for physicians. *Id.* at 166-67.

341 Clearly defined process and outcome criteria for paramedicals provide the basis for a standard of "defective" production of medical goods. *See* note 113 *supra.*

342 *See* Bay, *The Computer Will See You Now,* MED. DIMENSIONS Jan. 1978, at 4.

343 *Id.*

more cheaply than a physician who must rely upon his memory of medical school courses and his own experience.[344] It makes the presence of a physician unnecessary for most situations of health maintenance and enhances the ability of the paramedical to apply his knowledge of routine practice to particular health problems.[345]

A third force favoring medical labor diversification is the continuing trend of physician specialization. Medical school curricula and the rewards of certification continue to guide medical students into specialty practice.[346] The resulting short supply of medical personnel to do preliminary screening and refer patients for specialty care when it is required could offer opportunities for paramedicals who do not require the comprehensive medical school training of the physician.[347] But the public reaction to the shortage of general practitioners has compelled the profession to interfere with the natural movement toward specialization and reestablish the general practitioner under the guise of "primary-care physician."[348] Some medical schools have now instituted incentive programs in an effort to convince future physicians to choose family practice.[349] From the perspective of medical costs and access, the continued reluctance of medical students to accept family practice[350] can only be considered a fortunate turn of events. Primary practice places over-trained physicians in an unchallenging position and gives them justification for charging fees commensurate with their educational investment but excessive for their contribution to the health product.[351] Moreover, general practitioners have the strongest attitudinal incentives for delivering unnecessary services.[352] The federal government should discourage family practice by continuing its past refusal to pay general practitioners the

344 *Id.* at 5.
345 *Id.*
346 *See* Ebert, *supra* note 19, at 179.
347 *See* Scheffler, Weisfeld, Ruby & Estes, *supra* note 64, at 1060.
348 *See* Saward, *supra* note 23, at 199.
349 S. KLAW, *supra* note 22, at 254.
350 *Id.*
351 *See* Terris, *False Starts and Lesser Alternatives,* 53 BULL. N.Y. ACAD. MED. 122-23 (1977).
352 *See* note 65 *supra.*

same fees as specialists.[353] It should direct additional funding for primary care to paramedical training and utilization experiments.[354]

The advent of paramedicals as a dominant part of the medical workforce could do much to ease medical inflation and improve the access of all Americans to routine medical care. Performance of routine care by salaried nonprofessionals carrying out tested medical procedures can produce a medical good of proven quality that does not hide possibilities for high additional costs from service-oriented physicians. But the government must be vigilant to avoid a resurgence of the undesirable elements of service philosophy among the new medical employees. First, the states must fight professionalization of paramedicals by emphasizing the periodic inspection and licensing of health care facilities rather than one-time licensing of individuals and by encouraging fluidity in the definition of paramedical role responsibilities. Second, the federal government should enforce the antitrust laws vigorously against any incipient paramedical professional associations.[355]

Enlarging the role of paramedicals in the medical care industry during a period of physician oversupply may meet with determined opposition from the doctors' professional organizations. Recent projections indicate that such a market situation may well occur during the 1980s.[356] To counteract this trend, the federal government should limit the migration of foreign physicians to the United States. This movement against one aspect of the celebrated "brain drain" would also improve the quality of medical care in many developing countries.[357] The next section describes a second method of diverting medical students and trained physicians from practice for which they are overtrained. Doctors should

---

353 *See* Scheffler, Weisfeld, Ruby & Estes, *supra* note 64, at 1060.

354 *See* note 102 *supra.*

355 Reprofessionalization could encourage paramedicals to take on the undesirable traits of service-oriented physicians. *See* S. KLAW, *supra* note 22, at 261.

356 *See* Edwards & Morrow, *supra* note 64, at 791.

357 *See* Mick, *The Foreign Medical Graduate,* SCI. AM., Feb. 1975, at 14.

be incorporated into an expanded national commitment to biomedical research to reap its medical rewards.[358]

B. *Social Investment in Future Medical Goods*

Inventing goods that can replace services and constructing production capacity for them traditionally require substantial capital investment. A similar problem now exists for future medical goods that can do away with the need for many forms of costly therapeutic intervention by physicians that are very uncertain in value to health.[359] Recent critiques of medicalization have argued vigorously that the most important contributors to present health status and medical care effectiveness have been simple techniques such as vaccines, drugs, and purification devices.[360] These techniques applied the findings of early biological research and could be distributed as low-cost public or private medical goods.[361] Biomedical research has now advanced to the point where investment in basic research offers a credible prospect of a new abundance of medical goods that are directed at underlying disease mechanisms and are decisively effective.[362] Moreover, better understanding of the processes of disease generation through clinical experimentation and DNA research could also generate simpler treatment regimes that would enable less skilled paramedicals to administer care far more effective than the present complex repertoire of physicians. In combination, these effects offer an opportunity to reduce permanently the cost of medical care and remove the constraints that now deny access to care for millions of Americans.

But the federal government must be willing to commit more than its present token share of the budget to a continuing investment of social capital in biomedical research. Yearly fluctuations in the limited government authorizations

---

358 *See* Frederickson, *Health and the Search for New Knowledge,* in DOING BETTER, *supra* note 8, at 159.

359 *See* Rogers, *supra* note 60, at 87.

360 *See* Knowles, *supra* note 14, at 57.

361 *See* I. ILLICH, *supra* note 14, at 29.

362 Thomas, *Biomedical Science and Human Health: The Long-Range Prospects,* DAEDALUS, Summer 1977, at 163, 170.

for this research have made it very difficult for scientific institutes to plan their work and retain the personnel needed for successful study and interpretation of findings.[363] Because the funding for biomedical research is discretionary, it is often jeopardized by a misguided interest in fiscal austerity.[364] Moreover, the benefits of biomedical research can only be reaped in the long-run applications to medical care. The distant payoff discourages private research by businesses concerned with short-run profits and alienates congressmen who are sometimes led to expect instant returns.[365] Managers of research institutes must be more thorough in explaining the potential benefits of their activities and maintaining extensive public relations efforts with Congress if they are to accelerate and maintain a significant federal commitment to basic biological investigation and the clinical application experiments that will follow.[366]

Medical schools will also play a role in meeting the conditions for an expanded effort in biomedical research. Present curricula are well-designed to prepare doctors for basic and clinical research in medicine; indeed, they are often criticized for their abstractness.[367] Furthermore, there is a critical need for researchers with these types of skills.[368] The federal government should encourage medical students to leave the path of private practice and enlist in the more exciting and prestigious research positions that would be opened in a new national research effort.[369] Furthermore, these personnel should be organized to allow speedy application of research findings to the production of medical goods and clinical quality testing after important discoveries in basic research take

---

363 *See* Steinfeld, *Government and Private Medicine: Future Directions,* 140 MILIT. MED. 393, 396 (1975).

364 Dr. William Carey, American Ass'n for the Advancement of Science Newsletter, Nov. 21, 1977, at 1.

365 *See* Boston Globe, Dec. 18, 1977, § A, at 1, col. 1.

366 The biomedical research community, for example, should establish a basis for setting a reasonable level of support. *See* Frederickson, *supra* note 358, at 168.

367 *See id.* at 164-65.

368 *Basic Issues in Biomedical and Behavioral Research: Hearings Before the Senate Comm. on Labor and Public Welfare,* 94th Cong., 2d Sess. 232 (1976) (statement of Dr. Lee Clark).

369 *See* Frederickson, *supra* note 358, at 164-65.

place.[370] Redirection of medical students into research has the additional benefit of forestalling a glut of physicians and thereby increasing the likelihood that paramedicals will be permitted to enter the formerly exclusive domain of the professional medical service provider.

Conclusion

Severe reductions in federal support for biomedical research will accompany the enactment of a national health insurance program under the present structure of medical care.[371] Congress must make the difficult choice between attempting to subsidize increased current consumption of medical services through national health insurance and investing in research to produce a new array of medical goods and lower the ultimate cost of medical care to future consumers.

The choice becomes less disturbing when proper consideration is given to the service attitudes that guide the behavior of physicians in the present delivery system. These attitudes permit health care analysts to predict that new national health care financing programs will be self-defeating because they will generate overutilization that raises costs and reduces access for those who cannot circumvent the noneconomic barriers to care. Moreover, the inability and unwillingness of hospital and group practice administrators to develop and enforce criteria for necessary care limits the effectiveness of rationalized bureaucratic physician groups and government regulatory programs. Biomedical research, quality assessment, and paramedical promotion present a unique opportunity to increase the real supply of medical care and promote more effective medical intervention. The federal government and the states should act to replace the artificial scarcity of medical services with an abundance of medical goods.

---

370 Applied research must be well-coordinated with basic research to avoid premature development and the consequent waste of valuable social resources. *See* Thomas, *supra* note 362, at 169.

371 *See* Frederickson, *supra* note 358, at 168.

NOTE

PRICING BAD BLOOD: REASSESSING LIABILITY FOR POST-TRANSFUSION HEPATITIS†

EDWARD R. WIEST*

Recipients of blood transfusions have always been obligated to face risks beyond those that necessitated the use of blood. One of these risks has been the possibility that the blood employed to save a life might be carrying hepatitis viruses that pose a new threat to a patient's health. Another has been the risk that once a blood recipient has contracted post-transfusion hepatitis, the recipient will be obligated to pay out of his own resources the costs associated with the illness. Until the early 1970's, the absence of any means by which post-transfusion hepatitis could be prevented, combined with the apparent inevitability of occurrences of hepatitis in some transfusion recipients, prompted courts and legislatures to reject the imposition of liability without fault on blood suppliers implicated in cases of the disease.

Recent developments in medicine, however, indicate that some cases of post-transfusion hepatitis can be prevented. In this Note, Mr. Wiest considers the effect these advances may have on the tort liability of blood suppliers. He reviews the perfection of medical tests which can identify blood carrying one of the viruses associated with post-transfusion hepatitis and examines the impact of a recently discovered relationship between the use of blood donated by members of certain groups (most notably, unsupervised donors paid in cash for blood) and the incidence of hepatitis.

Mr. Wiest observes that the legislatures have banned the imposition of liability without fault on blood suppliers, but he asserts that these medical advances provide an adequate basis for invoking fault liability on behalf of hepatitis victims. He argues that a standard of care can now be developed for blood suppliers, including the use of tests to

---

* B.A., Pennsylvania, 1976; member of the class of 1979, Harvard Law School.

identify hepatitis viruses in donor blood and reliance on newly-imposed FDA rules mandating labelling of the theoretically more dangerous blood of paid donors. Through the imposition of tort liability on blood suppliers, Mr. Wiest concludes, the risks of post-transfusion hepatitis can be significantly reduced.

Introduction

It is an unfortunate truth that medical progress is often accompanied by the creation of new risks to its beneficiaries. The emergence of post-transfusion hepatitis[1] following the development of techniques for the transfusion of blood and blood components[2] is one example. Yet, as medical research begins to ameliorate the hazards that are the unwholesome fruit of progress, the legal system may lag behind in providing incentives and disincentives for the protection of

---

1 "Post-transfusion" hepatitis is now the preferred medical nomenclature for the disease; *see, e.g.*, Grady, *et al., Risk of Posttransfusion Hepatitis in the United States: A Prospective Cooperative Study,* 220 J.A.M.A. 692 (1972). It will be used throughout this Note. Formerly, the disease was known as "serum hepatitis"; it is also often referred to as "transfusion-related hepatitis."

2 The relationship between the transfusion of blood and ensuing cases of hepatitis was discovered shortly after development of practical methods of transferring blood from one person to another in the early 1940's. *See* A. ZUCKERMAN, HUMAN VIRAL HEPATITIS: HEPATITIS ASSOCIATED ANTIGEN AND VIRUSES 212 (2d ed. 1975).

This Note deals primarily with problems associated with occurrences of hepatitis following the transfusion of whole blood or components that can be obtained only through processing whole blood, *e.g.*, packed red cells. It will not consider issues connected with plasmapherisis, an increasingly used technique by which some components of blood plasma may be removed from a donor while all other components, including red cells, may be returned to that donor. The donor may therefore "give" far more frequently than a conventional donor. The process poses different problems from those associated with whole blood transfusion because: 1) the process is employed almost exclusively by commercial suppliers who pay all donors and 2) blood components from many donors are "pooled" before administration to patients. *See* Sapolsky & Finkelstein, *Blood Policy Revisited — A New Look at "The Gift Relationship,"* 46 THE PUBLIC INTEREST 15, 23 (1977).

This Note will not present a full discussion of the medical aspects of post-transfusion hepatitis. For such discussions in the legal literature, *see generally* Van Wormer, *Transfusion Associated Hepatitis,* 12 CAL. W. L. REV. 389 (1976); Ward, *Detecting Viral Hepatitis in Blood Transfusions: Recent Developments,* 12 CAL. W. L. REV. 380 (1976); Comment, *Blood Transfusions and the Transmission of Serum Hepatitis: The Need for Statutory Reform,* 24 AM. U. L. REV. 367, 372-381 (1975). *See also* A. ZUCKERMAN, *supra* note 2.

health care recipients. The slow response of courts and legislators to the recent development of methods by which post-transfusion hepatitis may be reduced — if not totally eliminated — exemplifies this syndrome.

Within the past ten years, methods have been developed which screen out of the blood donor pool many carriers of hepatitis viruses. Previously, the disease had been viewed as an unavoidable corollary to the transfusion of blood. Consequently, courts were reluctant to impose liability without fault on blood suppliers[3] implicated in the transmission of hepatitis, following the leading case of *Perlmutter v. Beth David Hospital*,[4] decided by the New York Court of Appeals in 1954.[5] The legislatures of forty-five states have enacted statutes exempting blood suppliers from liability without fault for the transmission of hepatitis.[6]

---

3 This Note will use the term "blood supplier" to refer to both the blood banks which collect blood from donors and the hospitals or other health care providers which transfuse the blood to recipients. Of course, many hospitals control facilities for the collection of blood. Where appropriate, distinctions will be drawn between hospitals, blood banks operated on a non-profit basis (*e.g.*, those operated by the American Red Cross), and those operated for profit (commercial blood banks). Some courts have drawn such distinctions. *See, e.g.*, Belle Bonfils Memorial Blood Bank v. Hansen, 579 P.2d 1158 (Colo. 1978) (blood bank may be held strictly liable though hospitals are exempt).

4 308 N.Y. 100, 123 N.E.2d 792 (1954). *Contra*, Cunningham v. MacNeal Memorial Hospital, 47 Ill.2d 443, 266 N.E.2d 897 (1970).

5 While *Perlmutter's* holding was that the transfer of blood was a service and not a sale subject to the Uniform Sales Act, the majority observed no means of detecting or eliminating the causative agent of the disease existed at the time. 308 N.Y. at 106-07, 123 N.E.2d at 795.

6 ALA. CODE § 7-2-314(4) (1975); ALASKA STAT. § 45.05.100(e) (Supp. 1977); ARIZ. REV. STAT. tit. 32, §§ 1481-82 (1976); ARK. STAT. ANN. §§ 82-1608 (1976), 85-2-316-3(d) (Supp. 1977); CAL. HEALTH & SAFETY CODE §§ 1603.1 to 1603.5 (West Supp. 1978), 1606 (West 1970); COL. REV. STAT. § 13-22-104 (1973); CONN. GEN. STAT. § 19-1391 (1977); DEL. CODE tit. 6, § 2-316(5) (1975); FLA. STAT. §§ 672.2-316(5) (1975), Act of June 21, 1977 ch. 77-307, 1977 Fla. Laws 1318 (codified at FLA. STAT. §§ 381.601 to 381.607); GA. CODE §§ 84-5501a to 5507a (Supp. 1977); 105-1105 (1975), 109A-2-316(5) (1975); HAW. REV. STAT. §§ 325-91, 327-51 (1976); IDAHO CODE § 39-3702 (1977); ILL. REV. STAT. ch. 91 §§ 181-183 (Smith-Hurd Supp. 1978), ch. 111 ½, §§ 620-1 to 620-5 (Smith-Hurd 1975); IND. CODE §§ 16-8-7-1 to 16-8-7-3 (1976); IOWA CODE ANN., § 142A.8 (West Supp. 1977-1978); KAN. STAT. ANN. § 65-3701 (1972); KY. REV. STAT. § 139.125 (1971); LA. CIV. CODE ANN. § 1764(B) (West Supp. 1977); ME. REV. STAT. ANN. tit. 11, § 2-103 (West Supp. 1977-1978); MASS. GEN. LAWS ANN. ch. 106, § 2-316(5) (West Supp. 1977-1978); MICH. COMP. LAWS ANN. §§ 691.1511 to .1512 (West Supp. 1977-1978); MISS. CODE ANN. § 41-41-1 (Supp. 1977); MO. ANN. STAT. § 431.069 (Vernon Supp. 1978); MONT. REV. CODES ANN. §§ 69-2203

Yet the assumption on which these acts are based — that the risk of post-transfusion hepatitis cannot be reduced — is no longer completely valid. It is now well established that, in general, donors paid in cash for their blood are far more likely to be hepatitis carriers than are so-called "voluntary" donors.[7] The isolation of Australia antigen, associated with Hepatitis B and the infective agent in many cases of post-transfusion hepatitis,[8] has led to the development and implementation of tests to identify the presence of that strain of virus in blood.[9] The body of judge-made and statutory law reflecting a belief that blood suppliers ought not to be held liable for a disease they are completely powerless to prevent no longer accurately reflects the realities of contemporary medicine.

---

to 2205 (Supp. 1977); NEB. REV. STAT. § 71-4001 (1976); NEV. REV. STAT. § 460.010 (1973); N.H. REV. STAT. ANN. § 507:8-b (Supp. 1977); N.M. STAT. ANN. § 12-25-5 (1976); N.Y. PUB. HEALTH LAW § 580(4) (McKinney Supp. 1977-1978); N.C. GEN. STAT. §§ 90-220.10, 90-220.13 (1975); N.D. CENT. CODE § 41-021-33(3)(d) (Supp. 1977); OHIO REV. CODE ANN. § 2108.11 (Page 1976); OKLA. STAT. tit. 63, § 2151 (1971); ORE. REV. STAT. § 97.300 (1977); PA. STAT. ANN. tit. 35, § 10021 (Purdon 1977) (Act of Jan. 28, 1972, No. 9) 1972 Pa. Laws 20; S.C. CODE § 44-43-10 (1976); S.D. COMPILED LAWS ANN. § 57-4-33.1 (Supp. 1977); TENN. CODE ANN. § 47-2-316 (5) (Supp. 1976); TEX. STAT. ANN. § 4590-3 (Vernon 1976); UTAH CODE ANN. § 26-29-1 (1976); VA. CODE § 32-364.2 (1973); WASH. REV. CODE § 70.54.120 (1976); W. VA. CODE § 16-23-1 (1972); WIS. STAT. § 146.31(2)-(3) (1975); WYO. STAT. § 342-316-3(d) (Supp. 1975).

7 *See, e.g.*, R. TITMUSS, THE GIFT RELATIONSHIP: FROM HUMAN BLOOD TO SOCIAL POLICY (1971); Allen & Sayman, *Serum Hepatitis from Transfusions of Blood: Epidimiologic Study,* 180 J.A.M.A. 277 (1962); Goldfield, *Some Epidimiologic Studies of Transfusion Associated Hepatitis* in TRANSMISSIBLE DISEASE AND BLOOD TRANSFUSION 141, 144 table 11-2 (T. Greenwalt & G. Jamison eds. 1975) [collection hereinafter cited as TRANSMISSIBLE DISEASE STUDY] (paid donors 2.2 times as likely to be hepatitis carriers than volunteers, even after all detected carriers removed from donor pool).

8 Hepatitis B was once regarded as the major strain responsible for post-transfusion hepatitis. Ward, *Detecting Viral Hepatitis in Blood Transfusions: Recent Developments,* 12 CAL. W.L. REV. 380 (1976). However, since tests to identify blood carrying Hepatitis B virus have been put into use, another strain of the disease, currently referred to as "non-A, non-B" hepatitis, has apparently become responsible for most cases. *See* Alter, *et al., Clinical and Serological Analysis of Transfusion-Associated Hepatitis,* 1975-II LANCET 838, 841 (89% of cases attributed to non-A, non-B); Prince, *et al., Long Incubation Post-Transfusion Hepatitis Without Serological Evidence of Exposure to Hepatitis B Virus,* 1974-II LANCET 241, 243-44, 245-46 (71% of all cases indicated no exposure to Hepatitis B or Hepatitis A). Some cases of post-transfusion hepatitis have also been caused by Hepatitis A (infectious hepatitis). *See, e.g.,* Hutchins v. Blood Services of Montana, 161 Mont. 359, 506 P.2d 449 (1973).

9 *See, e.g.,* Alter, *et al., Post-Transfusion Hepatitis after Exclusion of Commercial and Hepatitis-B Antigen Positive Donors,* 77 ANNALS INTERNAL MED. 691, 696 (1972).

The costs of post-transfusion hepatitis to individual victims and to the economy are immense. It has been estimated that the 100,000 acute and non-acute cases of the disease believed to have occurred in 1970,[10] resulting in 3,700 deaths, cost the economy as much as $250 million.[11] The cost individual victims must bear for hospital care and in lost income may approach $20,000.[12] The faultless recipient of hepatitis-carrying blood (in conjunction with his or her insurer) faces this loss without serious hope of compensation from the blood's suppliers.

This Note will examine the circumstances under which blood suppliers ought to be held liable for post-transfusion hepatitis, given their increased ability to prevent that disease. Part I will review the steps blood suppliers can now take to screen potential and actual carriers of hepatitis viruses from the blood donor pool. Part II will examine two proposals for protecting blood recipients — the elimination of paid donors from the blood supply pool and the imposition of liability without fault on blood suppliers. It concludes that neither of these legal weapons can be an effective means of combatting post-transfusion hepatitis. Part III will consider other methods by which the legal system may attack the disease, particularly the imposition of liability based on fault on blood suppliers. It concludes that, given the ability of medical science to establish a standard of care by which post-transfusion hepatitis may be reduced, fault liability may effectively be employed.

---

10 One of the great problems in dealing with post-transfusion hepatitis is the identification of those who have the disease. It has been estimated four times as many patients suffer from the anicteric form of the disease, with no unique external symptoms, than those who suffer from icteric hepatitis, characterized by jaundice and other obvious indicia. Seeff, *et al., VA cooperative study of post-transfusion hepatitis, 1969-1974: incidence and characteristics of hepatitis and responsible risk factors*, 270 AM. J. MED. SCI. 355, 357 (1975). *See also* A. ZUCKERMAN, *supra* note 2, at 92-94.

11 General Accounting Office, Hepatitis from Blood Transfusions: Evaluation of Methods to Reduce the Problem 2, (Feb. 13, 1976) (MWD-75-82) [hereinafter cited as GAO Study]. As many cases of anicteric hepatitis are never diagnosed or reported, *see* note 10 *supra*, the figure of 100,000 cases is a rough estimate.

12 Kessel, *Transfused Blood, Serum Hepatitis and the Coase Theorem*, 17 J.L. ECON. 265, 268-69 & n.19 (1974).

I. CURRENTLY AVAILABLE METHODS FOR THE REDUCTION OF POST-TRANSFUSION HEPATITIS

A major reason for the judicial[13] and statutory[14] exemption of blood suppliers from liability without fault was the belief of policymakers, at the time the exemption was granted, that post-transfusion hepatitis could not be prevented. This is no longer the case. Research establishing which groups of potential blood donors are more likely to be hepatitis carriers and the development of tests which indicate whether antigens associated with Hepatitis B virus are present in human blood have made it possible to reduce the risk of disease to blood recipients. As the federal government has asserted regulatory authority over blood suppliers, the Food and Drug Administration (FDA) has relied on these developments in establishing behavioral rules for blood bankers.[15]

A. *The Relationship Between Paid Blood Donors and Post-Transfusion Hepatitis*

Progress toward reducing the incidence of post-transfusion hepatitis began in the early 1960's with the publication of studies conducted by J. Garrott Allen indicating that a correlation existed between the use of blood obtained from donors paid in cash and the occurrence of hepatitis in the recipients of that blood.[16] While other researchers confirmed Allen's results,[17] this knowledge did not influence health policy planners until the early 1970's, when Richard Titmuss published in the United States his comparison of the U.S. and British blood distribution systems, *The Gift Relationship.*[18] Since the appearance of Titmuss' work, which denounced the use of paid donors both for safety reasons and as a matter of

---

13 *See Perlmutter*, 308 N.Y. 100, 106-07, 123 N.E.2d 792, 795.

14 *See, e.g.*, MICH. COMP. LAWS ANN. § 691.1511 (West Supp. 1977-1978).

15 *See* 21 C.F.R. Parts 610, 640 (1977) and text accompanying notes 39-52 *infra.*

16 Allen & Sayman, *supra* note 7, at 277 (1962).

17 *See, e.g.*, Alter, *et al., supra* note 9, at 691 (1972); Grady, *et al., supra* note 1, at 692 (1972); Walsh, *et al., Post-transfusion Hepatitis After Open Heart Operations: Incidence after the Administration of Blood from Commercial and Volunteer Donor Populations,* 211 J.A.M.A. 261 (1970).

18 *Supra* note 7.

social policy, the elimination of "paid" blood has become a major objective of government health planners.[19]

Findings of studies conducted after screening tests for Hepatitis B became available indicate the extent to which blood from donors paid in cash is more dangerous than blood supplied by volunteers. Admittedly, more than 90 percent of "paid" donors are *not* hepatitis carriers. Yet researchers found evidence of Hepatitis B antigens in paid donors between 3.46 and 6.4 times as often as in volunteers.[20] Even when all blood tested positive for Hepatitis B was withdrawn from the transfusion supply, donors paid in cash were implicated in cases of hepatitis more than twice as often as volunteers.[21]

Concern about the apparent effects of the use of cash incentives for the donation of blood underlies fears about the safety of using blood from donors paid in cash. Those willing to trade blood for quick cash, it is argued, are more likely than volunteers to donate while in ill health or to hide medical information that would disqualify them as blood providers.[22] Narcotics addicts are subjects of particular concern in this regard, because of the high risk that hepatitis may be transmitted through the sharing of needles for drug injections.[23]

It has been argued that hepatitis carrier status is more closely tied to low socio-economic status than to whether or not donors are paid in cash.[24] The low incidence of hepatitis

---

19 *See* Johnson, *Introduction: The Blood Market* in BLOOD POLICY: ISSUES AND ALTERNATIVES 1,3 (D. Johnson ed. 1977) (Proceedings of an American Enterprise Institute Conference) [hereinafter cited as AEI PROCEEDINGS].

20 Barker, *et al., Viral Hepatitis B: Detection and Prophylaxis* in TRANSMISSIBLE DISEASE STUDY, *supra* note 7, at 91 tables 7-9, 7-10.

21 Goldfield, *supra* note 7, at 144 table 11-2.

22 *See, e.g.,* R. TITMUSS, *supra* note 7, at 151-52. Of course, this requires that the prospective donor be aware that he had contracted hepatitis — a fact of which he may be unaware. *See* Seeff, *et al., supra* note 10, at 357 (1975).

23 GAO Study, *supra* note 11, at 20-25. FDA regulations prohibit blood suppliers from drawing blood from donors with visible needle marks on the arms. 21 C.F.R. § 640.3 (b)(7) (1977).

24 *See* GAO Study, *supra* note 11, at 18-25. A relationship may also exist between ethnicity and hepatitis carrier status. In Sweden, post-transfusion hepatitis is almost unknown; in Japan, it is a serious problem. Yet blood donors are paid in both societies. *See* R. TITMUSS, *supra* note 7, at 155-56, 185-86; Sapolsky & Finkelstein, *supra* note 2, at 18-19.

associated with blood suppliers who carefully supervise those donors paid in cash supports this position.[25] Yet the dramatic reduction in post-transfusion hepatitis reported where volunteers replaced paid blood donors justifies the categorical exclusion of paid donors wherever it is possible to do so.[26]

B. *Tests for Identifying Hepatitis Carriers*

Prior to the late 1960's, the only effective methods for identifying a given individual as a hepatitis carrier were based on a donor's medical history. If a prospective donor had ever had any form of hepatitis[27] or was known to have been implicated in a number of previous cases of post-transfusion hepatitis,[28] he or she was (and is) forbidden to give blood.

With the isolation in the late 1960's of Australia antigen, the discovery of its association with Hepatitis B virus, and the ensuing development of tests to detect the presence of the antigen in human blood, the situation changed radically. A committee of the National Research Council of the National Institute of Health, speaking for both the American Red Cross (the largest blood collecting entity) and the American Association of Blood Banks (AABB, an organization of over 1,000 hospital-related banks), began to recommend the use of tests for what became known as Hepatitis

---

25 GAO Study, *supra* note 11, at 10-11. The Mayo Clinic in Rochester, Minnesota, is one such organization. *See* Kessell, *supra* note 12, at 287 & n.71. *See also* Alsever & Van Schoonhoven, *Posttransfusion Viral Hepatitis (PTVH): Myths and Facts,* 31 ARIZ. MED. 263 (1974) (first time volunteer donors are more likely to be hepatitis carriers than known, "biologically tested," paid donors).

26 *See, e.g.,* Alter, *et al., supra* note 9, at 697 (70% of drop in post-transfusion hepatitis from 33 to 7.1% of patients undergoing major surgery tied to substitution of blood). *Cf.* Holley, Glenn & Linkenhoker, *Do Volunteer Donors Decrease Post-transfusion Hepatitis?: Study In a Military Donor Population,* 234 J.A.M.A. 1251 (1975) (volunteer pool of Vietnam returnees more dangerous than paid donors). *See also* Seeff, *et al., supra* note 10, at 359 t. II (71% drop in hepatitis followed reduction in use of paid donor blood from 91.2 to 4.1% of transfusions).

27 *See* 21 C.F.R. §§ 610.41, 640.3 (c) (1977) (FDA regulations currently in force). Of course, problems exist when prospective blood donors are not aware they ever had hepatitis. *See, e.g.,* Taswell, Shorter and Maxwell, *Control of Post Transfusion Hepatitis by Donor Selection and Case Investigation,* 47 MAYO CLINIC PROC. 98, 98-99 (1972).

Associated Antigen (HAA) as soon as the "methodologic, supply, and licensure problems [were] solved."[29] Individuals whose blood tested positively for HAA were to be permanently excluded from the donor pool for human use.[30] The recommendation was strengthened shortly thereafter by FDA regulations mandating the use of the most sensitive available tests on all blood collected for human use.[31]

While the exclusion of HAA-positive donors is not believed to have had as great an effect on the occurrence of post-transfusion hepatitis as has the exclusion of paid donors, results have been impressive. A study published in 1972 attributed 30 percent of a drop in the incidence of the disease from 33 to 7.1 percent among post-operative patients to the exclusion of HAA-positive blood supplied by volunteer donors.[32]

Tests currently available to detect blood carrying Hepatitis B virus, however, will not detect all carrier blood. Despite early concerns about the effectiveness of the third-generation radioimmunoassay (RIA) test now in use for detecting Hepatitis B carriers,[33] experts no longer regard that strain of the disease as the causative agent in most cases of post-transfusion hepatitis.[34] Instead, an enigmatic virus known as

---

29 *Editorial, Statement Concerning the Use of Hepatitis-associated Antigen Tests for Donor Screening in Blood Banks,* 11 TRANSFUSION 1, 2 (1971).

30 *Id.*

31 21 C.F.R. §§ 610.40, 41 (1977).

32 Alter, *et al., supra* note 9, at 696 (1972). The study was conducted using less sensitive tests than those currently employed.

33 It had been believed that even the third-generation RIA test now in use could only detect Hepatitis B antigens in 40% or less of blood carrying the virus (moderate sensitivity), Van Wormer, *Transfusion Associated Hepatitis,* 12 CAL. W. L. REV. 389, 400, 401 n.51, 401 n.61, *citing* AM. NAT. RED CROSS, EXPERIENCE IN HBAG TESTING BY COUNTER-ELECTROPHORESIS (CEP) AND RADIOIMMUNOASSAY (RIA) (1974). It had also been feared that the RIA test now in use was of such low specificity that excessive amounts of non-carrier blood would be identified as hepatitis-carrying, Kessel, *supra* note 12, at 268, but improvements in testing procedures have reduced the problem of false positives, *see* Dodd, *et al., Hepatitis B (Surface) Antigen Testing by Radioimmunoassay: Experience in a Very Large Donor Population,* 63 AM. J. CLINICAL PATHOLOGY 847 (1975).

34 *See* Gitnick, *Viral Hepatitis,* 128 WEST. J. MED. 117, 121 (1978); Gocke, *Post-Transfusion Hepatitis: A Status Report* in AEI PROCEEDINGS, *supra* note 19, at 11, 12-17 (1977); *see generally International Forum: How Frequent is Posttransfusion Hepatitis after the Introduction of 3rd Generation Donor Screening for Hepatitis B? What is its Probable Nature?* 32 VOX SANGUIS 346 (1977).

non-A, non-B hepatitis appears to be the cause of the bulk of cases.[35] While the availability of tests for HAA have enabled researchers to discover the existence of this strain of the disease, available tests cannot identify blood carrying non-A, non-B hepatitis virus.[36]

Despite these limitations, the existence of methods for detecting at least some blood carrying Hepatitis B virus prior to the infection of a hapless transfusion recipient is a significant advance. The value of such a test in disqualifying dangerous donors from the blood pool (along with those who were excluded by prior historical tests) cannot be denied.[37] Although no national registry of donors known or believed to be carriers is in existence, increasing the means by which hepatitis carriers may be identified will reduce the incidence of the disease in blood recipients.[38]

C. *Increasing Federal Involvement in Blood Banking*

Before 1970, blood suppliers were subject only to regulation by state agencies.[39] Since the enactment of amendments to the Public Health Service Act in 1970 that explicitly required the licensure of blood banks shipping products across state lines,[40] responsibility for the regulation of blood suppliers has shifted to the Bureau of Biologics of the FDA. While fewer than 165 organizations were required to obtain

---

35 *See* Alter, *et al., Clinical and Serological Analysis of Transfusion-Associated Hepatitis,* 1975-II LANCET 838, 841; Prince, *et al., Long Incubation Post-Transfusion Hepatitis Without Serological Evidence of Exposure to Hepatitis B Virus,* 1974-II LANCET 241.

36 Recently published studies indicate that, while the specific non-A, non-B virus is yet to be isolated, it can be transmitted (via human blood) to experimental animals. Alter, *et al., Transmissible Agent in Non-A, Non-B Hepatitis,* 1978-I LANCET 459; Tabor, *et al., Transmission of Non-A, Non-B Hepatitis from Man to Chimpanzee,* 1978-I LANCET 463. Such progress will aid in the future study of the non-A, non-B virus(es).

37 *See* GAO Study, *supra* note 11, at 26-39.

38 *See id.*; Department of Health, Education and Welfare, *National Blood Policy: Department Response to Private Sector Implementation Plan,* 39 Fed. Reg. 32,702, 32,703 (1974).

39 *See, e.g.*, CAL. HEALTH & SAFETY CODE §§ 1603, 1603.1, 1603.2 (West 1970, Supp. 1978); N.J. STAT. ANN. §§ 26:2A-1 to -12 (West 1964); N.Y. PUB. HEALTH LAW §§ 3100-3121 (McKinney 1971, Supp. 1976-1977).

40 42 U.S.C. § 262 (1976).

licenses, this step alone brought the suppliers of 60 percent of the blood collected in the United States under federal regulation.[41]

More than 5,000 blood suppliers not engaged in interstate activity were brought under the purview of the FDA soon thereafter. Asserting authority under section 510 of the Food, Drug and Cosmetic Act,[42] the FDA issued regulations requiring all intrastate blood suppliers to register as "drug" suppliers in early 1973.[43] While registered intrastate suppliers were originally subject only to periodic inspection under section 510(h) of the Act,[44] they were not required to follow procedures mandated for licensed interstate suppliers. In 1975, however, FDA required all blood suppliers, regardless of the "market" in which they operate, to follow the same procedures.[45]

The FDA's rules for blood bank operations were not the first set ever drafted for use by all segments of the industry. National organizations of blood suppliers, particularly AABB, had published manuals of recommended procedures.[46] The currrent FDA regulations, however, are the first to have the force of law on a nationwide basis, although they do not require any radical changes in blood supplier behavior. Blood suppliers may not accept blood from any donor with a history of viral hepatitis or any other disease transmissable by blood transfusion.[47] Donors' arms and

---

41 FDA, *Human Blood or Blood Products*, 37 Fed. Reg. 17,419 (1972); GAO Study, *supra* note 11, at 4-5. This is due primarily to the licensing of Red Cross-sponsored blood suppliers.

42 21 U.S.C. § 360 (1976).

43 *See* FDA, *Registration of Blood Banks and Other Firms Collecting, Manufacturing Preparing or Processing*, 38 Fed. Reg. 2965 (1973), 21 C.F.R. § 607.6 (1977).

44 21 U.S.C. § 360(e) (1976). *See* FDA, *supra* note 43, at 2965-66.

45 FDA, *Human Blood and Blood Products: Collection, Processing and Storage*, 40 Fed. Reg. 53,532 (1975). FDA has asserted it has the power to regulate the practices of intrastate blood suppliers to reduce the spread of disease across state lines. FDA, *Proposed Manufacturing Practice for Blood and Blood Components*, 39 Fed. Reg. 18,614, 18,614-15 (1974).

46 *See, e.g.*, AMERICAN ASSOCIATION OF BLOOD BANKS, STANDARDS FOR BLOOD BANKS AND TRANSFUSION SERVICES (7th ed. 1976); *see also* D. HUESTIS, J. BOVE & S. BUCK, PRACTICAL BLOOD TRANSFUSION (2d ed. 1976).

47 *See, e.g.*, 21 C.F.R. § 640.3(b)(6), (c) (1) (1977).

forearms must be free "from skin punctures or scars indicative of addiction to self-injected narcotics."[48] All blood must be tested for the presence of antigens to Hepatitis B; those whose blood has ever tested positive for the antigens are barred from giving blood.[49] Exclusion from the donor pool is also mandated where a person has either had close contact with a person suffering from hepatitis or has received a transfusion of blood suspected to be carrying hepatitis viruses.[50] Blood suppliers are also required to maintain records on the medical history of each donor and of the history of each unit following transfusion.[51] These records can tie the development of hepatitis in recipients to those who supplied the blood transfused to the patient. Regulations which became effective on May 15, 1978, require each container of blood or blood components to bear a label indicating whether its donor(s) were paid in cash for their blood or were volunteers.[52] The new FDA labeling rules parallel legislation previously in force in Illinois,[53] California,[54] Georgia,[55] and Florida.[56]

The establishment of national minimum standards for blood bank behavior is likely to have an impact on the occurrence of post-transfusion hepatitis, although the lack of complete nationwide data on the occurrence of the disease may make measurement difficult. More importantly, the FDA regulations may also serve as an authoritative standard for measuring the performance of blood suppliers, despite their infringement on the authority individual states have been able to exercise over blood suppliers within their borders.[57]

---

48 21 C.F.R. § 640.3(b) (7) (1977).

49 21 C.F.R. § 610.41 (1977). Tests used must be as sensitive as the radioimmunoassay (RIA) test that is the most sensitive test currently available.

50 21 C.F.R. § 640.3(c)(1), (2) (1977).

51 21 C.F.R. § 640.3(c)(2), (c) (3) (1977).

52 FDA, *Whole Blood and Components of Whole Blood Intended for Transfusion: Donor Classification Labeling Requirements*, 43 Fed. Reg. 2141, 2147-48 (1978) (to be codified at 21 C.F.R. §§ 606.120(b)(2), 640.2(f), 640.7(a),(f), 640.18(a), 640.26(b), 640.35(b), 640.57(b)).

53 ILL. REV. STAT. ch. 111 ½, §§ 620-1 to 620-5 (1975).

54 CAL. HEALTH & SAFETY CODE § 1603.5 (West Supp. 1978).

55 GA. CODE §§ 84-5501a to 5507a (Supp. 1978).

56 FLA. STAT. ANN. §§ 381.601 - 381.607 (West Supp. 1978).

57 *See* State v. Interstate Blood Bank, Inc., 65 Wis.2d 482, 494-98, 222 N.W.2d

II. Impractical Approaches to Reducing Post-Transfusion Hepatitis

Those who believe that legal measures can reduce the incidence of post-transfusion hepatitis have proposed two simple methods for alleviating the problem. One is the enactment of statutes or regulations that prohibit the payment of cash for blood donations, thus excluding paid donors from the blood supply system.[58] Another is the imposition of liability without fault on blood suppliers whose "product" caused a particular case of post-transfusion hepatitis.[59] Such liability aims to compensate the victim and provide incentives to blood suppliers to develop and employ safer techniques.

Neither solution requires the establishment of a complex administrative system; both provide direct or indirect means for the exclusion of the most dangerous donors from the blood supply. Yet neither technique is appropriate for use in the United States today. The current state of the blood supply system and the continuing inability of the medical profession to identify all hepatitis carriers makes the use of these broad-gauged proposals impractical. In addition, it is unlikely judges or legislators will be willing either to ban the paid blood donor or impose liability without fault.

A. *Can the Paid Blood Donor Be Eliminated?*

The correlation between the use of paid donors and the incidence of post-transfusion hepatitis has convinced many experts that the exclusion of the paid blood donor would be the most important step in eliminating the disease. Their arguments have been buttressed by the experience of the

---

912, 919-20 (1974) (federal licensing of interstate blood bank preempted Wisconsin statute prohibiting the operation of a blood bank for profit).

58 *See generally* R. Titmuss, *supra* note 7.

59 *See, e.g.*, Cunningham v. MacNeal Memorial Hospital, 47 Ill.2d 293, 266 N.E.2d 287 (1970); Franklin, *Tort Liability for Hepatitis: An Analysis and A Proposal*, 24 Stan. L. Rev. 439, 466-74 (1972); Havinghurst, *Legal Responses to the Problem of Poor Quality Blood*, in AEI Proceedings, *supra* note 19, at 21; Kessel, *supra* note 12, at 281; Note, *Strict Liability for Disease Contracted from Blood Transfusion*, 66 Nw. L. Rev. 80, 99 (1971); Recent Developments, 71 Colum. L. Rev. 487, 494-95 (1971).

British blood supply system. All British blood donors are volunteers — and hepatitis following transfusions is a rare occurrence.[60] But what works in Great Britain may not work in the United States, with its substantially different legal and medical systems.[61]

1. The British Blood Supply System

Titmuss' *The Gift Relationship* used Britain's all-volunteer blood supply system, the National Transfusion Blood Service (NTBS), as a standard against which the United States blood supply system was found to be inadequate.[62] NTBS collects all blood used in Great Britain and supplies it free of charge to all who need it, whether they are under treatment at National Health Service or private institutions.[63] While all adults medically capable of giving blood are encouraged to do so, NTBS relies on a cadre of roughly two percent of the adult population.[64]

Titmuss centered his work on the variance in blood donor motivation among societies like Britain, where all persons are guaranteed blood when needed without charge, and that of the United States, where no such assurances exist. Titmuss' most serious challenge to the American blood system rose from another set of observations, however. In Great Britain, where blood donors receive no compensation of any kind for their gift, post-transfusion hepatitis is almost non-existent.[65] In the United States, studies conducted prior to the general

---

60 *See* R. TITMUSS, *supra* note 7, at 154-55.

61 The argument set forth in this Note applies primarily to the collection of common blood types for transfusion as whole blood or red cells. It is acknowledged that persons of certain extremely rare blood types may have to be paid in cash for donations under any circumstances. *See, e.g.,* HEW, *National Blood Policy: Department Response to Private Sector Implementation Plan,* 39 Fed. Reg. 32,702, 32,702 (1974). This argument may also have limited applicability to the problem of plasmapherisis. *See* note 2 *supra.*

62 The discussion on the British blood system is drawn primarily from R. TITMUSS, *supra* note 7. *See also* Reddin, *Commentaries* in AEI PROCEEDINGS, *supra* note 19, at 59-60.

63 *See* Solow, Book Review, 80 YALE L. J. 1696, 1697 (1971).

64 R. TITMUSS, *supra* note 7, at 268-69 tables 19-20, 42-43 (1.2 million donors, 1.446 million units donated in 1968).

65 *Id.* at 154 n.2.

availability of the most sensitive tests for Hepatitis B indicate between three and four percent of blood recipients contracted hepatitis following transfusions.[66]

2. The Blood Supply System of the United States

The significant contrasts that exist between the blood supply systems of the United States and Britain may explain part of the difference in the occurrence of post-transfusion hepatitis in those countries. Blood collection in the United States is highly decentralized. More than 5,000 entities are subject to either licensure by or registration with the FDA.[67] While two large organizations dominate blood collection, the American Red Cross and the AABB,[68] no central control body exists.[69]

Furthermore, unlike in Britain, there is no nationwide guarantee of free blood available to Americans. Many blood suppliers, particularly those sponsored by the American Red Cross, operate on a "community responsibility" basis, making blood available to all those who need it for a fee which

66 *See, e.g.*, National Transfusion Hepatitis Study, *Risk of Posttransfusion Hepatitis in the United States: A Prospective Cooperative Study*, 220 J.A.M.A. 692, 695 table 4 (1972). The study was conducted between 1966 and 1970 at medical centers in 14 cities. 3.2% of the 4984 open-heart surgery patients who received any blood product (including plasma pooled from many donors, a product with a measurably greater probability of carrying hepatitis viruses) were detected to have contracted post-transfusion hepatitis. While the use of blood from donors paid in cash varied from center to center, 21% of blood used was supplied by paid donors otherwise unknown to those administering the transfusion. *Id.* at 698 table 9.

67 GAO Study, *supra* note 11, at 4.

68 *See* D. HUESTIS, J. BOVE & S. BUCK, PRACTICAL BLOOD TRANSFUSION 2-4 (2d ed. 1976). Red Cross-affiliated blood banks and AABB members each collect approximately 40% of the blood supply of the United States. Johnson, *Introduction: The Blood Market* in AEI PROCEEDINGS, *supra* note 19, at 1, 2.

69 The Red Cross and the AABB were parties for many years to an agreement by which they exchanged blood through a clearinghouse as needed. In response to HEW's National Blood Policy, the two organizations joined other concerned parties in the American Blood Commission (ABC) in 1973. *See* HEW, *National Blood Policy: Department Response to Private Sector Implementation Plan*, 39 Fed. Reg. 32,702 (1974); Surgeoner, *Progress Towards a National Blood System*, 291 NEW ENG. J. MED. 17 (1974); Surgeoner, *Progress Towards A National Blood System: The American Blood Commission*, 294 NEW ENG. J. MED. 1637 (1976). However, recent disputes between the two groups have left the ABC ineffective; in addition, the clearinghouse arrangement has been terminated. Schmidt, *National Blood Policy 1977: A Study in the Politics of Health*, 10 PROGRESS IN HEMATOLOGY 151, 168-71 (S. Brown ed. 1977); Stewart, *The Battle Over Blood Collection*, 3 AM. J.L. MED. 77, 87 (1977).

covers the expenses of processing and testing the blood.[70] But other suppliers, notably those controlled by hospital AABB members, are run on an "individual responsibility" basis. These blood banks demand that recipients of blood either "replace" all blood transfused (often at a ratio of greater than 1:1) or pay a replacement fee for each unit of blood transfused in addition to the fees charged for services associated with the transfusion.[71] Individuals may obtain blood protection for themselves, however, by donating small amounts of blood prior to need as part of a "blood assurance program."[72] Studies of blood donors in the United States indicate most are motivated, at least in part, by what they see as a need to replace blood received by themselves, their families, or their friends, or to obtain protection in the future.[73] In contrast, Titmuss has asserted British donors do not trade today's blood for yesterday's or tomorrow's, but give to express "a high sense of social responsibility towards the needs of other members of society."[74]

The most significant difference between the two blood systems is that the United States continues to rely on paid donors to supply some blood used for human transfusion. AABB members report that 18 percent of the 3.95 million units of blood collected by them (of 11.54 million issued for transfusion) in 1975 was from donors paid in cash.[75] The bulk of the remaining portion of the blood supply is collected by

---

70 *See* D. HUESTIS, J. BOVE & S. BUCK, *supra* note 68, at 3. The American Red Cross is the largest, but not the only, organization sponsoring such programs. *Id.; see also, e.g.,* Surgeoner & Cerveney, *A Study of the Conversion from Paid to Altruistic Blood Donors in New Mexico,* 18 TRANSFUSION 54, 56-58 (1978).

71 *See* D. HUESTIS, J. BOVE & S. BUCK, *supra* note 68, at 2-4. Fees for services rendered by Red Cross-operated blood suppliers ranged from $16.00 to $35.00 per unit transfused in 1977. Schmidt, *supra* note 69, at 164. Replacement fees charged by "individual responsibility" suppliers may be as much as $120.00 per unit transfused. HEW, *National Blood Policy: Department Response to Private Sector Implementation Plan,* 39 Fed. Reg. 32,702, 32,710 (1974).

72 *See, e.g.,* R. TITMUSS, *supra* note 7, at 82-84.

73 *See, e.g., id.* at 94 table 7 (52% of all donors in United States between 1965-67); Oswalt, *A Review of Blood Donor Motivation and Recruitment,* 17 TRANSFUSION 123, 123-26 (1977) (review of current literature on blood donor motivation).

74 R. TITMUSS, *supra* note 7, at 236, 224-36.

75 Hemphill, *Blood Collection and Use by AABB Institutions and Members,* 17 TRANSFUSION 403, 404 tables 3,4 (1977).

the Red Cross and other suppliers relying on volunteer donors. Yet the continued use of no less than 700,000 donors who are regarded as being members of a high-risk group is striking.

3. Obstacles to the Elimination of the Paid Blood Donor

Formidable arguments may be made for categorically forbidding the use of blood supplied by donors paid in cash for human transfusions. Where such steps have been taken, the rate of post-transfusion hepatitis has dropped significantly. Furthermore, the example of Great Britain confronts those who maintain the United States cannot meet all its blood needs through the use of volunteer donors. But can the United States eliminate the use of blood supplied by donors paid in cash at the present time? Arguably, the success of the British blood supply system is attributable to unique societal factors separate from the altruism Titmuss believes that an all-volunteer system promotes. Studies have indicated that while some paid donor blood is dangerous, some may be of equal quality to that supplied by volunteer donors. And the American legal system may present obstacles to the elimination of paid donors from the blood supply — even *if* alternative supplies of blood could become available immediately.

a. Britain and America: A Realistic Comparison

Whether the British and American blood supply systems are actually comparable is open to serious question. Even Titmuss has conceded that the National Blood Transfusion Service cannot be studied apart from the National Health Service.[76] And economist Robert Solow has pointed out the experience of World War II may have established a habit of regularly giving blood among Britons that did not cease at war's end.[77] Others have questioned Titmuss' conclusion that the British blood system as a whole is a model of efficiency to

76 R. TITMUSS, *supra* note 7, at 13.

77 Solow, Book Review, 80 YALE L. J. 1696, 1705 n.21 (1971). Titmuss' study indicated 5.7% of British donors surveyed gave "war effort" as the reason for their first gift of blood. R. TITMUSS, *supra* note 7, at 231.

be copied by Americans.[78] Whether a system providing *no* incentives to blood donors can work in the atomistic medical system of an American society unhardened by wartime experiences like Britain's is questionable.

b. Paid Blood Need Not Be Dangerous Blood

Calls for the elimination of the paid blood donor necessarily categorize all such donors as being more likely to be carriers of hepatitis viruses. Such need not be the case. In reviewing the correlation between paid blood donors and post-transfusion hepatitis, the General Accounting Office and others have argued that the key factor may be the socioeconomic status of those who would trade their blood for quick cash.[79] This observation rests on the experience of a number of non-profit blood suppliers that regularly offered money payments to blood donors. The largest of these organizations, United Blood Services, Inc.[80] compensated repeat donors who had not been involved in incidents of post-transfusion hepatitis from the early 1950's until 1972; hepatitis rates did not differ from those associated with volunteer donors.[81] More tellingly, the General Accounting Office reported that a medical center in Rochester, Minnesota (Mayo Clinic) paid sixty percent of its blood donors, but had the second lowest rate of the incidence of post-transfusion hepatitis of the entities it surveyed.[82] This blood supplier drew its blood from a pool of six to seven thousand donors, all of whom lived within fifty miles of the center and gave blood on an average of three times annually.[83] Relying on ex-

78 *See* Cooper & Cuyler, *The Price of Blood* (1968) (Hobart Paper 41, Inst. Econ. Affairs), *cited in* Solow, Book Review, 80 YALE L. J. 1696, 1701 n.9; Sapolsky & Finkelstein, *supra* note 2, at 21.

79 GAO Study, *supra* note 11, at 8.

80 The organization was formerly known as Blood Services, Inc. *See* Surgeoner & Cerveney, *supra* note 70, at 54n*.

81 *See* Alsever & Van Schoonhoven, *Post-transfusion Viral Hepatitis (PTVH): Myths and Facts,* 31 ARIZ. MED. 263 (1975). In response to public pressure, [United] Blood Services ceased paying donors in cash in 1972. *Id.* at 265. *See also* P. ROCA, DEDICATION, IMAGINATION AND A TOUCH OF GENIUS: THE STORY OF BLOOD SERVICES (1970) (Newcomen Society Lecture).

82 GAO Study, *supra* note 11, at 8.

83 *Id.; see* Kessel, *supra* note 12, at 287 n.71.

periences such as these, GAO has concluded that, while elimination of paid blood donors would be desirable in the long run, there should be no categorical exclusion of blood donors paid in cash.[84]

It must also be remembered that the elimination of paid blood donors would not eliminate all economic incentives for the donation of blood. While the number of blood suppliers making blood available on a "community responsibility" basis appears to be increasing,[85] many blood suppliers still expect recipients to replace blood transfused or to become a member of a blood assurance plan in order to receive blood without charge.[86] Under these circumstances, substantial incentives would continue to be offered for the gift of blood, even without payments in cash. If the existence of any incentives encourages a potential donor to lie about his or her medical history, eliminating the payment of cash for blood will not eliminate the problem.[87]

c. Legal Barriers to State Action Against Paid Blood Donors

Action by individual states to close down all blood banks relying on paid donors may be impossible under the legal system of the United States. Only one jurisdiction, Wisconsin, has attempted to bar the use of paid blood donors, under a statute that made it "unlawful to operate a blood bank for commercial profit."[88] That statute was held to be unconstitutional by the Wisconsin Supreme Court in 1974 in the case of

---

84 GAO Study, *supra* note 11, at 24.

85 *See* Surgeoner & Cerveney, *supra* note 70, at 56-57; *see also* Kellner, *The Need for Reform* in AEI PROCEEDINGS, *supra* note 19, at 137, 137-39.

86 *See* text accompanying notes 70-74 *supra*. HEW's National Blood Policy itself does not express any preference for either a individual or community responsibility system. *See* 39 Fed. Reg. 32,702, 32,710 (1974).

Yet it appears "community responsibility" is becoming the dominant practice among blood suppliers. *See, e.g.,* Surgeoner & Cerveney, *supra* note 70 (New Mexico blood supply system converted to community responsibility); *see also Blood and the Visible Hand*, REGULATION 11-12 (May/June 1978) (American Blood Commission is considering endorsing community responsibility on a nationwide basis).

87 Unhealthy blood donors may attempt to give blood even when no incentives are involved and altruism is the only possible motive. *See* Glazer, *Blood*, 24 THE PUBLIC INTEREST 86, 93 (1971). *Cf.* Kessel, *supra* note 12, at 267 (all blood should be bought for cash).

88 WIS. STAT. § 146.31 (1) (1973).

State v. Interstate Blood Bank, Inc.,[89] raising serious questions of whether any single state may take such action.

The court held the exclusion of commercial blood banks such as defendant Interstate's from Wisconsin to be a valid exercise of the police power.[90] All blood was collected for shipment out of the state, however, making the statute as applied to Interstate a burden on interstate commerce barred by article I, section 8 of the Constitution.[91] The Wisconsin statute was also held to be preempted by the federal statutes and regulations providing for the licensure of blood banks engaging in interstate commerce.[92] Under the Supremacy Clause,[93] Wisconsin could not block the operation of a blood supplier specifically licensed to operate in interstate commerce.[94] The state's argument that the legislation was a proper regulation of health was vitiated in this case by the fact that all of Interstate's blood was used outside Wisconsin and had no possible bearing on the local hepatitis rate.[95]

On its face, the doctrine of *Interstate Blood Bank* applies only to licensed blood suppliers in interstate commerce. Yet the court's broad construction of the preemption doctrine bodes ill for any continuing state regulation of blood suppliers in an age where federal regulation has become pervasive.[96] In the court's language, "when the federal government has undertaken a comprehensive regulatory and licensing system of an occupation engaged in interstate commerce . . . to insure the safety, potency, and purity of a particular

---

89 65 Wis.2d 482, 222 N.W.2d 912 (1974).

90 *Id.* at 490; 222 N.W.2d at 915. The court's syllabus noted the dangers of post-transfusion hepatitis without drawing any specific connection between paid blood and the disease. *Id.* at 486; 222 N.W.2d at 913-14.

91 *Id.* at 490-93, 222 N.W.2d at 916-17.

92 Id. at 494-98; 222 N.W.2d at 917-20. In this case, both Wisconsin and the Federal government regulated blood suppliers to block the spread of hepatitis. *Cf.* Huron Portland Cement Co. v. City of Detroit, 362 U.S. 440 (1961) (local air pollution ordinance held not to be preempted by the federal safety regulation applicable to same boiler).

93 U.S. CONST., art. V, cl. 2.

94 65 Wis.2d at 498-99; 222 N.W.2d at 920. While the court made no reference to legislative intent, it appears the statute was enacted in order to prevent the export of blood from Wisconsin. *See* Franklin, *supra* note 59, at 477 n.218.

95 65 Wis.2d at 491-92; 222 N.W.2d at 916.

96 *See* text accompanying notes 70-74 *supra.*

product, the states are preempted from prohibiting the same occupation as a means of accomplishing the same purposes."[97] Since the FDA has asserted the power to regulate intrastate blood suppliers in order to prevent the interstate spread of hepatitis,[98] under *Interstate Blood Bank*, a state could be barred from forbidding blood suppliers from operating in a manner condoned by FDA regulations.[99] States may continue to possess power under the Constitution to forbid completely the use of blood supplied by donors paid in cash,[100] but the collection of such blood could not be forbidden if even one state tolerated its importation of use.[101]

d. The Impracticality of Federal Action

Post-transfusion hepatitis is a national health problem. Particularly in light of the holding in *Interstate Blood Bank* that the federal government has pre-empted the regulation of blood suppliers, action by Congress on a nationwide basis may be the only means by which the use of paid donor blood can be forbidden. Certainly, the federal power over interstate commerce allows Congress to regulate or eliminate the movement of paid donor blood across state lines.[102] If it is accepted that the federal government also has the power to prevent the interstate spread of disease,[103] as the FDA has done in asserting jurisdiction to regulate intrastate blood suppliers,[104] Congress or its delegate may also forbid intrastate blood suppliers from making use of paid donor blood.[105] Yet one must still ask whether it is appropriate for

97 65 Wis.2d at 496-97; 222 N.W.2d at 919.

98 *See* 42 U.S.C. § 264(1976); FDA, *Proposed Manufacturing Practice for Blood and Blood Components,* 39 Fed. Reg. 18,614, 18,614-15 (1974).

99 *Cf.* Florida Lime and Avocado Growers v. Paul, 373 U.S. 132, *rehearing denied* 374 U.S. 858 (1964) (California could impose higher standards for avocados imported from Florida than those used for purposes of Federal marketing regulations).

100 *See Interstate Blood Bank*, 65 Wis.2d at 498, 222 N.W.2d at 920.

101 If the FDA's tolerance (through non-regulation) of the use of paid donors by intrastate blood suppliers was held to be pre-emptive, any action by individual states going beyond that point might be forbidden.

102 *See, e.g.*, Champion v. Ames (Lottery Case), 188 U.S. 321 (1903).

103 Public Health Service Act, § 361, 42 U.S.C. § 264 (1976).

104 *See* notes 45, 98 *supra.*

105 *See* Louisiana v. Mathews 427 F. Supp. 174, 176 (E.D. La. 1977) (upholding ban on sale and distribution of small turtles under 42 U.S.C. § 264 in both interstate and intrastate commerce).

Congress to exert its constitutional powers to their fullest extent and categorically forbid the use of paid donor blood.[106] And at this point, such federal action would be unjustified.

The first set of questions that must be answered if paid donor blood is to be eliminated on a national basis are those concerning the effect of such action on the blood supply as a whole. Admittedly, in some areas of the country, volunteer blood has been substituted for paid donor blood successfully over short periods of time. In Illinois, after the enactment in 1973 of legislation which discouraged, but did not forbid, the use of paid donor blood,[107] 98 percent of blood used between July 1, 1973, and July 1, 1974, within the state was drawn from volunteers.[108] Previously, 60 percent of blood transfused in Chicago had been that of paid donors.[109] In New Mexico, where, without any legal compulsion, the blood donor pool was converted from one relying on paid donors to an all-volunteer group between 1972 and 1974, with resources once devoted to payment and supervision of donors being transferred to volunteer donor recruitment.[110] These shifts reflect a growing understanding of blood donor motivation in the United States and what steps may be taken to increase voluntary giving.[111]

Yet, even with these local successes in the elimination of paid donor blood, and a steady nationwide decrease in the use

---

106 Private action to eliminate the use of paid donor blood may actually be foreclosed by federal antitrust statutes. In 1966 the Federal Trade Commission held physicians and hospitals who refused to obtain blood from suppliers who paid donors in cash constituted a conspiracy in restraint of interstate commerce. Community Blood Bank of the Kansas City Area, Inc., 70 F.T.C. 728 (1966) (3-2 decision). The Commission specifically refused to accept respondents' defense of medical justification, holding that in the absence of the legislative or administrative prohibition of "commercial" blood banking, the respondents had no right, in effect, to agree to put the complaining blood bank out of business. *Id.* at 943, 944. *But see id.* at 948, 956-58 (Elman, C., dissenting); *id.* at 958 (Reilly, C., dissenting).

The decision was reversed on the ground that the FTC had no jurisdiction over non-profit organizations. The medical justification defense was not reached. Community Blood Bank v. FTC, 405 F.2d 1011 (8th Cir. 1969).

107 Blood Labelling Act, ILL. REV. STAT. ch. 111 ½, §§ 620-1 to 620-5 (1975).

108 *Only 2 Per Cent Paid Donors: Illinois Volunteer Blood Law Results Surprising,* 48 HOSPITALS 17 (1974).

109 R. TITMUSS, *supra* note 7, at 97 (1964 figures).

110 Surgeoner & Cerveney, *supra* note 70, at 56-58.

111 *Id.* at 62; Oswalt, *supra* note 73.

of such blood, one dismal fact stands out. More than a decade after the dangers inherent in the use of paid donor blood became a matter of wide concern, paid donors still comprise roughly 10 percent of the national donor pool.[112]

Two conclusions flow from this persistent use of paid donor blood. First, since the health care professions have been seeking to reduce the use of paid donor blood to protect patients from hepatitis,[113] the continuing use of such blood many years after its inherent risks became known indicates continuing use of such blood may be necessary for some time to come in order to meet the demand for blood.[114] Furthermore, even if all use of paid blood could be halted, the temporary dislocation that could be caused by forbidding the use of paid blood might, of itself, create undue risks to patients in need of blood that outweigh the hepatitis problem. Given these constraints alone, Congress would be advised to move slowly toward a categorical ban on paid donor blood.

Second, it is not clear that a nationwide ban on the use of paid donor blood is the only solution to the hepatitis problem or that such a solution should be imposed on a nationwide basis. As a general rule, it may indeed be true that the incidence of post-transfusion hepatitis is directly proportional to the use of paid donor blood. Yet it is also well proven that those blood suppliers who carefully supervise paid donors are not tied to unusually high rates of post-transfusion hepatitis.[115] The application of resources to the payment and supervision of a small cadre of donors may be as efficient a means of combatting hepatitis as the application of resources to promoting voluntary gifts of blood.[116] Given the continuing atomistic nature of the American blood supply system,[117]

---

112 *See* text accompanying note 75 *supra*.

113 *See, e.g.*, HEW, *National Blood Policy: Department Response to Private Sector Implementation Plan*, 39 Fed. Reg. 32,702, 32,702-03 (1974) (major blood supplier organizations agree on desirability of eventual elimination of all paid blood donors).

114 It is also uncertain whether adequate supplies of very rare blood types can be maintained without some reliance on paid donors. *See* note 61 *supra*.

115 *See* sources cited in notes 79 to 84 *supra*.

116 *See* Kessel, *supra* note 12, at 272-75.

117 *See* text accompanying notes 67-68 *supra*.

a federal ban on the use of paid donor blood may unduly restrict local decisions on the best way to reduce hepatitis.[118] Together with the uncertain effect a federal ban on the use of paid blood would have on the supply of all blood, this imposition of a national choice on local communities militates further against federal action of this nature.

B. *Should Blood Suppliers Be Subject to Liability Without Fault?*

Products liability law has undergone drastic change in the past thirty years. Once, a consumer injured by defective goods could only secure a recovery on proof of negligence by the manufacturer.[119] Today, he or she may prevail without proving fault, relying on contractual theories of implied warranty,[120] or on the rapidly developing doctrine of strict liability in tort.[121] It is hardly surprising that victims of post-transfusion hepatitis have sought to employ these doctrines in actions against blood suppliers.

The imposition of liability without fault on blood suppliers has been suggested as a means of spreading the risk of post-transfusion hepatitis among all blood users and of providing incentives to those suppliers to develop better methods for preventing the disease. Yet these arguments have been rejected by almost all of the courts and legislatures which have ruled on the subject.

1. The Rationale for Imposing Liability Without Fault

The word "product" may be a term of art for lawyers. Yet few laymen would hesitate to call the fluid transferred from a blood supplier to a transfusion recipient a product. If blood may be so classified, one may ask why its suppliers should

---

118 Attempts by supporters of an all-volunteer blood supply system to forbid the use of paid donor blood may be characterized as a campaign by voluntary blood banks to put competitors out of business. *See* Kessel, *supra* note 12, at 282-88.

119 *See, e.g.*, MacPherson v. Buick Motor Co., 217 N.Y. 382, 111 N.E. 1050 (1916).

120 *See, e.g.*, Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 161 A.2d 69 (1960) (applying Uniform Sales Act); U.C.C. §§ 2-314 to 2-315.

121 *See, e.g.*, Greenman v. Yuba Power Products, Inc., 59 Cal.2d 57, 27 Cal. Repr. 697, 377 P.2d 897 (1963); RESTATEMENT (SECOND) OF TORTS § 402A (1965).

not be held liable, *regardless of fault*, if the product, transfused in a defective, hepatitis-carrying condition, causes disease in the recipient. In many senses, the transfusion of blood is a sale carrying with it a set of implied warranties.[122] It is certainly a transaction from which strict liability in tort may flow.[123] If merchants and manufacturers may be held liable for injuries on either of these doctrines, blood suppliers, arguably, should be treated no differently. Blood may be a special product in many respects, including its human source and its therapeutic uses. Yet a strong case may be made for not exempting blood suppliers from liability without fault.[124]

The imposition of liability without fault, particularly through the application of strict liability, may serve a number of purposes. It provides compensation to all those injured by the product. Imposing such liability may provide incentives to a manufacturer to improve its product; it may reallocate resources to shift the cost of "inevitable" injuries onto large entities which may be better able to bear them; it may permit the risks associated with a product to be spread among all those who benefit from the product.[125] The imposition of liability without fault on blood suppliers might achieve all these objectives.[126] Even if the processes now

---

122 *See* Russell v. Community Blood Bank, Inc. 185 So.2d 749 (Fla. App. 1966), *modified sub nom.* Community Blood Bank, Inc. v. Russell, 196 So.2d 115 (Fla. 1967); *id.*, 196 So.2d at 119 (Roberts, J. concurring). *Contra,* Perlmutter v. Beth Israel Hospital, 308 N.Y. 100, 123 N.E.2d 792 (1954). *Cf.* Hoffman v. Misericordia Hospital of Philadelphia, 439 Pa. 501, 506-09, 267 A.2d 867, 870-71 (1970) (whether blood is "sold" has no bearing on the application of implied warranties).

123 *See* Cunningham v. MacNeal Memorial Hospital, 47 Ill.2d 243, 266 N.E.2d 897 (1970). *But see, e.g.,* Shepard v. Alexian Brothers Hospital, 33 Cal. App. 3d 606, 611-12 n.3, 109 Cal. Repr. 132, 135 n.3 (1973); Brody v. Overlook Hospital, 127 N.J. Super. 331, 317 A.2d 392 (A.D. 1974), *aff'd per curiam* 66 N.J. 448, 332 A.2d 596 (1975); Hines v. St. Joseph's Hospital, 86 N.M. 763, 527 P.2d 1075 (Ct. App. 1974) (all refusing to impose strict liability on blood suppliers).

124 *See, e.g.,* Franklin, *supra* note 59, at 456-79; Havinghurst, *supra* note 59, in AEI PROCEEDINGS, *supra* note 19, at 21, 23-34; Kessel, *supra* note 12, at 281-82 (1974); Note, *Strict Liability for Disease Contracted from Blood Transfusion*, 66 NW.L. REV. 80 (1972); Recent Developments, 71 COLUM. L. REV. 487 (1971). *But see, e.g.,* Comment, *Blood Transfusions and the Transmission of Serum Hepatitis: The Need for Statutory Reform*, 24 AM. U.L. REV. 367, 406-08 (1975); Recent Developments, 69 MICH. L. REV. 1172 (1971).

125 *See, e.g.,* Franklin, *supra* note 59, at 461-74; Havinghurst, *supra* note 59, in AEI PROCEEDINGS, *supra* note 19, at 25.

126 *See* sources cited in notes 124, 125 *supra.*

available cannot eliminate all hepatitis-carrying blood from the supply available for transfusion,[127] incentives may be created for hospitals to reevaluate their choice of blood suppliers and for those suppliers to reconsider the nature of their donor pools.[128] Desirable measures would encourage blood suppliers to reconsider the make-up of their donor pools with an eye toward reducing reliance on paid donors or other groups associated with frequent incidents of post-transfusion hepatitis or relatively high percentages of Hepatitis B-carrying blood.

Resource allocation and risk spreading may also be improved if liability without fault is imposed on blood suppliers. Blood suppliers, and the hospitals that rely on independent blood suppliers, are larger entities than victims of post-transfusion hepatitis. They may be better able to bear the costs of the disease through reallocation of existing resources or the purchase of insurance.[129] Given that many patients benefit from the services of a blood supplier while few are victimized by predictably unpredictable bouts with hepatitis, arguably all blood recipients should help meet the related costs. Those transfusing the blood could administer the sharing of these costs by making a small addition to the fees already charged for the services associated with blood transfusion, providing a fund out of which the costs of hepatitis could be met.[130]

127 *See* text accompanying notes 33-36 *supra*.

128 Proper screening and selection of donors is an important method for the reduction of post-transfusion hepatitis which may be encouraged by the imposition of liability without fault. *See, e.g.,* Havinghurst, *supra* note 59, in AEI PROCEEDINGS, *supra* note 19, at 28-34; Taswell, Shorter, and Maxwell, *Control of Post-Transfusion Hepatitis by Donor Selection and Case Investigation,* 47 PROC. MAYO CLINIC 98 (1972). While GAO has proposed that blood suppliers make available to hospitals and other blood users data on the incidence of Hepatitis B carriers in their donor pool and incidents of hepatitis attributable to their blood, GAO Study, *supra* note 11, at 23-39, the FDA recently rejected a proposal that such information be made part of the label affixed to all blood containers. *See* FDA, *Whole Blood and Components of Whole Blood Intended for Transfusion: Donor Classification Labeling Requirements,* 42 Fed. Reg. 11,018, 11,021 (1977). *See also* Kessel, *supra* note 12, at 284.

129 *See, e.g.,* Recent Developments, 71 COLUM. L. REV. 487, 494-95 (1971); *but see* Comment, *Blood Transfusions and the Transmission of Serum Hepatitis: The Need for Statutory Reform,* 24 AM. U.L. REV. 367, 406-08 (1975); Recent Developments, 69 MICH. L. REV. 1172, 1184-85 (1971).

130 *See* Franklin, *supra* note 59, at 469-70 n.180, 472.

Some questions may be raised, of course, about the appropriateness of a policy imposing liability without fault on blood suppliers. Aside from those based solely on the current non-preventability of some cases of post-transfusion hepatitis (particularly those of the non-A, non-B strain),[131] most of these questions arise out of the structure of the blood supply system. Blood is not a product distributed by a small number of centrally-controlled nationwide entities. While the Red Cross and AABB dominate blood supply, in fact they merely represent a large number of independent entities.[132] These entities, by and large, do not support basic research on the transmission, detection, and prevention of hepatitis, although the Red Cross as an organization supports research.[133] If hepatitis cases not preventable by the exclusion of potential and identified carriers have any cause at all, it is in the failure of basic research to develop more certain means of prophylaxis. Yet the imposition of liability without fault on blood suppliers would assess the costs of that failure on entities that are neither responsible for unsuccessful research nor currently capable of sponsoring the further research that the threatened imposition of liability without fault is intended to promote. Admittedly, blood suppliers could pool resources in order to support the research needed to improve their product, much as Red Cross blood banks do

---

131 *See, e.g.*, Brody v. Overlook Hospital, 127 N.J. Super 331, 336-39, 317 A.2d 392, 395-98 (A.D. 1974), *aff'd per curiam* 66 N.J. 448, 332 A.2d 596 (1975); RESTATEMENT (SECOND) OF TORTS, § 402A, comment (exempting unavoidably unsafe products from rule of strict liability).

132 *See* Schmidt, *supra* note 69, at 154-55; GAO Study, *supra* note 11, at 4.

133 It is the author's impression that the National Institutes of Health (NIH) and other research-oriented organizations sponsor the bulk of published work on the transmission and prevention of hepatitis. *See, e.g.*, Alter, *et al., Transmissible Agent in Non-A, Non-B Hepatitis,* 1978-I LANCET 459 (sponsored by NIH); National Transfusion Hepatitis Study, *Risk of Posttransfusion Hepatitis in the United States: A Prospective Cooperative Study*, 220 J.A.M.A. 692, 700 (1972) (supported by National Heart Institute grants); Tabor, *et al., Transmission of Non-A, Non-B Hepatitis from Man to Chimpanzee*, 1978-I LANCET 463, 465 (sponsored in part by FDA). The Red Cross as an organization has sponsored some hepatitis research. *See* TRANSMISSIBLE DISEASE AND BLOOD TRANSFUSION (T. Greenwalt & G. Jamison eds. 1975) (proceedings of a Red Cross-sponsored conference). The AABB appears to concentrate its research program on technical procedures, although its journal, TRANSFUSION, publishes studies related to the hepatitis problem.

now. Yet forcing blood suppliers to make limited contributions to basic research may impose on the bank heavy financial burdens which may eventually be forced onto blood users through processing fees.[134]

The separation of suppliers and researchers in the blood supply system creates some doubt about the ability of the imposition of liability without fault on blood suppliers to provide incentives for the sort of research that will improve their product. The structure of the blood market also raises questions of whether liability without fault will improve resource allocation or lead to heightened spreading of risk. The typical hospital or blood bank may have a deeper pocket than the completely uninsured victim of post-transfusion hepatitis.[135] Yet it is uncertain whether relatively small blood suppliers can bear the costs of purchasing insurance to cover the risk of hepatitis.[136] Furthermore, it is unclear whether the imposition of liability without fault will in fact spread the risk of hepatitis among a group limited to all beneficiaries of blood transfusions. Some authorities have voiced fears that insurance costs would be spread among all users of a hospital or other facility at risk, not merely transfusion recipients.[137] While such an allocation would be easy to administer, it would also defeat the risk-spreading goals of liability without fault.

2. The Judicial Response to Post-Transfusion Hepatitis

Strong arguments have been raised in favor of imposing liability without fault on blood suppliers. But, for the most

---

134 *See, e.g.*, Recent Developments, 69 MICH. L. REV. 1172, 1187-88 (1971).

135 Presumably many victims of post-transfusion hepatitis will be compensated for medical expenses through health insurance already carried. However, many hepatitis victims may not carry sufficient insurance to cover all additional expenses, and fewer possess any insurance against loss of wages and similar costs that follow the additional hospitalization that may be necessary in cases of post-transfusion hepatitis.

136 Such concerns became a major part of the policy debate which followed the imposition of strict liability on Illinois blood suppliers in Cunningham v. MacNeal Memorial Hospital, 47 Ill.2d 443, 266 N.E.2d 897 (1970). *See, e.g.*, Recent Developments, 69 MICH. L. REV. 1172, 1184-85 (1971).

137 *Id.*

part, they have been rejected by the courts. At this time, no state's courts will impose liability on a blood supplier whose product has been implicated in a case of post-transfusion hepatitis without proof of fault.[138]

Perlmutter v. Beth Israel Hospital,[139] decided in 1956, was the first of many cases exempting blood suppliers from liability for post-transfusion hepatitis. In reversing a trial court's denial of the defendant hospital's motion to dismiss, the New York Court of Appeals held the supply of contaminated blood by the hospital to the plaintiff was a part of the medical services provided by defendant, not a sale.[140] As a result, the plaintiff did not have a cause of action for breach of the implied warranties created by the Uniform Sales Act. The court's holding rested on the technical distinction that blood transfusions were services and not sales. But Judge Fuld, writing for the majority, noted that any other result might lead to the imposition of liability without fault in a milieu where the causative agent of the disease could not be detected or eliminated.[141]

The court's holding that products liability principles would not be extended to blood transfusions was strongly criticized by three dissenting judges[142] and some commentators,[143] yet was unquestioned by any court of last resort until the late 1960's. While the supreme courts of Florida,[144] New Jersey,[145] and Pennsylvania[146] refused to follow the service/sales distinction drawn in *Perlmutter*, none sustained a cause of action for victims of post-transfusion hepatitis without proof of

---

138 *But see* Belle Bonfils Memorial Blood Bank v. Hansen, 579 P.2d 1158 (Colo. 1978) (holding blood bank supplier could be held liable without fault following "sale" of blood implicated in case of hepatitis prior to effective date of COLO. REV. STAT. § 13-22-104 (1973)).

139 308 N.Y. 100, 123 N.E.2d 792 (1954).

140 *Id.* at 104-06, 123 N.E.2d at 794-95.

141 *Id.* at 106-07, 123 N.E.2d at 795.

142 *Id.* at 107, 123 N.E.2d at 796 (Froessel, J., dissenting).

143 *See, e.g.*, Farnsworth, *Implied Warranties of Quality in Non-Sales Cases*, 57 COLUM. L. REV. 653, 672 (1957).

144 Community Blood Bank, Inc. v. Russell, 196 So.2d 115 (Fla. 1967).

145 Jackson v. Muhlenberg Hospital, 53 N.J. 138, 249 A.2d 65 (1969) (per curiam).

146 Hoffman v. Misericordia Hospital of Philadelphia, 439 Pa. 501, 267 A.2d 867 (1970).

fault, remanding cases in order to develop a record on whether hepatitis viruses could be detected in human blood.[147]

The *Perlmutter* approach was squarely rejected in 1970 by the Illinois Supreme Court, when, in *Cunningham v. MacNeal Memorial Hospital*,[148] it reversed the dismissal of a hepatitis victim's complaint based on a strict liability theory. The court, relying on section 402A(2)(a) of the Restatement (Second) of Torts and previous Illinois products liability cases,[149] held that the defendant could be liable as the supplier of a defective product, specifically rejecting the sales/service distinction of *Perlmutter*.[150] The Court also rejected the defendant's claim that the undetectability of hepatitis viruses was a defense to strict liability,[151] noting that under the standard of the Second Restatement, defendant's use of "all possible care" would thwart plaintiff's claim. The Court held hepatitis carrier blood to be "impure," and not covered by comment *k* to section 402A, which exempted the producers of "unavoidably unsafe" products from strict liability.[152] The court asserted that hospitals and other blood suppliers are better able to protect themselves against the newly imposed liability than is the faultless consumer.[153]

The *Cunningham* decision was subjected to severe criticism on the technical issues of whether blood is "unavoidably unsafe" and whether hepatitis-carrying blood is an impure substance for which its producer would be held strictly liable.[154] Other courts considering the issue of the

---

147 *Community Blood Bank*, 196 So.2d at 117-18; *Jackson*, 53 N.J. at 142, 249 A.2d at 68; *Hoffman*, 439 Pa. at 508 n.12, 249 A.2d at 870 n.12. *Cf. Community Blood Bank*, 196 So.2d at 118, 119-21 (Roberts, J. concurring) (liability without fault should be imposed).

148 47 Ill.2d 443, 266 N.E.2d 897 (1970).

149 Suvada v. White Motor Co., 32 Ill.2d 612, 210 N.E.2d 182 (1965) *cited in Cunningham*, 47 Ill.2d at 446-47, 457, 266 N.E.2d at 898-99, 904.

150 47 Ill.2d at 450, 266 N.E.2d at 900.

151 *Id.* at 453, 266 N.E.2d at 902-03.

152 *Id.* at 455-57, 266 N.E.2d at 903-04.

153 *Id.* at 457, 266 N.E.2d at 904.

154 *See, e.g.*, Comment, *supra* note 129; 24 AM. U.L. REV. 367 (1975); Recent Developments, 69 MICH. L. REV. 1172 (1971). *But see* Note, *Strict Liability for Disease Contracted from Blood Transfusion*, 66 NW. L. REV. 80 (1971); Recent Developments, 71 COLUM. L. REV. 487 (1971).

liability of blood suppliers for hepatitis have rejected *Cunningham.*[155] Where records of the ability of blood suppliers to identify hepatitis-carrying blood at the time of the plaintiff's infection have been developed, courts have held that the absence of tests by which carrier blood could be identified rendered strict liability inappropriate on policy grounds.[156] While appellate courts, on occasion, have remanded actions by post-transfusion hepatitis victims for trial on negligence issues[157] only one court of last resort has upheld a cause of action based on liability without fault since *Cunningham.*[157a]

3. Legislation Affecting Blood Suppliers' Liability

In states where courts have hinted that liability without fault should or could be applied to blood suppliers, state legislatures have responded quickly and negatively. For example, in Illinois after the *Cunningham* decision, medical organizations began a protest against the imposition of liability without fault. That protest led to enactment of a statute on July 2, 1971, declaring that no implied warranties would flow from the transfer of blood, nor would blood suppliers be held strictly liable for post-transfusion hepatitis.[158] *Cunningham* was effectively overruled, although the statute explicitly provided that blood suppliers would be held to a standard of due care in the provision of services.[159]

The action of the Illinois legislature in exempting blood suppliers from liability without fault is remarkable in only

---

155 *E.g.,* Shepard v. Alexian Brothers Hospital, 33 Cal. App.3d 606, 109 Cal. Repr. 132 (1973); Brody v. Overlook Hospital, 127 N.J. Super. 331, 317 A.2d 392 (A.D. 1974), *aff'd per curiam* 66 N.J. 448, 332 A.2d 596 (1975); Hines v. St. Joseph's Hospital, 86 N.M. 763, 527 P.2d 1075 (Ct. App. 1974). *See also* Hill v. Jackson Park Hospital 39 Ill. App.3d 203,349 N.E.2d 541 (1976) (rule of *Cunningham* overruled by ILL. REV. STAT. ch. 91, §§ 181-183 (Supp. 1977)).

156 *E.g., Brody,* 127 N.J. Super. at 336-40, 317 A.2d at 395-98; *Hines,* 86 N.M. at 764-65, 527 P.2d at 1076-77.

157 *E.g.,* Hoder v. Sayet, 196 So.2d 205 (Fla. App. 1967); Morse v. Riverside Hospital, 44 Ohio App.2d 422, 339 N.E.2d 846, 850 (1975).

157a Belle Bonfils Memorial Blood Bank v. Hansen, 579 P.2d 1158 (Colo. 1978).

158 Act of July 2, 1971, P.A. 77-184, §§ 1-3, 1971 Ill. Laws 383, ILL. ANN. STAT. ch. 91, §§ 181-183 (Smith-Hurd Supp. 1978, as amended).

159 *See, e.g.,* Glass v. Ingalls Memorial Hospital, 34 Ill. App.3d 337, 336 N.E.2d 495 (1975); ILL. ANN. STAT. ch. 91, § 183.

one respect. It took place *after* the courts had imposed such liability.[160] Following the decision in *Perlmutter*, states began to codify that case's holding that the transfer of blood was a service and not a sale leading to the creation of implied warranties.[161] Other states blocked the possibility of decisions following *Cunningham* in their own jurisdictions by enacting laws exempting blood suppliers from strict liability soon after *Cunningham* was decided.[162] Today, forty-five states have legislation in force restricting or forbidding the imposition of liability without fault on blood suppliers for post-transfusion hepatitis.[163]

Most of these statutes follow the holding in *Perlmutter* by declaring that the provision of blood for use in transfusions is a service and not a sale.[164] Many of these states have incorporated this "judgment" into the implied warranty provisions of the Uniform Commercial Code;[165] others have placed the exemption into the statutes regulating health care providers.[166] Another group of states specifically exempts blood suppliers from all liability without fault.[167] Only a few states,

---

160 Other states in which these statutes overruled in whole or in part the courts on the liability of blood suppliers were Florida, *see* Act of June 25, 1969, ch. 69-157, 1 1969 Fla. Laws 717, FLA. STAT. § 672.2-316 (5) (1973) (reversing *Community Blood Bank*) and Pennsylvania, *see* Act of Jan. 28, 1972, No. 9, 1972 Pa. Laws 20, PA. STAT. ANN. tit. 35, § 10021 (Purdon Supp. 1977) (reversing *Hoffman*).

161 Among the first states to enact these statutes were California, *see* Act of June 28, 1963, ch. 1055, 1963 Cal. Stat. 2486, CAL. HEALTH & SAFETY CODE § 1606 (West 1970); Massachusetts, *see* Act of Apr. 14, 1965, ch. 297, 1965 Mass. Acts 154, MASS. GEN. LAWS ANN., ch. 106, § 2-316(5) (West Supp. 1977-1978), and Mississippi, *see* Act of May 27, 1966, ch. 475, 1966 Miss. Laws 888, MISS. CODE ANN. § 41-41-1 (Supp. 1977).

162 Seventeen states — Arkansas, Colorado, Connecticut, Georgia, Hawaii, Idaho, Illinois, Kansas, Maryland, Missouri, Montana, New Hampshire, New Mexico, North Carolina, Texas, Utah and Washington — passed liability exemption statutes in 1971.

163 See statutes cited in note 6 *supra*.

164 Thirty-three states have taken this approach. *See* notes 165 and 166 *infra*.

165 *See, e.g.*, ALA. CODE § 72-314(4) (1975); ALASKA STAT. § 45.05.100(e) (Supp. 1977) (U.C.C. § 2-316(5)). *Cf.* U.C.C. § 2-316 (modification of warranties).

166 *See, e.g.*, CAL. HEALTH & SAFETY CODE § 1606 (West 1970); CONN. GEN. STAT. § 19-1391 (1975); N.Y. PUB. HEALTH LAW § 580.4 (McKinney Supp. 1977-1978); OHIO REV. CODE ANN. § 208.11 (Page 1976).

167 *See, e.g.*, HAW. REV. STAT. §§ 325-91, 327-51 (Supp. 1975); IND. CODE §§ 16-8-7-1 to 16-8-7-3 (West 1975) (also stating transfusions are services, not sales); MICH. COMP. LAWS §§ 691.1511 to 691.1512 (Supp. 1977-1978).

including Illinois,[168] Michigan,[169] Missouri,[170] and Virginia[171] appear to condition the exemption from liability on the continuing inability of blood suppliers to detect and eliminate all hepatitis carriers from the blood supply pool.[172]

While the statutes may vary in their precise terms, courts have tended to interpret them uniformly: blood suppliers are totally exempt from liability without fault.[173] Courts have allowed evidence of the current detectability of hepatitis carriers to be considered on the issue of negligence,[174] but in most states, such evidence cannot be considered in order to reevaluate the assumptions on which the exemption statutes are based. One Michigan court, reviewing the current state of medical knowledge, concluded that procedures for the elimination of hepatitis carriers were not sufficiently developed to prevent the continuing enforcement of an exemption statute conditioned on the non-existence of such procedures.[175]

III. Alternative Legal Means for Forestalling Post-Transfusion Hepatitis

Regardless of whether the imposition of liability without fault on blood suppliers can be justified on policy grounds, it is unlikely that the legislative decision not to impose such

168 Ill. Rev. Stat. ch. 91, § 183 (1975) (making reference to the state of the art). *See id.*, ch. 91, § 184, *as amended* P.A. 80-27, 1977 Ill. Legis. Service 121 (West 1977) (exemption expires in 1981, allowing review of exception policy in light of later developments).

169 Mich. Comp. Laws Ann. § 691.1511 (West Supp. 1977-1978).

170 Mo. Ann. Stat. § 431.069 (Vernon Supp. 1977).

171 Va. Code § 32-364.2 (1973).

172 Were completely effective tests for identifying hepatitis-carrying blood available, all exemption statutes would become superfluous, as failure to employ such tests would be negligent. *See* D. Huestis, J. Bove & S. Buck, Practical Blood Transfusion 373 (2d ed. 1976) (failure to use available tests for Hepatitis B carrier blood could be negligent); text accompanying notes 209-213 *infra*.

173 *See, e.g.,* Shepard v. Alexian Bros. Hospital, 33 Cal. App. 3d 606, 109 Cal. Repr. 132 (1973); Hines v. St. Joseph's Hospital, 86 N.M. 763, 527 P.2d 1075 (Ct. App. 1974); Jennings v. Roosevelt Hospital, 83 Misc. 2d 1, 372 N.Y.S.2d 277 (Sup. Ct. 1975); Morse v. Riverside Hospital, 44 Ohio App.2d 420, 339 N.E.2d 846 (1976). These statutes have been held to be constitutional. *E.g.,* McDaniel v. Baptist Memorial Hospital, 469 F.2d 230, 234 (8th Cir. 1972).

174 *See, e.g.,* Hutchins v. Blood Services of Montana, 161 Mont. 359, 506 P.2d 449 (1973); *Hines,* 86 N.M. 763, 765-67, 527 P.2d 1075, 1077-79.

175 Warvell v. Michigan Community Blood Center, 74 Mich. App. 440, 253 N.W. 2d 791 (1977).

liability will be reversed. This does not mean that there are no means by which the legal system can provide both compensation to some of the victims of post-transfusion hepatitis and an incentive to blood suppliers to take all reasonable steps towards the prevention of the disease. In an age where blood suppliers can reduce if not eliminate the number of incidents of hepatitis through such procedures as testing blood for Hepatitis B virus, the seemingly old-fashioned doctrine of liability through negligence may be a practical tool for enforcing the use of state-of-the-art methods. Where federal and state regulatory bodies have established standards of behavior for blood suppliers, there is no reason why those who fail to follow the minimum requirements of those standards ought not to be held liable.

A. *Can Blood Suppliers Be Held Liable for Negligent Conduct?*

In determining whether blood suppliers can and will be held liable for negligent conduct, two sets of questions must be considered. First, it must be asked whether courts will be willing to impose fault-based liability on blood suppliers, given the inapplicability of non-fault based theories of liability often characterized as short cuts to proof of negligence.[176] Unless courts are willing to define a standard of care for blood suppliers that obliges them to take reasonable steps to reduce post-transfusion hepatitis, the availability of negligence liability under a regime foreclosing other bases for recovery will be of no value.

Second, once negligence liability is accepted, issues of proof of the elements of negligence arise.[177] Did a blood supplier use the degree of care that would be employed by the reasonably prudent person in attempting to prevent post-transfusion hepatitis? Was the blood supplier's failure to follow that standard of care the cause of the plaintiff's infection? Unless a standard of care for blood suppliers can be established and

176 *See* Franklin, *supra* note 59, at 461-62.
177 *See* W. PROSSER, TORTS § 30 (4th ed. 1970).

the falling below the standard causally tied to the incidence of hepatitis, negligence-based liability cannot be imposed.

1. Defining a Standard of Care

At the heart of the rejection of liability without fault for blood suppliers has been the belief that they were unable to identify or eliminate the causative agents of hepatitis from blood.[178] Some cases of post-transfusion hepatitis may now be avoided, however, through the use of screening tests for Hepatitis B carriers and recognition that a relationship exists between the use of some paid donors and the incidence of disease.[179] A standard of care for blood suppliers can be developed from the information now available, and the failure to follow that standard ought to be a basis for the imposition of liability.

Establishing some such standard of care ought not be difficult.[180] Transfusing the blood of a known hepatitis carrier would certainly fall below the standard.[181] So would the use of a donor whose blood had tested positive for Hepatitis B virus, without any prior evidence of involvement with the disease, given the ability of a relatively cheap screening procedure.[182] Failure to test blood at all would be patently negligent.[183]

Defining other elements of the standard of care would be more difficult, but not impossible. Whether a blood supplier could be held liable for not investigating records of donors

178 *See, e.g.,* Brody v. Overlook Hospital, 127 N.J. Super. 331, 336-39, 317 A.2d 392, 395-98 (A.D. 1975); Perlmutter v. Beth David Hospital, 308 N.Y. 100, 106-07, 123 N.E.2d 792-95 (1954).

179 *See* text accompanying notes 16-38 *supra.* It appears, however, that no means currently exist by which hepatitis viruses, detected or undetected, may be removed from human blood. One process once hoped to be promising, the freezing and "washing" of red blood cells, has been asserted to be ineffective in a recent study. Alter, *et al., Transmission of Hepatitis B Virus Infection by Transfusion of Frozen-Deglycerolized Red Blood Cells,* 298 NEW ENG. J. MED. 637 (1978).

180 *See, e.g.,* Franklin, *supra* note 59, at 447-52.

181 This might not be the case in a life-threatening situation where the only donor(s) available were known hepatitis carriers. Presumably, however, some form of informed consent would have to be secured.

182 Third-generation RIA tests currently in use cost less than $5.00/unit to administer. *See* Havinghurst, *supra* note 59, in AEI PROCEEDINGS, *supra* note 19, at 31.

183 J. HUESTIS, J. BOVE, & S. BUCK, *supra* note 172, at 373.

disqualified for medical reasons outside its own organization or its immediate geographical area is open to question, especially in the absence of a national registry of disqualified donors.[184] The liability both of those blood suppliers relying on paid donors or on any donor pool associated with a high incidence of hepatitis and of hospitals that rely on such blood suppliers might depend on whether alternative sources of blood existed or could be developed within the community.[185]

This search for standards has been simplified, in any case, by the existence of several collections of recommended practices for blood suppliers. The AABB, in particular, has developed a set of procedures its members (and other blood suppliers) should follow on such matters as hepatitis testing, the exclusion of donors whose blood has been implicated in prior incidents of the disease, and the interviewing of prospective donors.[186] More importantly, regulations promulgated by some states[187] and the FDA[188] set forth state-of-the-art standards for the conduct of blood suppliers that have the force of law. Acts in direct violation of these regulations may be negligence *per se*.[189]

---

184 Federal agencies have stressed the need for such an agency in recent policy statements concerning the blood supply system. *See* HEW, *National Blood Policy: Department Response to Private Sector Implementation Plan*, 39 Fed. Reg. 32,702, 32,709 (1975); GAO Study, *supra* note 11, at 36-39.

185. Professor Franklin has questioned whether many hospitals have available to them alternative sources of blood, *supra* note 59 at 450-51. But this must be balanced against the recent experience of some blood suppliers who have successfully transformed their pools of blood donors from those consisting of people paid in cash to those of all volunteers. Surgeoner & Cerveney, *A Study of the Conversion from Paid to Altruistic Donors in New Mexico*, 18 TRANSFUSION 54 (1978); Correspondence, 16 TRANSFUSION 190 (1976) (Johns Hopkins Hospital Blood Bank, Baltimore, MD).

Some forms of negligent conduct related to hepatitis may be actionable independent of negligence in handling the blood itself. A physician, for example, might be held liable for malpractice if an unnecessary transfusion resulted in hepatitis. This may be so particularly in the case of single unit transfusions, where the risk to the patient from hepatitis may very well outweigh any possible medical benefits. *See* Franklin, *supra* note 59, at 454-55.

186 AABB, STANDARDS FOR BLOOD BANKS AND TRANSFUSION SERVICES (7th ed. 1974); AABB, TECHNICAL METHODS AND PROCEDURES (6th ed. 1974).

187 *See, e.g.*, 10 Codes, Rules & Regs. of New York, Subpart 58-2 (regulating materials to be used in blood testing).

188 *See* 21 C.F.R. Parts 606, 607, 610, 640 (1977).

189 *See, e.g.*, Martin v. Herzog, 228 N.Y. 164, 126 N.E. 814 (1920) (Cardozo, J.), W. PROSSER, TORTS § 36 at 200, 202 (4th ed. 1972). The doctrine of negligence *per se*

2. Problems of Causation

In applying the standard of care for blood suppliers established by the courts, the problem of causation remains. Modern medicine's increasingly sophisticated knowledge about the causes of hepatitis has made it easier for blood suppliers and other health care providers to claim that their blood was not the medium which caused a given case of post-transfusion hepatitis. Where once it was thought that the disease formerly known as serum hepatitis was transmitted only by human blood or implements that had been in contact with infected blood (*i.e.*, a hypodermic needle), it is now believed that the disease may be transmitted in media other than transfused blood.[190] Members of such diverse groups as male homosexuals[191] and members of the health care professions[192] have been identified as more likely both to be

is easily applicable to violators of FDA or state regulations applicable to blood suppliers. One who is within the class of people intended to be protected by such a regulation may assert a cause of action against one who has violated the rule and caused him injury. *See Martin*, 228 N.Y. at 168, 126 N.E. at 815. While the FDA has justified the extension of its regulatory authority to all blood suppliers in terms of preventing the interstate spread of hepatitis, *see* note 45 *supra*, those who contract the disease cannot be outside the scope of those protected by its rules. Victims of post-transfusion hepatitis should be allowed to assert this protection in a private cause of action.

190 *See* Mosely, *The epidemiology of virdl hepatitis: an overview*, 270 AM. J. MED. SCI. 253, 258-66 (1975).

191 *See, e.g.*, Dietzman, *et al., Hepatitis B Surface Antigen (HBsAg) and Antibody to HBsAg: Prevalence in Homosexual and Heterosexual Men*, 238 J.A.M.A. 2625 (1977).

192 *See* Denes, *et al., Hepatitis B Infection in Physicians: Results of a National Seroepidemiologic Survey*, 239 J.A.M.A. 210 (1978) which indicated 18.5% of physicians tested at A.M.A. conventions displayed evidence of previous hepatitis infections. Not surprisingly, those, such as surgeons, who came into frequent contact with blood or blood products were more likely to have contracted the disease than those who did not (*e.g.*, psychiatrists). *Id.* at 211. A control group of non-physicians evidenced an infection rate of 4.1%. See also Meyers, *et al., Lack of Transmission of Hepatitis B After Surgical Exposure*, 240 J.A.M.A. 1725, 1726-27 (1978) (documenting limited transmission of Hepatitis B by orthopedic surgeon to patients before surgeon's infection was diagnosed).

Evidence that many members of the health care professions may be unsuspecting hepatitis carriers has raised serious ethical problems in those professions. *See* Blumberg, *Bioethical Questions Related to Hepatitis B, Antigen*, 65 AM. J. CLINICAL PATHOLOGY 848 (1976); Mosely, *The HBV Carrier — A New Kind of Leper?* 292 NEW ENG. J. MED. 477 (1975) (Editorial). The problem is exacerbated at this time by the absence of knowledge of the precise degree of risk posed by such carriers to their patients, and whether that risk differs among individual carriers, as recent studies indicate it may. *See also* Blumberg, *Hepatitis: The Plight of the Carrier*, THE SCIENCES (March 1978) at 10.

hepatitis carriers and to transmit the disease independently of any blood transfusion.

Under these circumstances, can a hepatitis victim tie his disease closely enough to the administration of blood to establish a blood supplier's negligence as the proximate cause of disease? Some advances in medicine's understanding of hepatitis may aid the victim in obtaining recovery. It is now well established that the incubation period for the strains of hepatitis typically transmitted by human blood, Hepatitis B and non-A, non-B hepatitis, is generally no less than six weeks.[193] Should a transfusion recipient begin to show symptoms of hepatitis approximately six weeks after the administration of blood, a case can be made that the transfusion was the cause of disease, allowing further investigation into whether the blood suppliers and health care providers involved followed the appropriate standard of care.[194]

Another problem of causation is that adherence to some standards of care will prevent some strains of hepatitis and not others. Physicians today can identify patients infected with the Hepatitis B virus, which *can* be identified in donor blood, and distinguish them from those apparently infected by the non-A, non-B strain for which no test is currently available.[195] Obviously, while adherence to a standard of care, in the testing of blood, for example, might have prevented an infection of Hepatitis B, similar steps would currently be of no avail in combatting non-A, non-B.[196]

---

193 *See* Gocke, *Post-Transfusion Hepatitis: A Status Report* in AEI PROCEEDINGS, *supra* note 19, at 11, 12 table 1; Gitnick, *Viral Hepatitis,* 128 WEST J. MED. 117, 120-21 table 2 (1978). By comparison, the incubation period for Hepatitis A (infectious hepatitis) is between two and six weeks.

194 Even if it could be proved definitively that a plaintiff's hepatitis was not transmitted by a transfusion, there might be a recovery available if it could be established that any of the health care personnel who were responsible for that patient's treatment were identified or identifiable hepatitis carriers capable of transmitting the disease. Whether and how liability would be imposed under those circumstances may depend on what action health care professionals themselves may believe are appropriate for dealing with hepatitis carriers. *See* sources cited in note 192 *supra.*

195 *See* Alter, *et al., supra* note 8 at 838; Prince, *et al., supra* note 8 at 244. Progress has been reported toward isolating and identifying the so-called non-A, non-B virus. *See* sources cited in note 36 *supra.*

196 Other elements of a standard of care may be applicable regardless of the

This problem of the relative preventability of the two strains of virus may become critical given current attitudes towards proximate cause in medical malpractice actions. It has been held, for example, that a physician could not be liable for the death of a patient when it was more likely than not that his negligent conduct had no bearing on the eventual demise of his patient.[197] Particularly where it is believed the plaintiff was the victim of non-A, non-B hepatitis, such reasoning could lead to the conclusion that blood suppliers powerless to identify the disease in donor blood could not be held liable for negligence under any circumstances.[198] This may be a risk transfusion recipients may have to bear until effective means of identifying or preventing all strains of hepatitis are developed.

3. Judicial Attitudes Toward a Negligence-Based Theory of Liability

Strong arguments have been made in favor of imposing liability without fault on blood suppliers. Only in a few cases have they been embraced by a court of last resort.[199] The imposition of negligence liability on blood suppliers could meet a similar fate. No jury verdict of negligence against a blood supplier or other health-care provider has been affirmed on appeal. But appellate courts have been willing to delineate standards by which the performance of blood suppliers could be measured.

---

strain of virus causing the disease. For example, removal from the blood supply pool of donors repeatedly implicated in cases of post-transfusion hepatitis would be a step whose effectiveness would not vary with the strain of disease involved.

197 Cooper v. Sisters of Charity, 27 Ohio St.2d 242, 251-54, 272 N.E.2d 97, 103-04 (1971).

198 This result should not occur if the standard of care includes procedures which are effective against post-transfusion hepatitis in general, rather than only one strain. *See* note 196 *supra*.

199 *But see* Belle Bonfils Memorial Blood Bank v. Hansen, 579 P.2d 1158 (Colo. 1978) (holding blood bank could be held liable without fault).

A number of cases have been remanded for development of a record on the ability of physicians to prevent post-transfusion hepatitis. Community Blood Bank v. Russell, 196 So.2d 115 (Fla. 1967); Jackson v. Muhlenberg Hospital, 53 N.J. 138, 249A.2d 65 (1969) (per curiam); Hoffman v. Misericordia Hospital of Philadelphia, 439 Pa. 501, 267 A.2d 867 (1970).

While a number of recent cases have reconsidered the issue of the liability of blood suppliers since tests for Hepatitis B became available in the early 1970's,[200] only one jury finding of negligence has been considered by a court of last resort, in the case of *Hutchins v. Blood Services of Montana.*[201] In 1968, plaintiff received blood supplied by defendant, a non-profit organization who paid donors in cash. The donor who supplied the blood transfused to the plaintiff apparently was healthy at the time of the donation but developed acute infectious hepatitis (Hepatitis A) several days later. Plaintiff also contracted the disease.

The Montana Supreme Court reversed a jury verdict for the plaintiff on the issue of negligence, rejecting medical testimony on the availability of tests for Hepatitis A and the relative risks of paid donors. Instead, the court held Blood Services, which followed AABB standards of care not surpassed by other banks, could not be held liable for negligence.[202]

Standards of care for blood suppliers have also been delineated by an Ohio appellate court in reversing a summary judgment for defendant on negligence in *Morse v. Riverside Hospital.*[203] It held that the defendant could be liable for 1) failing adequately to question donors on their medical histories; 2) failing to test all blood collected for hepatitis viruses; and 3) not excluding those associated with prior cases of hepatitis from the blood donor pool.[204] The case was remanded for trial on all three issues.[205]

---

200 *E.g.,* McDaniel v. Baptist Memorial Hospital, 469 F.2d 230, 234 (6th Cir. 1972) (applying Tennessee law); Hines v. St. Joseph's Hospital, 86 N.M. 763, 765-67, 527 P.2d 1075, 1077-79 (Ct. App. 1974); Jennings v. Roosevelt Hospital, 83 Misc.2d 1, 372 N.Y.S.2d 277 (Sup. Ct. 1975).

201 161 Mont. 359, 506 P.2d 449 (1973).

202 *Id.* at 362-64, 506 P.2d at 451-53. The majority also distinguished between prison donors and drug addicts asserted to be major hepatitis risks in the testimony and the blood donor implicated in the case. One judge dissented, asserting the donor had been improperly interviewed. *Compare id.* at 366, 506 P.2d 453 *with id.* at 367, 506 P.2d 453 (Harrison, John C., J. concurring in part, dissenting in part).

203 44 Ohio App.2d 422, 339 N.E.2d 846 (1973).

204 *Id.* at 425-26, 339 N.E.2d at 850. *See also* Martin v. Southern Baptist Hospital, 352 So.2d 351, 353 (La. App. 1977), where similar standards were set forth.

205 *Morse,* 44 Ohio App.2d 422, 339 N.E.2d 850.

Admittedly, how trial on such issues as outlined in *Morse* would be conducted is an open question. Even if all implicated donors were available for reexamination, determining the adequacy of the process by which their medical history was compiled would be difficult, even though hindsight had proved the original history wrong. Yet courts appear to be willing to let negligence issues pertaining to post-transfusion hepatitis go to trial, and, presumably, to sustain verdicts for plaintiffs in those cases where defendant blood suppliers have not followed generally accepted standards of behavior.

B. *A Second Look at the Exemption Statutes*

Legislative enactments have played a pivotal role in the insulation of blood suppliers from liability without fault. They still have a role to play in a world where liability would be imposed following negligent conduct. Courts developing a standard of care to which blood suppliers can be held may make reference to governmental regulations as one source of those standards.[206] Where legislators have defined a set of circumstances under which blood suppliers will not be held liable, they should set forth explicitly those circumstances under which liability will be imposed.[207] It cannot be gainsaid that certain statutes, particularly those which have required the labeling of blood containers to identify them as coming from paid or volunteer donors,[208] may have impact on the incidence of post-transfusion hepatitis without regard to the specific standard of care applied to blood suppliers.

---

206 *See* text accompanying notes 187-189 *supra*.

207 Only a few states have set forth such standards. *See, e.g.*, CAL. HEALTH & SAFETY CODE §§ 1603.1 to 1603.2 (West Supp. 1977-1978) (requiring hepatitis testing and exclusion of implicated donors); MICH. COMP. LAWS ANN. §§ 691.1511 to 691.1512 (West Supp. 1977-1978) (exemption from liability without fault limited to undetectable diseases); MO. REV. STAT. ANN. § 431.069 (Vernon Supp. 1977) (exemption similar to Michigan's); MONT. REV. CODES ANN. §§ 69-2203 to -2205 (Supp. 1977) (mandating testing for hepatitis carriers); VA. CODE § 32-364.2 (1973) (exemption similar to Michigan's).

208 *See, e.g.*, Blood Labeling Act, ILL. REV. STAT. ch. 111½, §§ 620-1 to 620-5 (1975).

1. The Need for Explicit Legislative Standards

In one sense, blood suppliers got the best of the bargain in many of the states where exemption from liability without fault was granted by the legislatures. Blood suppliers escaped from the threat of implied warranty and strict liability theories of recovery that could serve as short cuts to proof of negligent conduct. In many jurisdictions, they did so without finding imposed upon themselves a standard of care against which their conduct could be measured. Only five of the forty-five states exempting blood suppliers from liability without fault by statute also state in the statute books that blood suppliers will be held liable for breaching a specific standard of conduct if post-transfusion hepatitis viruses become detectable.[209] Most states which say anything at all in the statute books maintain blood suppliers will be held liable for their own fault — without defining what fault is.

Victims of post-transfusion hepatitis need not rely on proof of failure to meet a *legislatively* defined standard of care in order to set forth a cause of action for negligence. Setting forth the standard of care blood suppliers ought to follow in the absence of one defined by statute, however, is likely to require the presentation of expert testimony by the plaintiff.[210] Whether it is fair to place that burden on a plaintiff who is categorically barred from employing non-fault based theories is doubtful.

Few problems exist in establishing what standards can and should be adopted by legislatures for the behavior of blood suppliers. The FDA standards which all blood suppliers must follow in any case may be incorporated by reference into state statutes as a definition of the standard of care,[211] as may AABB-recommended procedures which also reflect the state of the art of blood banking.[212] Adoption of either set of rules

209 *See* note 201 *supra.*

210 In medical malpractice actions, for example, the burden is on the plaintiff to present expert testimony on the community's standard of medical care. *E.g.,* Boyce v. Brown, 51 Ariz. 416, 77 P.2d 455 (1938).

211 *See, e.g.,* 10 Codes, Rules & Regs. of N.Y., Subpart 58-2 (materials used in blood testing must meet standards set by the FDA).

212 *See* sources cited in note 86 *supra.*

by the states would not require heavy research expenditures. Certainly, most of the elements of the standard of care for blood suppliers are well known. They would include use of the most sensitive available screening tests for Hepatitis B carriers, exclusion from donor pools of all those with histories of either contracting or transmitting hepatitis, and close examination of all prospective donors for needle marks.[213] Where the state has barred a potential plaintiff from recovering from blood suppliers without proof of fault, it ought to at least make clear the standard by which a blood supplier's fault can be measured.

2. Labeling Statutes: Informing Blood Users

Statutes can establish a standard of care for blood suppliers, breach of which will be a basis for liability for negligence. But legislation may also aid in the prevention of post-transfusion hepatitis without imposing any changes in the basis for liability. One example of this is the Illinois Blood Labeling Act.[214] While it is unlikely the standards it sets forth for health care providers will ever be breached, it appears that the Act's exposure of the use of paid donors' blood and the circumstances under which it is used in Illinois has led to a substantial reduction in the use of such blood, and, concurrently, a measurable reduction in the incidence of hepatitis. The fear of exposure of the use of paid donor blood may be as important a tool in reducing disease as the fear of adverse judgments.

The provisions of the Blood Labeling Act are quite simple. All blood transfused within Illinois must be labeled to indicate whether it came from a donor paid in cash or a "volunteer".[215] If paid donor blood is used, the hospital record must contain a notation indicating why such blood was used instead of volunteer blood.[216] If physicians,

213 *See* text accompanying notes 16-38 *supra*.

214 ILL. REV. STAT. ch. 111½, §§ 620-1 to 620-5 (1975). Similar state statutes are in force in California, Georgia and Florida, *see* notes 54 to 56 *supra*, and regulations requiring labeling on a nationwide basis were put into effect by FDA on May 15, 1978. *See* note 52 *supra*.

215 ILL. REV. STAT. ch. 111½, § 620-2.

216 *Id.* § 620-4.

hospitals and blood suppliers violate the Act, they lose their exemption from liability without fault.[217] In short, the statute requires disclosure to a physician that paid donor blood is being transfused and obliges health care providers to justify its use.

The requirement that doctors record the reasons for the use of paid donor blood preserves evidence of the standard of care employed by health care providers for use in actions based on negligence. Yet it is difficult to envisage a situation where those obeying the law would be held liable for negligent use of paid donor blood. If paid donor blood was the only blood available for a patient in an emergency, life-threatening situation, it is unlikely health care providers would be held liable on a negligence theory.[218] Similarly, it is doubtful that a court would impose liability in a situation where physicians chose to risk the use of paid donor blood rather than delay major, non-elective surgery.[219]

While it appears that the Act places no great pressure on health care providers to cease using paid donor blood if its use can be justified, the enactment of the Act has virtually eliminated the use of paid donor blood in Illinois. Within one year of its effective date, the use of paid donor blood had dropped to only two percent of total transfusions.[220] During the 1960's, by comparison, usage of paid donor blood approached sixty percent of the total amount transfused.[221] At one facility where paid donor blood usage dropped from 92

---

217 ILL. REV. STAT. ch. 91, § 183 (1975).

218 The situation might differ, however, if the transfusion were not necessary. This would be particularly true in the case of single-unit transfusions, which have become increasingly unpopular among physicians, in part because of the risk of hepatitis. *See* Franklin, *supra* note 59, at 454-55.

219 The use of blood in a purely "elective" procedure might not lead to the same result. In an age where unnecessary surgery has become a major concern of health policy planners, it would not be surprising that the decision to operate, not that to use paid donor blood, might be deemed to be negligent.

220 *Only 2 Per Cent Paid Donors: Illinois Volunteer Blood Law Results Surprising*, 48 HOSPITALS 17 (1974). Through early 1978, no comparable studies appear to have been published for those jurisdictions (California, Georgia and Florida) which enacted labeling statutes after Illinois.

221 R. TITMUSS, *supra* note 7, at 97.

percent to 4 percent of blood transfused, the incidence of post-transfusion hepatitis dropped 63 percent.[222]

The explanation for this massive reduction in the use of paid donor blood, when those who could justify its use had little to fear from being held liable for negligence, may lie in the visibility the statute gave the use of a more dangerous form of treatment. When labeling requirements obliged health care providers to make explicit that blood used in transfusions may not have been the safest variety available, physicians apparently began to pressure hospitals and their blood suppliers to switch to safer blood donor pools.[223] In this light, the more recently enacted California, Florida, and Georgia labeling statutes[224] and the new FDA labeling regulations[225] may have similar results, even in the absence of the justification provisions found in Illinois law.

The Illinois experience indicates that statutes need not set forth standards of conduct likely to be cited in negligence actions in order to create incentives for health care providers to act to reduce the incidence of hepatitis. Merely increasing the visibility of a health care provider's decisions may reduce the number of questionable decisions, such as the use of paid donor blood, as effectively as imposing legal penalties for such conduct.

Conclusion

The question of whether and how liability ought to be assessed against blood suppliers for post-transfusion hepatitis is entangled in medicine's day-by-day progress towards developing means by which the disease may be eliminated. In a world where some carriers of hepatitis viruses can be identified and eliminated from the blood donor pool and some cannot, and where some paid blood donors are

222 Seeff, *et al., Rates of Post-Transfusion Hepatitis,* 292 NEW ENG. J. MED. 532 (1975).

223 *See* Kessel, *supra* note 12, at 284.

224 CAL. HEALTH & SAFETY CODE § 1603.5 (West Supp. 1978); FLA. STAT. ANN. §§ 381.601-381.607 (West Supp. 1978); GA. CODE §§ 84-5501a to -5507a (Supp. 1978).

225 *See* FDA, *Whole Blood and Components of Whole Blood; Donor Classification Labeling Requirements,* 43 Fed. Reg. 2142, 2147-48 (1978).

far more dangerous than most volunteers but others are just as safe, devising a legal regime that will protect blood recipients, offer incentives to blood suppliers to prevent the disease, and continue the flow of blood is a formidable task. States may not be able to ban the use of paid donors under the pre-emption doctrine; the federal government has not yet shown any signs of whether it will attempt to do so. Theories of liability built on implied warranty or strict liability doctrine might offer some protection and would compensate hepatitis victims. Yet legislative action has effectively closed off either theory as a possible vehicle of legal relief.

The victim of post-transfusion hepatitis is thus left to rely on the negligence of blood suppliers as the only means by which he or she could secure a recovery. But the existence of methods by which blood suppliers can now reduce the risk of post-transfusion hepatitis and their adoption into law through the nationwide FDA regulations and varying state enactments gives blood recipients a standard of care to enforce against blood suppliers. It must be conceded that negligence-based theories will offer little succor to those who are victimized by incidents of hepatitis that cannot yet be prevented.[226] But until fully effective tests for detecting all hepatitis carriers or a vaccine[227] is developed, all society can do is ask blood suppliers to use the best tools available to them. Negligence-based liability may be the best tool available.

---

226 Administrative insurance schemes may be appropriate method for compensating victims of presently unpreventable incidents of hepatitis. *See, e.g.*, Franklin, *supra* note 59, at 478; Comment, *Blood Transfusions and the Transmission of Serum Hepatitis: The Need for Statutory Reform*, 24 AM. U.L. REV. 367 (1975).

227 A vaccine against Hepatitis B is apparently ready for testing on human subjects. *See* Krugman, *Viral hepatitis type B: prospects for active immunization*, 270 AM. J. MED. SCI. 391 (1975); Purcell & Gerin, *Hepatitis B subunit vaccine: a preliminary report of safety and efficacy tests in chimpanzees*, 270 AM. J. MED. SCI. 395 (1975); Hilleman, *et al., Purified and inactivated human Hepatitis B vaccine: progress report*, 270 AM. J. MED. SCI. 401 (1975). If a safe and fully effective vaccine were developed, failure to employ it on transfusion recipients would be negligent.

NOTE

HOSPITAL COST CONTROL: SINGLE-EDGED INITIATIVES FOR A TWO-SIDED PROBLEM

RONALD GREENSPAN*

Unchecked by market forces or effective regulation, the cost of hospital care has risen sharply and steadily since 1950. Believing that this trend represents a misappropriation of societal resources and a threat to continued funding of alternative government programs, the Carter Administration has introduced a bill designed to limit hospital revenues, while Senator Herman Talmadge has sponsored another measure aimed at improving hospital efficiency.

Neither of these proposals, however, addresses or solves both of the hospital cost problems, excessive services and inefficient hospital operation. Mr. Greenspan therefore presents a third approach. His proposal integrates elements of the Carter and Talmadge initiatives in order to address both objectives of hospital cost control while avoiding the disadvantages of the proposals considered individually.

Introduction

In assembling the world's most sophisticated hospital care system,[1] the United States has created a Gargantua with a gluttonous appetite for our national resources. Two proposals currently under consideration in Congress are aimed at returning this overgrown king to a diet of social control.

Until recently the hospital care system underwent substantial and unchecked expansion. For the past twenty-five years, the goal of government programs has been to extend the availability of hospital care by reducing the system's geographical disparities and by minimizing ability to pay as a

---

* B.A., U.C.L.A., 1976; member of the class of 1979, Harvard Law School.

1 R. RUSHMER, HUMANIZING HEALTH CARE: ALTERNATIVE FUTURES FOR MEDICINE 89 (1975).

criterion for receiving medical care.[2] The pursuit of this goal has been costly: hospital expenditures rose from $3.7 billion in 1950[3] to $55.4 billion in 1976, and if left unchecked, they are expected to surpass $100 billion by 1982.[4] This swift growth has drawn attention to the system's inefficiencies and has raised doubts about the prospective benefits of increased expenditures for hospital care. It is clear that political considerations and humanitarian objectives make it impossible to respond by reinstituting a market system in which the recipient alone pays the costs of his care at the time of delivery. Such a system would mean a reduction in demand for services, but it would also mean that necessary hospital care would be withdrawn from those unable to pay. Cost containment programs have been initiated at the state level, but they have been sporadic and generally unsuccessful. To respond to the swift growth in expenditures, therefore, initiatives which propose intensified federal action have been introduced in Congress by the Carter Administration and Senator Talmadge.

The objective of the Carter Administration proposal is to curtail the rapid expansion of hospital services[5] by placing a temporary ceiling on total hospital revenues and by severely reducing and subjecting to governmental approval capital outlays for new equipment and expanded or improved

2 Davis, *The Impact of Inflation and Unemployment on Health Care and Low-Income Families,* in HEALTH: A VICTIM OR CAUSE OF INFLATION? 57 (M. Zubkoff ed. 1976); R. ANDERSEN, J. LION, & O. ANDERSON, TWO DECADES OF HEALTH SERVICES: SOCIAL SURVEY TRENDS IN USE AND EXPENDITURE 34-35 (1976).

Despite governmental efforts, problems in these areas remain. *See* Davis, *Achievements and Problems of Medicaid,* 91 PUB. HEALTH REP. 309 (July-Aug. 1976); Davis, *Equal Treatment and Unequal Benefits: The Medicare Program,* 53 THE MILBANK MEMORIAL FUND QUARTERLY/HEALTH & SOC'Y 449 (1975) [hereinafter HEALTH & SOC'Y]; Dunlol & Zubkoff, *Inflation and Consumer Behavior in the Health Care Sector,* in HEALTH: A VICTIM OR CAUSE OF INFLATION? 86 (M. Zubkoff ed. 1976); V. FUCHS, WHO SHALL LIVE? 13-14 (1974). But further consideration of these problems is beyond the scope of this Note.

3 Gibson & Mueller, *National Health Expenditures, Fiscal Year 1976,* 40 SOC. SEC. BULL. 3, 15 (April 1977).

4 CONGRESSIONAL BUDGET OFFICE FOR THE SUBCOMM. ON HEALTH AND SCIENTIFIC RESEARCH, 95TH CONG., 1ST SESS., THE HOSPITAL COST CONTAINMENT ACT OF 1977: AN ANALYSIS OF THE ADMINISTRATION'S PROPOSAL 13 (Comm. Print 1977) [hereinafter CBO FOR HEALTH].

5 CONGRESSIONAL BUDGET OFFICE, EXPENDITURES FOR HEALTH CARE: FEDERAL PROGRAMS AND THEIR EFFECTS 27-28 (1977).

facilities. The objective of the Talmadge proposal, on the other hand, is to promote more efficient utilization of hospital resources by rewarding those hospitals which deliver inexpensive care and by penalizing those which provide inordinately expensive treatment. It further seeks to promote efficiency by compensating hospitals for any financial detriment suffered by eliminating excess capacity.[6]

The goal sought by each bill merits fulfillment, but neither bill adequately counters the problems of excessive supply and demand for services and the concomitant disregard for efficiency. After evaluating each of the bills for its contribution toward restraining the growth of total hospital costs, new facilities, and consumer demand, this Note urges that the two be fashioned into a unified measure. Combining the revenue limit and the efficiency incentives would provide an integrated remedy for the twin cost problems of excessive and inefficient delivery of hospital services. This step would also alleviate many of the defects which hinder the measures when applied individually. Furthermore, fusing the bills would establish internal incentives for institutions to plan their capital expenditures more rationally, thus eliminating the need to include administratively complicated and intrusive capital spending restraints.

I. Delivery of Hospital Services

A. *Cost Problem*

The economic resources diverted from other sectors of the national economy to fashion and operate our extensive

6 Representative Tim Lee Carter (R-Ky.) introduced a third bill, H.R. 8687, which places primary responsibility for initiating cost containment programs on the states, with the federal role restricted to setting a maximum revenue limit, funding the start-up costs, and providing technical assistance. States would be required to institute cooperative agreements between health planning agencies and a mandated state budget commission. The budget commission would prospectively review and approve budgets for all hospitals in the state. This Note will not examine H.R. 8687, but interested readers may note that a similar program is in operation in Rhode Island and is discussed briefly at note 92 *infra*. Also, on February 28, 1978, the House Ways and Means Subcommittee on Health approved a substitute for the Administration's bill drafted by Representative Rostenkowski (D-Ill.) which holds open the possibility of a revenue ceiling, pending the results of a hospital industry voluntary expenditure reduction program.

system of institutional health care[7] have been enormous. Between 1950 and 1965, the year before enactment of medicare[8] and medicaid,[9] national health expenditures tripled and total hospital costs increased even more.[10] In the subsequent eleven year period, during which the federal government aggressively sought to eliminate the recipient's ability to pay as the system's predominant rationing device, hospital expenditures quadrupled, consuming ever-increasing proportions of total health care expenditures[11] and of the gross national product.[12] As a result, total hospital expenditures have ballooned by 1500 percent during the combined twenty-six year period.[13]

Such a rapid shift in the allocation of national resources is not necessarily undesirable. An examination of industrially developed countries shows that expenditures for health care as a proportion of national income are greater in higher-income countries.[14] This observation suggests that at least part of our increased hospital expenditures may reflect a world-wide preference for allocating the fruits of economic expansion, such as the United States enjoyed during the first

---

7 J. NEWHOUSE, INCOME AND MEDICAL CARE EXPENDITURES ACROSS COUNTRIES 2 (1976) (the author's calculations, based on United Nation's data, show that the United States has the largest per capita expenditure on medical care). A demonstration of this nation's emphasis on technology is the estimated need for CT scanners at one per 375,000-750,000 people and the predictions that there will be 1,425 to 2,500 scanners in operation (an average of about one per 115,000 people) by the year 1980. AMERICAN HOSPITAL ASSOCIATION, CT SCANNERS: A TECHNICAL REPORT 72, 113 (1977). In contrast, Sweden with the second largest per capita health budget, estimates its need at one scanner per four million people. *Id.* at 71.

8 Social Security Act Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 290 (1965).

9 *Id.*

10 Total health expenditures increased during this period from $12.027 billion to $38.892 billion and hospital expenditures from $3.698 billion to $13.152 billion; this is an increase in hospital costs as a percentage of total health care costs from 30.7% to 33.8%. Gibson & Mueller, *supra* note 3, at 15.

11 By 1976, hospital costs of $55.7 billion accounted for 39.8% of total health care outlays. *Id.*; AMERICAN HOSPITAL ASSOCIATION, HOSPITAL STATISTICS at v (1977).

12 Hospital expenditures increased from 1.89% of the gross national product in 1966 to 3.29% in 1976. AMERICAN HOSPITAL ASSOCIATION, *supra* note 11, at v.

13 *Id.* Over one-half of the increase in cost per patient day since 1960 is attributable to rising input prices and wage rates. Increased intensity of services comprises the remainder of the increase, with the non-labor component accounting for four times the expenditure increase caused by the addition of personnel. CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 29 (table 9).

14 J. NEWHOUSE, *supra* note 7, at 8.

two and a half post-war decades. Also, rapid technological and methodological changes in hospital treatment have presented the consumer with a new array of services, raising the possibility that consumer preferences will now be better satisfied with more hospitalization rather than other economic goods.[15] Expenditures have also increased as a natural result of medicine's success in extending the lives of more individuals into the later, medically more costly portion of the lifecycle.[16] Finally, the dramatic increase in the portion of the federal budget devoted to health care over the past ten years[17] may indicate a consensus in favor of increased consumption of medical care.

However, decades of compounding expenditure increases have made the budgetary tradeoffs painfully apparent, leaving few who now advocate an unfettered continuation of the current hospitalization system.[18] Automatic cost increases in the medicare and medicaid programs will consume over 14

---

15 Rosenthal, *Inflation: Directions for Research*, in HEALTH: A VICTIM OR CAUSE OF INFLATION? 322 (M. Zubkoff ed. 1976).

16 Individuals over 65 years old spent an average of $1360 per person on health care in 1974, while those less than 65 years old spent $375 per person. From 1950 until 1974, the percentage of the population over 65 years old increased from 8% to 10%. CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 8.

Ironically, advances in medical technology must result in overall increased medical costs: because the advances permit an individual to live through formerly fatal diseases or afflictions, the individual will live longer and generally get more medical treatment. Vidaver, *Underfinanced Services in the Public Sector*, 9 MED. CARE 169, 179 (1971).

17 Federal outlays for health have risen from $2.5 billion in 1966 to $42 billion ($24.2 billion in 1966 dollars) in 1976, an increase from 2.5% to 11.4% of the federal budget. THE BUDGET OF THE UNITED STATES GOVERNMENT 1972, at 572; M. KALEDA, C. BURKE & J. WILLIEMS, THE FEDERAL HEALTH DOLLAR: 1969-76 at 8 (1977); ECONOMIC STATISTICS BUREAU, THE HANDBOOK OF BASIC ECONOMIC STATISTICS 102 (1977) (the CPI increased from 97.2 to 170.5 between 1966 and 1976). Thirty-nine billion dollars of the 1976 expenditures were devoted to the health care system; 91% of that amount was spent to provide or compensate individuals for health care services (the remaining 9% underwrote investment programs in research, manpower training, construction, and system design and organization). KALEDA, BURKE, & WILLIEMS, *supra*, at 66.

18 However, Senator Magnuson (D-Wash.) has stated, "The American people must be guaranteed the best care available, when needed and without being limited by cost." W. MAGNUSON & E. SEGAL, HOW MUCH FOR HEALTH? 1 (1974). Similarly, the Federation of American Hospitals is critical of any plan which places a dollar value on human life or rations medical care or technology. 35 CONG. Q. WEEKLY REP. 918-19 (1977).

percent of the increase in federal spending during fiscal year 1979.[19] Outlays by state and local governments, which are already hard-pressed to meet other financial obligations, rose to $6.5 billion for the medicaid program and to over $9 billion to finance government-owned community hospitals in 1976.[20] The soaring cost of assuring the poor and the elderly access to medical care through these endeavors[21] threatens their continued funding at adequate levels.[22] Furthermore, escalating costs constrain our options for redesigning the health care delivery system. President Carter has announced that hospital costs must be controlled before any national health insurance program can be instituted.[23]

Beyond the concern for government budgets, it is doubtful that committing an ever-growing portion of the nation's resources to traditional health care institutions is the most efficient method to improve health. Despite the massive increase in medical expenditures over the last two decades, the average life expectancy remained virtually unchanged until 1968, and since then has been rising at about 2 percent per year, but without evidence that this has resulted from increased medical expenditures.[24] Analyses of relative cost efficiency suggest that directing resources away from medically unproven, technologically sophisticated equipment[25] and procedures,[26] and toward certain social and environmental health

---

19 This assumes adoption of the Administration's cost containment program. 35 CONG. Q. WEEKLY REP. 358 (1977); NEWSWEEK, January 30, 1978, at 22.

20 AMERICAN HOSPITAL ASSOCIATION, *supra* note 11, at 19.

21 In 1974, government outlays accounted for 80% of the health expenditures for those below the poverty line. KALEDA, BURKE & WILLIEMS, *supra* note 17, at 12, 21.

22 34 CONG. Q. WEEKLY REP. 2127 (1976) (statement by Governor Busbee).

23 *Id.* at 787; CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 60.

24 DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, FORWARD PLAN FOR HEALTH, FISCAL YEAR 1977-81, at 43 (1975).

25 There is no data which proves the effectiveness of much of the frequently-purchased sophisticated equipment in reducing mortality or morbidity (incidence of disease). J. NEWHOUSE, *supra* note 7, at 13. But this does not negate this equipment's possible usefulness in alleviating symptoms, relieving communal anxiety, and providing improved prognostic information through a higher degree of exactness. *Id.*

26 Patients suffering from angina without left-side coronary blockage (90% of those afflicted) show no difference in mortality rate whether treated by a heart bypass operation or by medication. Murphy, Hultgren, Detre, Thomsen & Takaro, *Treatment of Chronic Stable Angina*, 297 NEW ENG. J. MED. 621 (1977). This study

programs would yield significant improvements in mortality rates.[27] Similarly, studies show that decreased use of hospitals would not adversely affect health.[28]

Even where hospitalization is necessary, resources often are utilized inefficiently. Over-construction is one example. The national community hospital occupancy rate for 1976 was a sparse 74.6 percent.[29] Expensive specialized facilities often are not fully occupied or are occupied by patients who do not require or benefit from such intensive services.[30] Further, managerial inefficiencies are suggested by the not uncommon variation of up to 50 percent in per capita hospital expenditures across geographic regions, even after compensating for differences in patient mix between hospitals.[31] Such expenditure discrepancies result from operational inefficiencies and from medically unjustifiable differentials in the number of hospital admissions and in lengths of stay.[32]

Thus, two types of measurable inefficiency in the delivery of medical care contribute to the hospital cost problem: first,health services are delivered in a fashion which is unduly expensive and second, greater overall national health could be obtained, given the same level of expenditure, from a different mix of health services. Apart from these inefficiencies, aggregate hospital expenditures probably also represent a

---

indicates that surgery for heart disease can be reduced by approximately one half, saving $500 million per year. NEWSWEEK, October 3, 1977, at 102.

27 Auster, Levenson & Saracherk, *The Production of Health, an Exploratory Study,* in ESSAYS IN THE ECONOMICS OF HEALTH AND MEDICAL CARE 156 (V. Fuchs ed. 1972) (the authors estimate that mortality will be reduced more by additional expenditures on education than by an equal increase in medical care); L. Lave, *Air Pollution Damage: Some Difficulties in Estimating the Value of Abatement,* in ENVIRONMENTAL QUALITY ANALYSIS (A. Kneese & B. Bower ed. 1971) (a 50% reduction in the level of air pollution would lower the economic cost of morbidity and mortality almost as much as finding an immediate and complete cure for cancer).

28 Hutter, Sidel, Shine & DeSanctis, *Early Hospital Discharge after Myocardial Infarction,* 288 NEW ENG. J. MED. 1141 (1973); Klarman, *Approaches to Moderating the Increases in Medical Care Costs,* 7 MED. CARE 175, 177-79 (1969).

29 In 1976, community hospitals had 956,284 beds, and they recorded an average daily census of 713,011. AMERICAN HOSPITAL ASSOCIATION, *supra* note 11, at 18.

30 A 1969 survey showed operating rooms in three New England states used at an average of 45% of capacity. R. WARD, THE ECONOMICS OF HEALTH RESOURCES 61 (1975).

31 V. FUCHS, *supra* note 2, at 89.

32 *Id.*

wasteful, ill-proportioned allocation of our finite resources between the sectors of the economy.[33]

B. *Market Structure*

The usual mechanism which moves a market system toward the production of the optimum level of each product, *i.e.*, individual consumers apportioning their income so that they receive equal benefit from the marginal purchase of each item,[34] does not function well in the health care sector. Without guidance from consumers, we cannot conclusively determine whether a reallocation of our limited resources away from hospitals would be socially beneficial. Yet, the factors which perpetuate hospital inefficiencies also bias the economy toward providing excessive hospital services, to the detriment of competing social interests.[35]

The delivery of hospital care is marked by four characteristics which free it from market control and thus make it impervious to the constraints which normally regulate prices and allocate resources between economic sectors. First, over 91 percent of all hospital bills are paid by so-called third-party payors, that is, by entities other than the

---

33 Our actions clearly belie the sometimes voiced assertion that health is worth any cost. Cigarette smoking, overeating, polluting the air, and driving automobiles are all proven detriments to our health, yet each of them provides millions of individuals with a benefit or pleasure that outweighs its deleterious effect upon their health. The latter two in particular represent clear economic tradeoffs. If desired enough, less respiratory disease or fewer deaths and injuries on the highway could be purchased with reduced economic output, increased expenditures on pollution control devices and roadways, and the installation of automobile airbags.

34 C. FERGUSON, MICROECONOMIC THEORY 481-82 (3d ed. 1972).

35 An economic analysis suggesting the contrary proposition is based upon the socially beneficial externalities of health care. Since the individual recipient of medical care only considers the personal and not the societal benefits of medical treatment (like the control of contagious diseases and the maintenance of the national economic product), individual decision-makers demand a suboptimal amount of medical care. M. WEINSTEIN & W. STASON, HYPERTENSION: A POLICY PERSPECTIVE 20-77 (1976). However, this argument seems inappropriate when considering incremental expenditures on hospital care, since they almost certainly will not be directed at the communicable diseases and have not been shown to confer a positive economic benefit.

patient or the providing hospital.[36] Second, most third-party payors, including both the federal government and most of the Blue Cross organizations, compensate hospitals not according to prospectively established charges or fees, but according to a retrospective analysis of the cost of services rendered.[37] Third, the delivery of hospital services is dominated by institutions not motivated by profit considerations.[38] Nonprofit hospitals may adopt and pursue their own institutional goals as long as their operating revenues, plus gifts and endowment income, balance expenses.[39] Because administrators of nonprofit hospitals are not beholden to stockholders, they are free to seek both prestige among their associates and higher compensation, which are gained according to the quality and quantity of care rendered in their institution.[40] Fourth, because patients frequently lack the knowledge to determine their actual medical needs, their

---

36 In 1976, publicly financed programs paid 55% of all hospital costs, private insurance 35%, and patients 9% (numbers rounded off). HOUSE SUBCOMM. ON HEALTH, AND SUBCOMM. ON HEALTH AND THE ENVIRONMENT, 95TH CONG., 1ST SESS., STAFF REPORT ON S. 1391, H.R. 6575, AND S. 1470, at 1. In 1950, only 9% of hospital costs were not borne directly by the patient. Medicare and medicaid increased the incidence of third-party payors to 175% of its 1965 level. Klarman, *Reimbursing the Hospital — The Differences the 3rd Party Makes,* 36 J. RISK & INS. 563 (1969).

The Internal Revenue Code encourages taxpayers to purchase the most comprehensive medical insurance available by not taxing employee medical insurance benefits, by allowing employers a business deduction for insurance premiums, and by granting individual purchasers a deduction of one half of their premium. I.R.C. §§ 104-106. These and other related provisions save taxpayers $8.8 billion per year. CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 18, *citing* FIVE-YEAR PROJECTIONS: FY 1978-1982, SUPPLEMENT ON TAX EXPENDITURES (1977).

37 "Charges" refers to the rates that an uninsured private individual pays for hospital services. These rates are established in advance and have no necessary link with the provider's actual cost. R. WARD, *supra* note 30, at 66.

38 Nongovernment, not-for-profit hospitals comprise 57% of the community hospitals, state and local government hospitals 30%, and proprietary (for-profit) institutions 13%. AMERICAN HOSPITAL ASSOCIATION, *supra* note 11, at 19.

39 P. Ginsburg, *Resource Allocation in the Hospital Industry: The Role of Capital Financing,* 35 SOC. SEC. BULL. 20-25 (October 1972). Even the need to balance expenses with revenues may not create a base-line in the short-run if the management and board of trustees of the hospital are willing to expend otherwise recoverable capital rather than to vote themselves out of jobs by closing an institution operating at a deficit. Havighurst, *Regulation of Health Facilities and Services by "Certificate of Need,"* 59 VA. L. REV. 1143, 1161-62 (1973).

40 Newhouse, *Toward a Theory of Nonprofit Institutions: An Economic Model of a Hospital,* 60 AM. ECON. REV. 64-67 (1970). This basic model can be embellished by hypothesizing a weighted index-of-care which values a staff in accord with its eminence. R. WARD, *supra* note 30, at 56.

demand for hospital services is heavily influenced by physicians whose personal interests favor a high level of services.[41]

These deviations from the classical economic model[42] go far toward explaining both the rapid growth of and the continued excess supply in the hospital sector. By increasing its number of beds and specialized facilities, a hospital heightens its prestige[43] and reduces internal friction caused by operating near capacity.[44] The high frequency of cost reimbursement permits these administrative luxuries by assuring hospitals a recovery of the expenses incurred to acquire and maintain underutilized facilities.[45]

The lack of market controls perpetuates a related cause of the hospital cost problem, the improper composition of the supply of hospital services.[46] An increase in a hospital's technological sophistication, even beyond the level at which cost exceeds patient benefits, will increase both the hospital's prestige and its size, since more elaborate facilities attract staff physicians,[47] who in turn attract patients. The physicians will also urge administrators toward greater

41 R. WARD, *supra* note 30, at 57.

42 The classical competitive model assumes the existence of profit-maximizing producers who sell their goods and services at uniform market-determined prices to knowledgeable consumers (whose expenditures diminish their own limited financial resources). G. BACH, ECONOMICS, AN INTRODUCTION TO ANALYSIS AND POLICY 362-63 (7th ed. 1971).

43 Reder, *Economic Theory and Nonprofit Enterprise: Some Problems in the Economics of Hospitals,* 55 AM. ECON. REV. 472, 478-79 (May 1965).

44 J-L. MIGUE & G. BELANGER, THE PRICE OF HEALTH 57 (1974).

45 Weiner, *"Reasonable Cost" Reimbursement for Inpatient Hospital Services under Medicare and Medicaid: The Emergence of Public Control,* 3 AMER. J. L. & MED. 1, 32-33 (Spring 1977). Retrospective cost reimbursement divides the total cost of a service for a given period by the actual number of users. The 1972 Amendments to the Social Security Act, 86 Stat. 1329 (1972), allow the Secretary of HEW to disallow excessive medicaid costs and to set prospective medicare reimbursement rates. To date, the Secretary has only established guidelines for routine costs (room and board), and they are set so that well over 80% of all hospitals will be fully compensated. In fiscal year 1975, the first full year of the guidelines, 345 hospitals exceeded the guidelines by a total of $36 million (less than .1% of all expenses), and preliminary data indicated that not a significantly greater number would be in violation during fiscal year 1976. STAFF OF THE SUBCOMM. ON HEALTH AND THE ENVIRONMENT OF THE HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, 95TH CONG., 1ST SESS., HOSPITAL COST CONTAINMENT (1977) [hereinafter INTERSTATE AND FOREIGN COMMERCE REPORT].

46 *See* note 30 and accompanying text *supra.*

47 "Staff physicians" are doctors in private practice who are on the staff of a certain hospital and who therefore have admission privileges for their patients there.

technological expenditures,[48] because technology will add sophistication to their practice, generate income without a personal capital investment, and potentially aid their patients (though not necessarily commensurately with the cost).[49] Moreover, the composition of newly acquired capital items has probably been affected by recent proposals which suggest forced hospital closings as a remedy for the excess support of facilities.[50] These suggestions have created an environment ripe for a destructive competition for technologcial superiority, which would generate otherwise irrational expenditures by those hospitals hoping that modern facilities will provide a hedge against involuntary closure.[51]

Mirroring the excessive supply of services is a distorted demand for hospitalization and specialized facilities. By reducing or eliminating the cost of a service to the patient, payment by third parties encourages the demand for and use of specialized facilities[52] whose cost exceeds their value to the patient.[53] The resulting heightened demand will raise the

---

48 THE BOSTON CONSULTING GROUP, INC., REIMBURSING HOSPITALS ON INCLUSIVE RATES 17 (1970).

49 Stevens, *Hospital Market Efficiency: The Anatomy of the Supply Response,* in EMPIRICAL STUDIES IN HEALTH ECONOMICS 236 (H. Klarman ed. 1970). *See* note 53 *infra.*

50 *See* CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 52-53.

51 This attitude may explain the 24.3% increase during the past two years in community hospital assets per bed and some of the disproportionately large gain by hospitals with less than 100 beds during the past year. AMERICAN HOSPITAL ASSOCIATION, *supra* note 11, at xvii.

52 Davis, *Hospital Costs and the Medicare Program,* 36 SOC. SEC. BULL. 18, 24 (August 1973); Salkever & Bice, *The Impact of Certificate-of-Need Controls on Hospital Investment,* 54 HEALTH & SOC'Y 185, 197 (1976) (insurance coverage has a greater correlation with assets per bed than with bed supply).

53 A fully insured patient will demand any procedure which confers a benefit, regardless of its total cost. A partially-insured patient will respond similarly once he has spent his policy's deductible amount. If subject to a coinsurance provision, a patient will consume services until his fraction of the cost exceeds the marginal benefit received, a level above the point where total cost exceeds total benefit. These observations are valid for a consumer at any budget level and do not depend upon expenses surpassing an individual's income.

Price elasticity for general hospital care and length of stay is relatively low (approximately .3). R. WARD, *supra* note 30, at 93-94. One would expect higher elasticities for relatively expensive and substitutable tests and technologically sophisticated equipment. G. BACH, *supra* note 41, at 318. Thus, insurance will artificially inflate the demand for ancillary services more than for routine services.

price of using these facilities for all patients. Also, unnecessary demand for inpatient treatment is encouraged by medical insurance, which frequently fails to cover costs for more economical outpatient procedures.[54]

The highly judgmental nature of medical practice compounds the distortions present in the supply and the demand functions individually, for excess beds will give rise to heightened demand.[55] The physician's inexact arts of diagnosis and prescription, especially in the area of elective procedures, will certainly be influenced by the ready availability of hospital beds, by administrative pressure to maintain adequate occupancy rates, and by the physician's financial incentive to provide services.[56] Patients lack the medical knowledge to supervise their physician's decisions and are imbued with an overriding loyalty to his opinion. Obtaining a second medical opinion prior to hospitalization might partially break the causal link between bed availability and demand for services, but it would not counter such influences as administrative pressure to fill empty beds by admitting patients unnecessarily in advance of surgery and needlessly extending hospital stays.[57]

---

54 A study showed that 25% of the operations in an east coast suburb for which patients were hospitalized were performed on an ambulatory basis in a west coast prepaid health system without adverse health effects. V. FUCHS, *supra* note 2, at 59, *citing* Hughes, Lewit, Watkins & Handschin, *Utilization of Surgical Manpower in a Prepaid Group Practice* (National Bureau of Economic Research Working Paper 19) (1974).

55 This phenomenon, which occurs irrespective of the prevailing level of hospital use, has been dubbed "Roemer's law," after the first individual to document its existence. Klarman, *supra* note 36, at 556. The net result of more sophisticated studies, while not unanimous in their conclusions, support a causal link between bed supply and amount of hospitalization. P. O'DONOGHUE, EVIDENCE ABOUT THE EFFECTS OF HEALTH CARE REGULATION 62-63 (1974).

56 A recent study, showing that physicians and their spouses undergo an equal or greater number of selected operations than other similarly situated professionals, discounts the role played by venal considerations in determining the number of surgical operations. Bunker & Brown, *The Physician-Patient as an Informed Consumer of Surgical Services,* 290 NEW ENG. J. MED. 1051 (1974). However, this does not lessen the implications of bed supply upon demand or demonstrate that the current number of operations is socially advantageous or that the lay individual receives the most economical treatment consonant with medical effectiveness.

57 V. FUCHS, *supra* note 2, at 59. For instance, hospital administrators might pressure staff physicians to admit patients on Friday when surgery is not scheduled until early the following week so as to boost otherwise low weekend occupancy rates.

Efficiency is not rewarded and inefficiency is not deterred within the hospital care sector. In no other major economic sector does the consumer possess so little knowledge of his needs or is the provider clothed in such reverence. Patients who infrequently use hospital facilities develop no basis on which to compare institutions, so that they routinely accept their doctor's recommendation of treatment facility, especially when any cost differential is paid by an insurer. A doctor saves time and furthers his own convenience by seeking staff privileges at, and thus assigning his patients to, only one or two hospitals,[58] and different hospital operating costs are not considered when choosing among available hospitals.[59] Even if a patient has a preference for a particular hospital, his allegiance to a trusted physician can be expected to outweigh that preference and incline him toward accepting care at the hospital to which the doctor sends him. Certain of reimbursement for all but the most unreasonable expenditures, the hospital will also give priority to objectives other than the economical delivery of services. In fact, certain current reimbursement formula which provide for accelerated depreciation or a bonus payment based on certain expenditures reward institutional spending rather than efficiency.[60]

In sum, the evident high cost of hospitalization, which results from misallocation of resources and institutional inefficiency, is a consequence of an even more basic condition: the lack of market control on hospitals.

II. Previous Government Health Care Programs

The fundamental importance of health care and the absence of suitable market regulating devices has prompted federal involvement in this sector since the end of World War II. A brief review of some of these efforts reveals the origins of

---

58 J-L. Migue & G. Belanger, *supra* note 44, at 15.

59 E. Kaitz, Pricing Policy and Cost Behavior in the Hospital Industry 78 (1968).

60 Medicare, for example, originally compensated hospitals for costs, plus 2% of gross expenditures. 20 C.F.R. § 405.428 (1977). It presently provides a reimbursement bonus of 8% of nursing staff expenditures. 20 C.F.R. § 405.430 (1977).

both the current cost control proposals and the framework within which they will operate.

Immediately following World War II, Congress instituted a program designed to remedy perceived shortages of medical facilities. The Hill-Burton Act,[61] from its enactment in 1946 to its expiration and replacement by the Health Planning and Resource Development Act of 1974,[62] helped finance the construction of almost 496,000 hospital beds, moderated geographic disparities in supply, and increased the bed-to-population ratio from 3.3 to 4.4 per 1000.[63]

The success of its initial programs allowed Congress in 1966 to shift the focus of its health care goals from expanding the system of institutional care to making medical treatment available to those otherwise unable to afford it. The medicare[64] and medicaid[65] programs were the instruments by which the government sought to replace ability to pay with need for medical treatment as the criterion for receiving care. In an effort to secure the support of medical providers for these redistributive undertakings and because of the vexing problem of defining a standard unit of health care, the initial statutes included a cost-of-service payment system. Originally, hospitals were compensated according to estimates of their costs of treatment, and, at the end of their accounting period, they received retroactive adjustments so as to assure that their actual costs were paid.[66] Regulations promulgated by the Department of Health, Education, and Welfare (HEW) only denied recovery of clearly unreasonable costs.[67]

61 Hospital Survey and Construction Act, Pub. L. No. 79-725, 60 Stat. 1040 (1946).

62 42 U.S.C. § 300k (Supp. V 1975).

63 CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 19.

64 79 Stat. 290 (1965) (codified in scattered sections of 42 U.S.C.). Medicare is a basic hospital insurance plan providing a broad range of hospital and post-hospital services, subject to deductible and coinsurance provisions, for all persons who reach age 65 and are covered by the social security retirement program. The plan also contributes one half of the cost of a voluntary supplementary medical insurance plan covering physician services. Davis, *Equal Treatment and Unequal Benefits: The Medicare Program*, 53 HEALTH & SOC'Y 449 (1975).

65 79 Stat. 290 (1965) (codified in scattered section of 42 U.S.C.). Medicaid is a partially federally funded program administered by the states which provides reimbursement to health care providers for services rendered to qualifying indigents.

66 Weiner, *supra* note 45, at 7-8.

67 *Id.* at 9-13.

The medicare and medicaid programs, while progressing significantly toward their distributional goal, demonstrated that no nation can afford to satisfy every health care demand or deliver the quantum of services that providers would choose.[68] The elimination of price rationing catapulted national health expenditures upward, subsidized overexpansion of the supply of hospital facilities, and added new force to the distorting effects of third party payors upon the composition of services.

Alarmed by the rapidly rising costs of federal programs, Congress reacted with the 1972 amendments to the Social Security Act.[69] It granted the Secretary of Health, Education, and Welfare authority to set prospective limits on reimbursements for hospital care and, under what is commonly known as the section 1122 program, to disallow reimbursements for interest and depreciation on those capital expenditures deemed unnecessary by state health planning agencies.[70] These alterations, however, only slightly reduced the outlay for what remains today an essentially retrospective, cost-based payment system.[71]

The 1972 amendments also sought to alter physician behavior by establishing Professional Standards Review Organizations (PSROs) to monitor the necessity for and economic efficiency of care provided under federal programs.[72] However, since these local organizations are operated by private physicians who frequently delegate review responsibilities to hospital-based committees, their potential effectiveness is questionable, for there is doubt about the rigor with which doctors will criticize their colleagues.[73] Empirical evidence from early programs, most of which were initiated prior to the federal legislation, indicates

---

68 *See also* M. COOPER, RATIONING HEALTH CARE 8-10 (1975).

69 Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1386 (1972) (codified at 42 U.S.C. § 1320a-1 (Supp. V 1975)).

70 *Id.* § 221.

71 *See* note 45 *supra.*

72 Social Security Amendments of 1972, Pub. L. No. 92-603, § 249F, 86 Stat. 1429 (current version at 42 U.S.C.A. § 1320(c) (West 1974, Supp. 1977 & Supp. 4 1978)).

73 R. WARD, *supra* note 30, at 78.

mixed results.[74] Consequently, the most promising benefit from this program would be an improvement in the quality of medical care by reducing poor medical practices, rather than a significant decline in expenditures.[75]

Continued price escalation following the 1972 amendments and concern about the medley of new hospital services led to the Health Planning and Resource Development Act of 1974, which requires the HEW Secretary to designate a Health Systems Agency (HSA) for each of the nation's 205 health service areas. Hospital capital expenditures in excess of $100,000 must receive a certificate-of-need from the local HSA,[76] which is to be guided in its considerations by a state health master plan developed by a Statewide Health Coordinating Council and by rules promulgated by the Secretary.[77] These state planning agencies, except the five established prior to the 1974 legislation, have been weak planners. Hampered by budget constraints,[78] by local political pressures to approve projects,[79] by inadequate decision criteria,[80] and by the inability to ensure compliance with their decisions,[81] they have been generally impotent to effect significant cost reductions.[82]

Congress proceeded concurrently against economy-wide in-

---

74 CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 37.

75 *Id.* at 38.

76 All states must have an approved certificate-of-need program in operation by September 30, 1980, or else be excluded from most federal health grants. CBO FOR HEALTH, *supra* note 4, at 35.

77 42 U.S.C.A. §§ 300k-1 to 300k-2 (West Supp. 1977). On September 26, 1977, the Secretary issued bed-to-population ratio standards. This followed a finding by the Senate Committee on Human Resources that the Secretary had not timely promulgated necessary regulations for the development and implementation of state health and medical facility plans. SENATE COMM. ON HUMAN RESOURCES, 95TH CONG., 1ST SESS., THE HOSPITAL COST CONTAINMENT ACT OF 1977: SUMMARY AND ANALYSIS OF CONSIDERATION 24 (1977) [hereinafter HUMAN RESOURCES REPORT].

78 H.R. REP. NO. 93-1392, 93rd Cong., 2d Sess. 64 (1974).

79 Havighurst, *supra* note 39, at 1183-84.

80 Cohen, *Regulating Health Care Facilities: The Certificate-of-Need Process Reexamined*, 10 INQUIRY 3, 7-8 (Sept. 1973).

81 35 CONG. Q. WEEKLY REP. 2129, 2131 (1977). Consequences of proceeding without a permit are limited to nonreimbursement under the medicare and medicaid programs for interest and depreciation on unapproved expenditures.

82 CBO FOR HEALTH, *supra* note 4, at 35.

flation with the Economic Stabilization Program (ESP),[83] taking special recognition of the health care sector's peculiarities. The Phase One price freeze included hospitals, but left uncontrolled cost reimbursements which were not considered "prices."[84] Phase Two, and its continuation as Phase Three, which did not apply to most other sectors, limited each hospital's total revenue per inpatient day, adjusted for changes in volume, to an annual increase of six percent.[85] Phase Four was an improvement over previous plans because it based the reimbursement limit on revenues per admission. However, its application to hospitals was precluded by the expiration of the ESP in 1974. Significantly, the ESP direct wage-and-price controls reduced the rate of increase of hospital expenditures by 25 percent[86] and produced the first and only year since 1950 during which the hospital industry did not grow faster than the general economy.[87] However, the year after the lifting of ESP controls, hospital expenditures climbed an unprecedented 17.6 percent.[88] This jump may indicate an inability to suppress indefinitely hospital cost increases by means of a revenue ceiling alone. But the progressive decline during the three years of ESP controls, 1971-1973, of hospital expenditures as a proportion of the GNP suggests that more-carefully devised government controls might genuinely be able to alter the structure of the hospital market.

While mostly confining its own efforts to tinkering with cost-based reimbursement formulations, the federal government has encouraged others to experiment with more fundamental market alterations designed to reintroduce

---

83 Economic Stabilization Act Amendments of 1971, Pub. L. No. 92-210, 35 Stat. 743 (1971).

84 Ginsberg, *Inflation and the Economic Stabilization Program,* in HEALTH: A VICTIM OR CAUSE OF INFLATION? 31, 34 (M. Zubkoff ed. 1976).

85 The six-percent lid was subdivided to allow a 5.5% increase in wage expenses and a 2.5% increase in nonwage expenses; 1.7% of total expenditures was to be devoted to new technology. HUMAN RESOURCES REPORT, *supra* note 77, at 8.

86 INTERSTATE AND FOREIGN COMMERCE REPORT, *supra* note 45, at 4.

87 AMERICAN HOSPITAL ASSOCIATION, *supra* note 11, at v.

88 *Id.* at xiii.

operating efficiencies and cost competition.[89] State programs, including line-by-line budget reviews,[90] payments according to a prospectively determined formula,[91] and negotiated rates,[92] have been tried but with frequently insignificant results.[93] Prepaid health maintenance organizations (HMOs) received legislative sanction in 1973,[94] and again in 1974.[95] The advantages of HMOs, as claimed by their proponents, include price competition between health care providers, inducement to practice preventive medicine, incentives to avoid overuse of existing facilities, and lack of pressure to purchase unneeded equipment.[96] Despite some

---

89 The Department of Health, Education and Welfare has been evaluating state and local experiments and financing other local demonstration and evaluation projects under authority included in the Social Security Act Amendments of 1967 and 1972, and § 1526 of the National Health Planning and Resource Development Act of 1974. HUMAN RESOURCES REPORT, *supra* note 77, at 10.

90 Eighteen of the 35 hospitals in Connecticut voluntarily submitted the budgets of those departments which were under tightest administrative control for prospective approval by peer review panels. Budget targets were retrospectively adjusted for volume changes and reimbursement was based on the greater of cost or target level. Elnicki, *SSA-Connecticut Hospital Incentive Reimbursement Experiment Cost Evaluation,* 12 INQUIRY 47 (March 1975).

91 New York has been operating two experimental per diem-based prospective reimbursement programs since 1970. Rate increases are determined for each hospital by applying a standardized formula to past costs. Reimbursement for routine costs is limited to 110% of the categorical mean in which a hospital is placed. Groupings are based on size, type, ownership, and geographical location. Also, rates are computed as if the hospital maintained a standardized minimum occupancy. The reimbursement rate is final regardless of actual cost, but retrospective appeals are permitted and are frequent. 2 HEALTH CARE MANAGEMENT REV. 15 (Fall 1977).

92 The Rhode Island hospital association annually negotiates with Blue Cross to establish a statewide "maxicap" for total hospital revenues. Individual hospitals then negotiate their own budget with Blue Cross. Settlements are not final, however, until all negotiations are completed and the statewide total has been held within the maxicap (the 1975 cap was 13.85% above the previous year's expenditures, but actual expenditures increased slightly over 15%). Each hospital retains 50% of its operating savings beneath its projected budget and receives no compensation for costs in excess of its budgeted allowance. *Id.* at 13, 21.

93 A study of five experiments, all using per diem reimbursements based upon expected costs, shows savings of one to four percent in per diem costs. However, net savings were lower because the average length of stay in these hospitals did not fall as rapidly as in non-experimental hospitals. CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 39-41.

94 Health Maintenance Organization Act of 1973, Pub. L. No. 93-222, 87 Stat. 914 (current version at 42 U.S.C.A. § 300(e) (West 1974 & Supp. 1977)).

95 Health Maintenance Organization Amendments of 1976, Pub. L. No. 94-460, 90 Stat. 1945 (codified at 42 U.S.C.A. § 300(e) (West Supp. 1977)).

96 *See* Roberts & Bogue, *The American Health Care System: Where Have All The Dollars Gone?* 13 HARV. J. LEGIS. 635, 646-47 (1976).

studies which indicate cost advantages,[97] other studies have questioned whether HMO subscribers are representative[98] and whether sufficient population densities exist to make them practicable and competitive with each other on a wide scale.[99]

In short, few would be tempted to describe the history of government cost control programs for hospitals as a chronicle of successes. Indeed, as the hospital cost problem has become more severe, the need for a different approach to the problem has become apparent.

III. Cost Control Proposals

Because expenditures for hospital care are annually displacing larger amounts of personal and federal spending and because existing government programs held no promise of significantly retarding the increases or controlling the causes, it was not surprising that potent and multiple hospital cost control bills were introduced during the first session of the Ninety-fifth Congress.

A. *The Carter Administration Proposal*

The Carter Administration forwarded to Congress a proposal, S. 1391 and H.R. 6575,[100] which would (1) place a ceiling on each hospital's total revenue and revenue per patient and

---

97 R. Ward, *supra* note 30, at 14, 15.

98 *Id.* at 14; *see* note 99 *infra;* Roemer & Schonick, *HMO Performance: The Recent Evidence,* 51 Health & Soc'y 271, 276-78 (1973).

99 Reinhardt, *Proposed Changes in the Organization of Health-Care Delivery: An Overview and Critique,* 51 Health & Soc'y 169 (1973).

Conspicuously absent from previous programs designed to foster competition are efforts to encourage ownership of conventional hospitals by profit-seeking investors. Reluctance to try this approach may be attributable to the political consequences of challenging the powerful constituency of nonprofit institutions, *see generally* Marmor, Wittman & Heagy, *Politics, Public Policy, and Medical Inflation,* in Health: A Victim or Cause of Inflation? 299, 308-09 (M. Zubkoff ed. 1976), and the ignominy of appearing to support the notion of making a profit from sickness. Yet, even if proprietary hospitals were to be assisted, continued cost-based reimbursement would lessen their incentive to economize, and comparative cost studies with similarly sized nonprofit hospitals do not show that proprietary hospitals have an overall advantage. Steinwald & Newhauser, *The Role of the Proprietary Hospital,* 35 Law & Contemp. Prob. 816, 837 (1970); Ruchlin, Pointer & Cannedy, *A Comparison of For-Profit Investor-Owned Chain and Nonprofit Hospitals,* 10 Inquiry 13, 14-15, 21 (Dec. 1973).

100 Identical measures, known as the Hospital Cost Containment Act of 1977,

(2) limit and allocate community hospital capital expenditures.[101] This proposal would apply only to short-term acute-care hospitals and not to outpatient services, HMOs, hospitals less than two years old, and federal hospitals.[102]

1. Limits on Revenue

Title I of S. 1391 limits each hospital's annual revenue to its adjusted "base year" (usually 1976) revenue, plus an annually determined percentage increase. The amount of the increase will be uniform across the nation and is cumulative even if the actual increase in a hospital's revenue falls short of the permitted percentage in any individual year. For example, if a hospital's adjusted base year revenue is $1 million and an annual 10 percent increase is allowed in each of the following two years, then for the first year (following the base year), the hospital's revenues are to be kept beneath $1.10 million; and for the second year, they are to be kept beneath $1.21 million, even if the actual first year revenues were less than the permitted $1.10 million. The permitted revenue increases are determined by a formula which reflects economy-wide price increases (inflation) and which also contains a fac-

---

were introduced by Senators Kennedy, Hathaway, and Anderson and by Representatives Rogers and Rostenkowski on April 26, 1977. Owing largely to the efforts of Senator Kennedy, chairman of the Health and Scientific Subcommittee, a modified version of S. 1391 was approved by the Senate Committee on Human Resources on September 3, 1977. COMMITTEE ON HUMAN RESOURCES, 95TH. CONG., 1ST. SESS., THE HOSPITAL COST CONTAINMENT ACT OF 1977: SUMMARY AND ANALYSIS OF CONSIDERATION 63-86 (1977) [hereinafter S. 1391 as approved]. A report to the full Senate will be filed if and when the bill is approved by the Finance Committee.

Hereinafter in the text S. 1391 refers to the bill as approved by the Human Resources Committee. Comparisons with the text of the original proposal will be noted when significant.

101 A "capital expenditure" is the construction, purchase, or lease of a facility or equipment which substantially changes the bed capacity or services of an institution.

102 Excluded are hospitals which are affiliated with HMOs, are less than two years old, have two thousand or less admissions annually, or have between 2000 and 4000 admissions annually and are sole community providers. S. 1391 as approved, *supra* note 100, § 121. S. 1391, as first introduced, did not exclude hospitals with fewer than 4000 admissions but did subject them to more lenient revenue constraints. *Hearings on S. 1391 Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources,* 95th Cong., 1st Sess., Vol. 1, at 3-41 (1977) [hereinafter S. 1391 original proposal].

tor permitting a rise in the amount of hospital services rendered per patient (intensity).[103]

The national revenue ceiling formula is tailored to each hospital by adjusting for changes in the institution's patient volume. Change in volume is measured by the average of the percentage change in number of admissions and in number of patient days. Total revenue may increase above the formula amount by the estimated marginal cost of treating additional patients, estimated to be 50 percent of the average per-patient revenue, for patient loads in excess of 102 percent; and the total revenue must decrease by 50 percent of the average per-patient revenue for loads beneath 90 percent of the base-year volume. No upward adjustment in total revenue is allowed, however, for volume increases over 115 percent of the base-year load, and the revenue ceiling decreases by the entire amount of the per-patient rate for declines in volume beneath 85 percent of the base-year load.[104] In order to assure equitable price increases among the different payors for hospital services, the average per-patient revenue from each cost payor (*e.g.*, medicare or Blue Cross) and aggregate charge payors (those who pay posted fees) may not increase by more than the amount per patient which corresponds to the above described formula limiting total revenues.[105]

The hospital revenue ceiling is enforced by the nonpayment of medicare and medicaid funds in excess of its prescribed level, by suspending the hospital or cost payor from these programs at the Secretary's discretion, and by imposing a 150 percent excise tax on hospitals and cost payors for payments above the ceiling. A hospital which exceeds its prescribed revenue limit will be exempted only if it places an amount equal to the excess revenues in escrow until such time as future charges fall below the established limit by that amount.[106]

---

103 S. 1391 as approved, *supra* note 100, at § 112.

104 *Id.* § 113. This formulation is similar to Phase Four of the Economic Stabilization Program. *See* text at notes 83 to 87 *supra.*

105 *Id.* § 111.

106 *Id.* § 116.

Exceptions to the revenue limits may be granted to hospitals by the Secretary, based on clear minimum standards and subject to his discretion. Secretarial consideration will be given to unusual costs, due either to extraordinary volume changes or to HSA-approved alterations in services or physical facilities;[107] the unusual costs must also have brought the threat of short-range financial insolvency upon the hospital, as indicated by the existence of a current-asset-to-current-liability ratio of less than two.[108] A hospital which has excessive costs due to inordinate patient volume changes receives a corresponding extension of the range of volumes for which it may increase or decrease its revenues by the standardized marginal cost of treatment; that is, a volume increase over 115 percent of base year load will be compensated, at one-half of the normal rate, to the full extent of the increase. If the circumstance justifying the exception is a change in services or physical plant, the relief is limited to removing the hospital's imminent financial crisis by a sufficient increase in the revenue ceiling to raise the current-asset-to-current-liability ratio to two. Alternatively, a hospital may petition for an exception if its revenues have declined because of a change in services offered or a substantial shift in the composition of its cost payors.[109] A hospital so excepted will have its revenue ceiling adjusted so that the ceiling's subdivision, which limits the amount of revenue received from any particular payor, or the ceiling's diminution because of an approved shift in services, will no longer cause the total revenue actually received to be beneath the hospital's otherwise-allowed total revenue ceiling. The bill also empowers the

---

107 The Secretary shall also consider an exemption requested by a hospital if that hospital changes services for which reimbursement is received from a cost payor, or if the basis used by a reimbursing cost payor has changed, or if the proportion of changes attributable to any cost payor has changed significantly. *Id.* at §115.

108 While a ratio of 2:1 is commonly accepted as an indication of financial well-being, it is not such an indication with respect to not-for-profit hospitals. A current ratio of 2:1 for these hospitals is considered "ideal," while a ratio of 1.5:1 is "normal," and a ratio of 1:1 is "problematic." Arthur Andersen, Saint John's Hospital and Health Center and Saint John's Hospital and Health Center Foundation: Hospital Financial "Rules of Thumb" (Aug. 18, 1978) (manuscript on file at Harvard Journal on Legislation).

109 S. 1391 as approved, *supra* note 100, at § 115.

Secretary to conduct an efficiency review of any hospital granted an exception and to discontinue the exemption for non-compliance with his recommendations.[110]

The bill provides that wage increases for nonsupervisory personnel are to be automatically "passed through" by raising the revenue ceiling by the fraction of the wage increase which corresponds to the fractional portion of total costs attributable to wage expenses.[111] For example, if wage costs constitute 60 percent of a hospital's total cost and they increase 5 percent, then the total revenue ceiling will be increased by 3 percent.

About 60 percent of the approximately 4000 nonfederal short-term acute-care hospitals, which account for 93 percent of national community hospital expenditures, will be within the scope of S. 1391.[112] But somewhat fewer than this number will be restricted to the prescribed revenue limits in S. 1391 because some will be granted exceptions. The permitted increase in hospital revenues, including adjustments for wage increases and volume changes, will be restricted to approximately 10 percent in the program's first year and will decline to 9 percent by its third year.[113] Annual nationwide savings are expected to rise from $2.4 billion in 1978 to $18.8 billion in 1982,[114] and reductions in federal outlays for the same two years are projected to rise from $1.24 billion to $9.17 billion.[115]

2. Capital Expenditure Control

Title II of S. 1391 empowers the Secretary to set a national ceiling on hospital capital expenditures, not to exceed $2.5 billion annually. This amount will be allocated by the Secretary to the states, initially on the basis of population,

---

110 *Id.* § 115(d).

111 *Id.* § 124. The original bill contained an optional pass-through at the discretion of the hospital administrator.

112 HUMAN RESOURCE REPORT, *supra* note 77, at 29.

113 *Id.* at 27-28.

114 CBO FOR HEALTH, *supra* note 4, at 13.

115 HUMAN RESOURCES REPORT, *supra* note 77, at 27.

but later on the basis of enumerated factors and on any other factors that the Secretary deems relevant.[116]

S. 1391 also places a qualified moratorium on any single capital expenditure by a hospital which exceeds $150,000 (hereinafter capital project). A hospital may not undertake a capital project without a certificate-of-need from an approved state program, unless it already had contracted to acquire or had state approval to acquire the new facility.[117] The bill also amends the requirements for Secretarial approval of state certificate-of-need programs as contained in the Public Health Service Act.[118] Henceforth, the Secretary is to deny approval to any state program which does not limit certificates-of-need to projects with an aggregate value within that state's annual capital allowance as determined by the Secretary, or to any program which fails to classify as "not appropriate" any existing health facility that if newly proposed would not qualify for a certificate-of-need.[119] In states without an approved program, all capital projects which require a certificate-of-need are treated as though they have no certificate; in these states, therefore, there would be a total moratorium on major acquisitions. Furthermore, the bill removes the financial burden of retiring an existing facility, designated by the state as "not appropriate," by granting to the affected institution an amount equal to the indebtedness then outstanding on the decommissioned asset.[120]

The bill's restrictions upon the proliferation of facilities are enforced by a combination of penalties and restrictions on government payments. Hospitals which proceed with a capital project that requires, but has not been granted, a certificate-of-need are liable in a civil suit for damages in an

116 S. 1391 as approved, *supra* note 100, at § 201.

117 *Id.* §§ 201(b)(1)(B) & (b)(2).

118 Pub. L. No. 93-641, § 1515, 88 Stat. 2239-41 (current version at 42 U.S.C.A. § 3001-4 (West Supp. 1977)).

119 S. 1391 as approved, *supra* note 100, at § 205. The original bill did not require the disapproval of existing facilities. In order to lessen the hardship inflicted by the adopted provisions, grants up to the amount of outstanding debt on disapproved facilities may be made to institutions that retire such assets.

Bed-to-population standards originally fixed in the bill have been incorporated into HEW regulations. *See* note 77 *supra.*

120 *Id.* § 206. The dependence on HSAs continues present policies. *See* text at notes 77 to 82 *supra.*

amount not less than twice the prohibited expenditure nor more than twice the operating revenues derived therefrom.[121] Existing facilities or services deemed "not appropriate" will be denied reimbursement for care rendered to recipients of government assistance in an amount equal to ten times the capital expended for their purchase.[122] As enforced by these penalties, the qualified moratorium would cause capital spending in 1982 to tumble from a projected $14.1 billion to $4.6 billion, of which $2.5 billion would be subject to certificates-of-need.[123]

If both the revenue ceiling and the qualified capital expenditure moratorium provisions are enacted, the decline in capital spending should not affect total savings induced by the proposal because of the already constraining impact of the revenue limitations. If only the capital expenditure limit is adopted, on the other hand, the savings from reduced expenditures and operating costs are projected to be $780 million in the first year and $15.1 billion after five years.[124] But patients would not necessarily benefit from these savings unless a mechanism were to be included to ensure that the savings are passed on to the consumer rather than reinvested in the hospital.[125]

B. *The Talmadge Proposal*

Senator Talmadge's initiative, S. 1470,[126] seeks to promote efficiency by reimbursing hospitals according to a prospective formula and by eliminating or redistributing underutilized hospital beds. The formula's application is limited to

121 *Id.* § 202.
122 *Id.* § 205(d).
123 CBO FOR HEALTH, *supra* note 5, at xx.
124 *Id.*
125 Additional paperwork necessitated by this bill is held to a minimum. Accumulation and computation of data necessary for routine compliance will total 105 hours per year per hospital (double this amount for hospitals not currently participating in any federal program). In addition, an estimated seven hundred applications for exemption from the revenue ceiling will be filled, each requiring approximately 40 hours to prepare. HUMAN RESOURCES REPORT, *supra* note 77, at 29-31.
126 S. 1470 and H.R. 7079 are known as the Medicare-Medicaid Administrative and Reimbursement Reform Act. S. 1470, 95th Cong., 1st Sess. (1977) [hereinafter S. 1470]. They were introduced on May 5, 1977, and May 10, 1977, respectively, by Senator Talmadge and Representative Rogers.

routine hospital services (principally room and board) and only those provided to patients under the medicare and medicaid programs. While the bill was originally introduced as a supplement to the Administration's plan, its different conception of the problem and thus different objective—it seeks to induce individual institutional efficiency rather than limit the total revenues of the hospital sector—soon became apparent.[127] As a result, Senator Talmadge subsequently announced his willingness to expand his legislative framework to incorporate all hospital care payors and to include the panoply of available services.[128]

The Talmadge bill* categorizes hospitals according to size, type, and unspecified "other criteria" and (after the establishment of a uniform cost accounting system) provides reimbursement to each hospital based on its categorical average per diem cost for routine operating services.[129] To account for disparities in wage levels, the bill divides this categorical average into wage and nonwage cost components; a hospital is paid the average nonwage cost and is also paid the average wage cost, adjusted to account for the local wage level. The reimbursement rate is further adjusted semiannually to reflect price increases in the mix of goods and services comprising hospital purchases. Under the bill, hospitals will be reimbursed by the government for their actual cost of service rendered to medicare and medicaid patients only up to 120 percent of the average adjusted per diem rate for their category.[130] By advising patients in advance, however, a

---

*This article discusses the bill as drafted but treats the bill as if it applied to all payors and services in order to compare the bill with the Administration proposal as a solution to the hospital cost problem.

127 *See* 35 CONG. Q. WEEKLY REP. 1163 (1977).

128 *Hearings on S. 1470 Before the Subcomm. on Health of the Senate Comm. on Finance,* 95th Cong. 1st Sess. 71-72 (1977) (statement of Senator Talmadge) [hereinafter cited as *Hearings on S. 1470*].

129 The Secretary of HEW is instructed to develop methods for extending this system to all other costs as soon as practicable. S. 1470, *supra* note 126, at § 2(c). Senator Talmadge reported that his staff anticipates being able to include 80% of total expenditures by the date of passage. *Hearings on S. 1470, supra* note 128, at 72.

130 S. 1470, *supra* note 126, at § 2(b). A hospital whose costs exceed 120% of the mean of its own category may receive reimbursement as if it had been classified in the next closest bed-size category. *Id.*

hospital can charge them personally for any excess costs which the government refuses to reimburse. If a hospital's costs are less than the adjusted average, it receives a bonus of the lesser of 5 percent of its actual costs or 50 percent of the difference between the adjusted average and its actual cost.[131] This plan includes exemptions for hospitals in underserved locations and for those with demonstrably special circumstances. Hospitals in states with cost control plans are also excluded.[132]

A Hospital Transitional Allowance Board is established to promote the closing of unnecessary hospital facilities. It may award reimbursement for lost revenue to not more than fifty hospitals which voluntarily retire excess bed capacity or under-utilized services before January 1, 1981.[133] The bill also eliminates statutory barriers to the conversion of low-occupancy, rural short-term hospital beds into long-term skilled nursing facilities.

The Talmadge proposal also strengthens the penalties for violating section 1122(b) of the Social Security Act, which requires any capital expenditure of $100,000 or more to be approved by the regional HSA.[134] Hospitals which purchase a capital asset without a permit will be denied medicare and medicaid reimbursement for the attributable interest on borrowed funds, depreciation, return on equity, and operating costs.[135] Furthermore, every health care facility is required to publish a prospective annual operating budget and a five-year capital expenditure plan.[136]

The Secretary would, under S. 1470, first establish categorical reimbursement rates in January 1979,[137] and hospitals will be assessed penalties and receive incentive

---

131 *Id.*
132 *Id.* § 2(e).
133 *Id.* § 3.
134 The required HSA approval has questionable value. *See* text at notes 77 to 82, *supra.*
135 *Id.* § 4(c).
136 *Id.* § 4(e).
137 *Id.* § 2(b).

payments beginning in fiscal year 1981.[138] Savings by 1982 are expected to range between $100 and $400 million.[139]

IV. Criticism of the Proposals

The Carter Administration proposal and the Talmadge proposal represent significantly different approaches to the hospital cost control problem. The strengths and weaknesses of each approach can be readily identified by looking at the proposals' effects on three factors—the costs of hospitalization, the supply of hospital facilities, and the demand by patients for hospital services.

A. *The Carter Administration Proposal*

President Carter's initiative, through its revenue ceiling provision, will succeed in reducing the growth rate of expenditures for hospitalization. It does not assure, however, that the slowed growth will be achieved through greater efficiency and fewer purchases of unnecessary facilities. Nonetheless, by forcing physicians and hospitals to give greater consideration to the consequences of their resource allocation decisions, the proposal will induce a shift in hospital services toward those patients whose medical demand is most acute.

1. Costs of Hospitalization

The Administration bill will boldly terminate uncontrolled growth in the dedication of our society's finite resources to hospital-based health care. Through its revenue ceiling, the Carter proposal places a statutory limit upon the increase in national spending on hospitalization. However, the arbitrariness of the formula which establishes the level of the revenue ceiling indicates a failure to make the explicit judgment which must underlie a reasoned proposal, that is, a

138 *Hearings on S. 1470, supra* note 128, at 72.

139 CBO FOR HEALTH, *supra* note 4, at 27-28. This estimate of savings is imprecise, but it is the only one available. Based on the hospital industry response to the ESP, this estimate may poorly predict hospital behavior today under a program with a longer preparatory period. Also it may not adequately anticipate changes in hospital operations induced by the legislation. *Hearings on S. 1470, supra* note 128, at 72-73.

failure to make or to recognize the need for a political determination of the particular growth rate of hospital services that our society desires. Furthermore, the bill's potential for limiting total expenditures is not matched with similar efficacy in making hospital operations more efficient, the other aspect of the hospital cost problem.

The dynamics of the revenue ceiling formula assure that its benefits will be amplified over time. Annual revenue increases are permitted by the amount of inflation during the previous year, plus one-third of the difference between the rate of inflation and the rate of national hospital expenditure increases over the previous two years.[140] The result is that initial reductions in hospital expenditures will narrow the difference between expenditures in this sector and price increases economy-wide, which in turn will cause continued future formula reductions toward the general level of inflation.

Increases in the intensity of hospital services, as measured by the differential between the rate of expenditure increases and inflation, will immediately begin to lag behind the projected rate of real economic growth.[141] While a net growth in hospital services will continue, this slowdown in intensity growth will reverse the twenty-seven year trend of allocating an increasing share of our national product to this sector. More of the surplus generated by economic growth can then be committed to other medical programs or other economic sectors with greater potential benefit.

The efficacy of this proposal should also be enhanced by excluding from the revenue ceiling hospitals which have fewer than 2000 admissions per year, or which are sole providers of service to a rural area and have fewer than 4000 admissions

---

140 S. 1391 as approved, *supra* note 100, at § 112.

141 During the first year of the program, the increase in intensity will fall from its preceding eleven-year annual average of 6.1% to 3.21%. The fifth year should see the rate of increase below 2%. CBO FOR HEALTH, *supra* note 4, at 14-15. This compares to a projected rate of real economic growth of 4% to 4½% during 1978. JOINT ECONOMIC COMMITTEE, THE 1977 MIDYEAR REVIEW OF THE ECONOMY 14, H.R. Rep. No. 95-652, 95th Cong., 1st Sess. (1977).

per year.[142] This excludes 40 percent of all hospitals but only 7 percent of total hospital revenue.[143] These exclusions also ensure that a small hospital which provides the only institutional care in an area is able to respond to the demands of increased community population,[144] thereby permitting delivery of the improved medical services needed by the rural public.[145]

There appears to be no reason, however, to urge the particular formula included in the bill as the vehicle to reduce the growth rate of hospital services. The formula was chosen without any indication of an underlying principle which would justify the projected rate of growth of the revenue ceiling.[146] Furthermore, there is no reason to consider the measure of permitted growth in the intensity of services rendered, one-third of the difference between the rate of increase of economy-wide prices and the rate of national hospital expenditures, as intrinsically appropriate. The formula's tendency toward randomness is aggravated by the fact that prices for the particular mix of products which hospitals purchase have recently been rising faster than the "GNP implicit price deflator," which is used to adjust the revenue ceiling under the Administration proposal.[147] Therefore, until the Secretary of HEW exercises his authority[148] to replace the price deflator with a more accurate index

---

142 S. 1391 as approved, *supra* note 100, at § 121.

A definite pattern of hospital facility expansion has been documented. Virtually all hospitals contain facilities to provide a basic core of five services. They can only afford to add facilities which enhance the quality of the basic services as patient volume expands. The mean number of patients admitted to these "quality-enhancing" hospitals is 3,706 per year. The next stage of expansion, in which a hospital adds more complex facilities, does not occur until a hospital exceeds the statutory exemption for low volume hospitals (mean number of admissions is 8,911 per year). Berry, *On Grouping Hospitals for Economic Analysis,* 10 INQUIRY 5, 9-11 (Dec. 1973).

143 HUMAN RESOURCES REPORT, *supra* note 77, at 29.

144 The number of small hospitals subject to high patient load volatility was over 300% greater than large hospitals during 1975. *Id.*

145 Portnoy & Casady, *Rural Health Program Priorities,* 50 HOSPITALS 68 (1976); Navarro, *The Political and Economic Determinants of Health and Health Care in Rural America,* 13 INQUIRY 111, 111-13 (June 1976).

146 *See* HUMAN RESOURCES REPORT, *supra* note 77, at 15-16.

147 CBO FOR HEALTH, *supra* note 4, at 21-22.

148 S. 1391 as approved, *supra* note 100, at § 131(a)(1).

of hospital input costs, the rate of intensity growth allowed will be reduced by extraneous price fluctuations. A further capricious reduction in the intensity growth permitted some hospitals will be caused by limitations on the adjustments used to bring "base year" revenues current with the legislation's effective date. These adjustments are restricted to 15 percent per year[149] in order to prevent deliberate expansion by hospitals anticipating regulation and to disallow permanent incorporation of innocent, yet excessive, recent rate increases. But those hospitals whose revenues expanded beyond the 15 percent limit because of legitimate circumstances, such as population growth in their service areas, will have no alternative but to absorb the disallowed increase through slower future growth.

By dint of legal compulsion, total hospital revenues will be confined to the prescribed statutory level, but this does not assure that hospital administrators will have the power to so restrict expenditures. An institution's expenditures reflect the composite decisions of private physicians and their patients on the desired amount of hospitalization, tests, and other services. Administrators do not participate in these utilization decisions, except to the extent which they can influence physicians to restrain increases in admissions, tests, and treatment, or can dampen demand by restricting the growth of available services and facilities. Critics have been quick to reprove the indirectness of the linkage between revenue and expenditure control that is so crucial to achieving the proposal's objectives.[150] But data gathered from the ESP[151] and state experimental programs suggest that administrators can alter the average length of stay and admissions when it serves their interest.[152] Besides, these same

149 *Id.* § 111(a)(1). Four and one half percent of the hospitals regulated by this measure exceeded a 15% growth rate in admissions during 1975. INTERSTATE AND FOREIGN COMMERCE REPORT, *supra* note 45, at 52.

150 The bill, as approved, exempts outpatient facilities included in the original proposal such as emergency room and walk-in clinics, so that administrators will not curtail these vital community services which are within their direct control. S. 1391 as approved, *supra* note 100, at § 112(b).

151 INTERSTATE AND FOREIGN COMMERCE REPORT, *supra* note 45, at 4-5.

152 Dowling, *Prospective Reimbursement of Hospitals,* 11 INQUIRY 163, 170 (Sept. 1974).

critics charge that hospitals will circumvent the program by altering their case mix,[153] and this criticism is valid only if administrators have power to influence utilization decisions.

There are, in fact, two methods by which administrators can restrain service increases. They can persuade physicians to reduce unneeded treatment or they can refrain from providing a beneficial service; the bill encourages the first method. Reducing the volume of unneeded treatment appears favorable to a hospital administrator because it allows him to devote increased resources to each patient and thereby better pursue his objective of quality of service. This incentive exists under the Administration bill because a hospital's revenue ceiling remains constant during the first 10 percent decrease in patients treated.[154] The administrator's alternative method of restraining service increases, reducing the growth of facilities, probably cannot be accomplished quickly enough to curtail demand in the near future. Commitments for the average hospital construction project, requiring six years planning,[155] are likely to have already been made well into the future. Consequently, even the immediate imposition of the capital ceiling will leave capital facility expansion exceeding the 1975 rate until 1981.[156]

The revenue ceiling's potential for successfully curtailing the excessive growth of spending on hospital services does not extend to the other component of the cost problem, inefficient hospital operation.[157] In fact, not only does S. 1391 fail

---

153 35 CONG. Q. WEEKLY REP. 917-91 (1977).

154 Total revenues do not change as long as volume remains between 2% and 10% below the base year amount. This allows a hospital to provide an 11% increase in intensity of services per patient without a reduction in total revenue. Volume reductions beneath 10% will continue to raise per-patient intensity, but at the consequence of decreased total revenue. HUMAN RESOURCES REPORT, *supra* note 77, at 16.

155 COMPTROLLER GENERAL OF THE U.S. FOR THE SENATE COMM. ON LABOR AND PUBLIC WELFARE AND THE HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, 92D. CONG., 2D SESS., STUDY OF HEALTH FACILITIES CONSTRUCTION COSTS 171-72 (Joint Com. Print 1972).

156 CBO FOR HEALTH, *supra* note 4, at 40.

157 "Efficiency" may be defined as the least expensive combination of inputs to produce a given output, or the manipulation of a given amount of inputs to achieve the maximum output. Reinhard, *supra* note 99, at 180-81.

to promote efficiency, it will reward past managerial inefficiencies. The bill does, however, minimize the systemic inefficiencies of artificially increased volume and prolonged hospitalization that have heretofore plagued cost control programs. Nonetheless, it inadequately deals with the related evasion of private hospitals' denying treatment to high-cost patients. Further, the wage pass-through provision encourages the inefficient use of hospital assets.

Regardless of its effect upon future efficiency, S. 1391 imposes a significant injustice upon previously efficient hospitals. Because the revenue ceiling increases by a uniform percentage of past costs, those hospitals which have historically operated at inefficiently high cost will be able to enjoy larger dollar revenue increases. Rather than needing larger gains, it is these institutions which should more easily be able to trim their budgets than the institutions which have previously kept expenses to a minimum.

A hospital may avoid improving efficiency, or even increase the cost per unit of care delivered, and still remain within its revenue ceiling by reducing the number of patients treated or the services rendered.[158] A hospital might only be induced to operate more efficiently if its management cannot effect these reductions and if its costs are increasing faster than the formula permits. A hospital's desire to serve its community and retain its proportional patient load, however, weighs in favor of operating efficiencies rather than service reductions.

A recurrent problem with governmental attempts to control hospital costs is an increase in hospitalization beyond a medically justified level that is caused by the methods used to measure the volume of care rendered. Our abilities to diagnose ailments and measure fine gradations in health improvement have not advanced to the point where reimbursement can be based on the benefits of treatment,[159] the actual product of hospitalization. Instead, hospitals must be reimbursed according to the particular equipment, personnel, and

---

158 *See* note 39 and accompanying text *supra.*

159 Shuman, Wolfe & Hardwick, *Predictive Hospital Reimbursement and Evaluation Model,* 9 INQUIRY 17, 23 (June 1972).

processes which they utilize in the delivery of health care. This creates the opportunity for hospitals to avoid regulatory objectives by altering their patterns of operation so as to maximize the revenue as measured by the process-oriented formula for volume. Thus, cost control programs which limit revenues according to a per diem basis tend to generate medically unnecessary extensions of patient visits which lower the cost of treatment per day,[160] but increase total expenditures. This tendency was empirically demonstrated by the ESP, which caused an approximately 50 percent reduction in increases in hospital room and board rates but only a 25 percent reduction in increases per adjusted admission.[161] Because drafters of S. 1391 learned from the ESP experience, the bill is not burdened by the problem of inducing extended stays. It avoids the problem by averaging the number of admissions into the per diem volume measurement used in the ESP, thereby diluting the revenue advantages to a hospital which extends patient visits.

The Administration proposal also deals with another problem raised by incorporating this admissions factor: the possibility that hospitals seeking to maintain their average costs within the revenue limit will alter their patient mix toward those who are cheaper to treat and will induce unnecessary admission of low-cost patients.

Computing volume by averaging the number of patient-days with the number of admissions diminishes the benefits to a hospital from deliberately altering its patient mix. Those patients who are cheapest to treat per admission presumably will have the shortest stays. Therefore, for each percentage increase in low-cost patients admitted, the permitted revenue will be adjusted upward less than one percent, more nearly reflecting the true cost of treating the resulting patient mix. Further evasion is discouraged by its raising the revenue ceiling only after the first 2 percent rise in volume, thereby forcing the hospital to absorb initial cost increases. And volume

---

160 V. FUCHS, *supra* note 2, at 10.
161 INTERSTATE AND FOREIGN COMMERCE REPORT, *supra* note 45, at 4.

changes above this level permit revenue increases at approximately marginal cost only,[162] which minimizes any remaining incentive to increase admissions as a way to pad the regulations. In any event, it is much more difficult for a hospital to effect these evasions than to subvert a pure per diem standard by extending hospital stays for extra tests.[163]

S. 1391 responds only in part to hospitals attempting to avoid adopting efficiency-improving measures. While it deters hospitals from increasing their admission of low-cost patients, it does not adequately respond to the converse problem of private hospitals avoiding high-cost patients. In an attempt to relieve the regulatory pinch on their budgets, private hospitals may relegate those patients whose payor reimburses at a level less than the posted charges to municipal hospitals.[164] S. 1391 empowers the Secretary to investigate allegations of such behavior and to suspend a guilty institution from participating in federal reimbursement programs;[165] and any person may bring a civil action to obtain an injunction against the offending institution either directly or by compelling action by the Secretary.[166] Despite the fact that these sanctions are an improvement over the original bill, which deposited enforcement responsibility with the untested and understaffed HSAs, it still lacks adequate sanctions to deter violations and punish proven violators. Denying violators participation in the medicare and medicaid programs only compounds their shunning of those patients whose reimbursement rate is frequently below posted charges.[167] It would be better to impose sanctions which reduce the revenue ceiling commensurate with the advantages the violating hospital's administrators had hoped to obtain.

Hospital inefficiency is encouraged by the mandatory wage

---

162 HUMAN RESOURCES REPORT, *supra* note 77, at 16.

163 Altmen & Eichenholz, *Inflation in the Health Industry — Causes and Cures,* in HEALTH: A VICTIM OR CAUSE OF INFLATION? 25 (M. Zubkoff ed. 1976).

164 35 CONG. Q. WEEKLY REP. 917-19 (1977).

165 S. 1391 as approved, *supra* note 100, at § 126.

166 *Id.* § 130.

167 CBO FOR HEALTH, *supra* note 4, at 6.

"pass-through" provision of S. 1391. While the mandatory nature of the pass-through is better in one respect than its optional nature in the original bill, it presents problems of excessive wage increases and of distortions in the relative use of capital and labor. If the bill did not contain special accomodation for wage increases, the formula's automatic movement toward allowing revenue increases equal only to the price deflator would unfairly penalize hospital workers. The inexorable decline in the revenue ceiling's rate of growth would prevent hospitals, unless they decrease the level of services, from increasing worker compensation in line with economy-wide wage increases, which historically rise faster than prices.[168] Nonsupervisory health care employees, a traditionally underpaid group when compared with "private sector nonagricultural industry employees,"[169] should not be singled out to shoulder the burden of controlling excessive hospitalization. Their relative lack of bargaining power when hospital administrators face budget constraints was shown during the ESP. Between 1971 and 1974, hospital employee earnings declined from 86 percent to 81.8 percent of the wages paid in the private sector,[170] and this inter-industry disparity will be aggravated under the program unless accomodation is made for wages to increase faster than inflation.

The most disadvantageous method of solving the wage problem is to allow an optional wage pass-through, as the original version of S. 1391 did. It permitted a hospital's administration and employees to agree to concentrate wage increases and claim the pass-through in every other year rather than every year; thus, the employees would not only gain the full wage pass-through, but the hospital would also be able to

---

168 U.S. DEPARTMENT OF COMMERCE, BUREAU OF THE CENSUS, STATISTICAL ABSTRACT OF THE UNITED STATES 415 (1977).

169 INTERSTATE AND FOREIGN COMMERCE, *supra* note 45, at 54 (Table C-4). The accompanying minority report states that benefits to hospital workers from the 1967 extension of the Fair Labor Standards Act and increased unionization have raised their wages to a level higher than comparable workers. *Id.* at 59. However, the sources it cites do not support this conclusion.

170 *Id.* at 54.

increase its revenue by the full amount allowed for both wage and non-wage expenditures in years without a wage increase. The mandatory pass-through in the committee-approved bill eliminates this loophole, but it will also lead to inordinately high payroll expenses by removing managerial incentives to resist wage increases.[171] The capital spending moratorium aggravates the wage-inflating effect by foreclosing alternative uses for the hospital's surplus funds. Because administrators are assured that future labor cost increases can be passed on to the consumer and will not affect their own budget, they will be artificially predisposed toward substituting labor for capital. Thus isolated from the true costs of their labor, hospitals can be expected to deviate from utilizing the most efficient mix of capital and labor.

2. Supply of Facilities

The Administration's proposal seeks to improve the efficiency of the hospital system, first by reducing and rationally allocating the growth of capital assets, and second, by eliminating the current excess of facilities. By restricting the total value of certificate-of-need permits which can be issued nationally, the bill will succeed in reducing capital expenditures. But it fails to provide any assistance to the HSAs, on which it depends, to improve their heretofore inadequate ability to direct permits to efficient institutions or medically necessary projects. A reduction in the excess supply of facilities will probably also not be achieved, for local political pressures will probably militate toward incurring the disadvantages from having an unapproved certificate-of-need program, rather than toward agreeing to eliminate some facilities within community hospitals.

Achieving the objectives of S. 1391's permit program depends upon the effectiveness of the HSAs, but as currently constituted, HSAs often suffer the debilitating problems that beset government agencies: domination by the knowledge-rich institutions over which the agency has osten-

171 This provision will cause an estimated 0.5% annual wage increase above wage increases that would otherwise be granted. *Id.* at 28.

sible control,[172] inability to withstand community pressure for increased local services,[173] and an absence of determinate guidelines which encourage cost consciousness.[174] A recent study confirms the inability of the HSAs, especially when drafted into participation by the federal government, to plan and regulate effectively: the twenty-six states which have instituted HSAs since 1971 have failed to achieve even the minimal cost savings recorded by the five states which had pioneered this regulatory scheme.[175] S. 1391 proposes to correct this problem partially by limiting the value of certificates-of-need which the HSAs can issue annually, thus preventing them from acceding to local pressure for expansion. Nonetheless, the apparent arbitrariness of $2.5 billion as the national capital expenditure limit, which, along with the allotment formula, will be the determinant of the quantity of approved projects in each locality, is disturbing. The failure of the proposed legislation to include anything that would improve heretofore inadequate local agency planning[176] compounds the capriciousness of the capital spending regulation. Deriving social benefits from regulation, as opposed to merely allocating regulated benefits, requires the wisdom to allocate the scarce permits only to the most salutary undertakings, but the administration proposal does not in any way confer such planning ability.

A minimum level of sophistication in local decisions is assured by requiring federal approval of area master plans.[177] But this supervision endows the Secretary with a negative power which is to be exercised only prior to the operation of the HSAs' certificate-of-need program. Such authority can merely ensure that general national interests are respected in initial guidelines; it cannot improve decisions concerning a

---

172 P. O'DONOGHUE, *supra* note 55, at 65.

173 COUNCIL ON WAGE AND PRICE STABILITY, THE COMPLEX PUZZLE OF RISING HEALTH CARE COSTS: CAN THE PRIVATE SECTOR FIT IT TOGETHER? 36 (1976).

174 Havighurst, *supra* note 39, at 1176-77.

175 CBO FOR HEALTH, *supra* note 4, at 35.

176 Havighurst, *supra* note 39, at 1198-99.

177 S. 1391 as approved, *supra* note 100, at § 201(b)(6)(B).

specific institution or service. The most important of the national objectives is probably the limitation of new bed construction: preventing an increase of surplus beds is essential and should not be left to local decision-making because empty beds contribute heavily to both excessive costs and induced demand. Stringent conditions which limited new or expanded hospital capacity to 17 of the 205 national health areas[178] were excised from the original version of S. 1391[179] and have since been adopted as HEW guidelines.[180] Moving the stringent limitations from their statutory foundation to the more malleable form of HEW regulations, to which master plans presumably must conform, allows modification as required by population shifts and geographic inequalities in the initial guidelines.[181]

One likely benefit of the bill would be improvement in the management of hospitals. There will be increased pressure to improve forecasting, budgeting, and cost control techniques as hospitals find themselves required to monitor the quality, quantity, and scope of services in order to stay within their revenue allowance.[182] Hospitals can also be expected to acquire a greater cost consciousness if they must systematically report and justify to an external panel their need for capital expenditures.[183] By forcing hospitals to compete before HSAs for a limited number of certificates-of-need, S. 1391 will induce them to hone their management skills. A limited number of certificates will also reinforce a hospital administrator's bargaining position with his physicians when self-interest prompts the doctors to demand additional

178 CBO FOR HEALTH, *supra* note 4, at xxi.

179 S. 1391 original proposal, *supra* note 101, at § 201. This restriction forbade construction unless the bed to population ratio was less than four per thousand and the occupancy rate exceeded 80%.

180 35 CONG. Q. WEEKLY REP. 2129, 2130-31. (1977).

181 CBO FOR HEALTH, *supra* note 4, at 51. Criticism has been directed at including the minimum occupancy standard because it reduces from 72 to 17 the number of areas that can add to their bed capacity. The 17 remaining areas are concentrated in the East where days of hospitalization per person are already high. *Id.* at 43. Instead of including the occupancy standard, the bed to population ratio could be lowered to 3.5 per thousand, thereby restricting expansion to 29 areas which are more widely dispersed throughout the country. *Id.* at 51.

182 Dowling, *supra* note 152, at 164.

183 *Id.*

facilities or equipment suited for their particular specialties.[184] And this shift should mean that more power will rest with those who favor planning the hospital as a coherent unit, and so should mean that future growth will correspond better to general community needs.

The Administration proposal includes certain non-hospital purchases in the capital expenditure limitations. While this feature should not be part of any permanent regulation, it is one of the unavoidable short-run costs of capital expenditure regulation. A significant long-range prospect for reducing over-all medical costs is the transfer of simple surgical and diagnostic procedures from the hospital to the doctor's office.[185] If individual doctors or moderate-sized physician group practices had to compete with hospitals for scarce permits for facilities, this transfer could be thwarted because the doctors might not prevail against a hospital's community stature and its plea for additional sources of revenue to cover large overhead costs.[186] On the other hand, if the proposed capital regulations did not include non-hospital purchases, doctors might hastily try to capitalize on the hospitals' inability to compete by purchasing certain equipment that in the long-run would be more efficiently used in a hospital.[187] Such unsupervised diffusion of equipment would complicate the task of curbing excessive utilization by forcing future, more permanent reforms to include the 250,000 physicians as well as the 6,000 hospitals.[188]

S. 1391 recognizes the desirability of including extant, as well as proposed, facilities in any comprehensive area-wide facility plan. But effectively coordinating the supply of existing services requires the decommissioning of unneeded facilities, a politically distasteful task for which the bill does

---

184 Salkever & Bice, *supra* note 53, at 180-90. This effect may be one of the reasons for the hospital industry's willingness to endorse capital spending restraints.

185 *See* Mechanic, *Approaches to Controlling the Costs of Medical Care: Short-Range and Long-Range Alternatives,* 298 NEW ENG. J. MED. 249, 251 (1978).

186 *See* Havighurst, *supra* note 39, at 1210-11.

187 CBO FOR HEALTH, *supra* note 4, at 46.

188 *Id.*

not adequately provide. Successfully overcoming the provincial protectionism that blocks the forced retirement of unneeded beds would save an estimated $6.95 billion annually.[189] S. 1391 ventures toward this goal by refusing to acknowledge any state certificate-of-need program as satisfactory unless the program provides for finding an existing service "not appropriate" if the service would not satisfy the standards of need as applied to a proposed new facility. Facilities so classified will suffer significant reductions in medicare and medicaid payments.[190] For those states which undertake to decertify unneeded facilities, the bill lessens the burden on their affected institutions by compensating them for the debt outstanding on closed facilities;[191] and for those hospitals which will remain open, it provides a minimal incentive to terminate services designated as "not appropriate" by not commensurately reducing the revenue ceiling.[192]

Even so, few states are likely to consider the limited benefits from gaining the Secretary's approval of their certificate-of-need program to be worth the probable closure of some of their community hospitals or certain facilities therein. The local political arena, where concentrated pressure from hospitals can be most easily applied, is particularly ill-suited for the passage of legislation disadvantageous to local institutions.[193] A more politically palatable alternative is for the states to adopt what is referred to as a section 1122 medicare and medicaid payment agreement (which only penalizes a facility which has actually applied for and been denied a permit). Although this option also requires the state to submit to a complete capital expenditure moratorium until 1979 on projects costing more than

---

189 CBO FOR HEALTH, *supra* note 4, at 49. If the reduction is spread evenly across all institutions, instead of closing entire facilities, the savings will shrink considerably. CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 54 n.9.

190 S. 1391 as approved, *supra* note 100, at § 205.

191 *Id.* § 206.

192 *Id.* § 114(c).

193 COUNCIL ON WAGE AND PRICE STABILITY, *supra* note 173, at 36.

$150,000, it would produce less local antagonism than identifying particular hospitals for sanction.[194]

3. Demand by Patients

Although the provisions of S. 1391 which are to control the supply of hospital facilities may fall prey to the HSAs' inadequacies and to local political pressure, the hospital system will be indirectly steered toward providing the medically most needed services by the operation of the revenue ceiling and its effect on demand. The ceiling will heighten and regularly renew the medical community's awareness of the social consequences of unrestrained hospital spending.[195] As a result, the physician, gatekeeper of our medical facilities,[196] will more carefully consider the efficacy of alternatives to hospitalization for his patients. He will also be pressured by administrators to eliminate extraneous hospital treatments, so that the available amount of hospital care, now limited by the revenue ceiling, will be allotted most effectively. The ceiling will also motivate physicians to restrain volume if the cost of treating an additional patient exceeds 50 percent of average cost; in such a situation, added patients or services will reduce the institution's operating surplus which could otherwise be spent on amenities desired by physicians.

These reductions in demand, prompted by the revenue ceiling, depend on the physician's discretion in allocating hospital services and so pose some acute ethical concerns. Some believe that the maintenance of the physician-patient relationship is a personal right of the highest order and that it is immorally violated by inducing the doctor to refrain from

---

194 Because the states share the expense of medicaid with the federal government, they too would benefit from decertifying unnecessary facilities. Yet these savings are currently within reach of any state that adopts a program similar to this federal proposal. Therefore, no impetus for decertification greater than that which already exists will result from cost savings attainable under the federal program.

195 Fuchs depicts the current attitude of health practitioners as "monotechnic," which he defines as the failure to recognize competing claims to resources and differing value structures. V. FUCHS, *supra* note 2, at 5.

196 Without a physician's concurrence, a patient is denied access to drugs, tests, and hospitalization. *Id.* at 57.

delivering maximum treatment to each and every patient.[197] Physician discretion would indeed be a problem if the physician were required to balance the use of economic resources for his patient's medical treatment with the use of those resources for some larger, abstract social benefit. But S. 1391 does not require the physician to do that. Instead, based on a predetermined social commitment to health care,[198] (and, hopefully, promulgated general guidelines), the physician is only to allocate among potential recipients the available medical care. Those who tenaciously assert the importance of the physician-patient relationship would condemn this exercise of discretion as well. But when hospital resources are finite, unyielding adherence to such an abstract principle is impossible. For the only alternatives to physician discretion are to invest remote legislators or bureaucrats with the power to decide who is to receive treatment or to invest them with the power to declare a set of absolute allocation guidelines. Neither alternative can hope to match the physician's ability to respond to the myriad of medical and personal complications which affect the potential efficacy of treatment.[199] As a result of allocation decisions by government officials, an unknown number of persons would suffer illness and death. Furthermore, the patients' feelings of betrayal would abound when they know that remedies for their afflictions exist, but are unavailable because of wasteful allocation by remote officials. The Administration bill recognizes this situation and does not try to remove from doctors the delicate task of allocating available facilities.

The decrease in demand indirectly fostered by this program will forestall the consumer experience of shortages that

---

197 Fried, *Rights and Health Care — Beyond Equity and Efficiency,* 293 NEW ENG. J. MED. 241, 243-44 (1975).

198 Even the moral objectors to allotment by physicians recognize the desirability of a socially planned determination of total hospital services, Fried, *supra* note 194, at 243, if not its inevitability. Hiatt, *Protecting the Medical Commons: Who is Responsible?* 293 NEW ENG. J. MED. 235, 239-40 (1975).

199 Even if a government agency could fashion satisfactory criteria, the therapeutic relationship would be made a shambles as those mechanically denied treatment plead for mercy before a deliberately impersonal regulatory mechanism. *See* Fried, *supra* note 197, at 243-44.

would otherwise result from the slowed growth rate of supply. Instead of the consumer confronting shortages, which would occur if supplies were to grow slower than demand, hospitals and doctors, who will continue to experience cost-free expansion, will now feel constrained within non-price limits restricting their ability to provide increased services. Thus, the initiative to relax the restrictions of S. 1391 will more likely come from providers facing a "shortage" of permits than from a citizenry unable to obtain necessary services.

B. *The Talmadge Proposal*

Senator Talmadge's proposal to reward efficient hospitals and penalize prodigal ones will encourage some institutions to reduce their costs relative to the industry average, but it will not directly constrain the industry's total revenue growth. The bill's incentive theory and reimbursement scheme are not properly formulated to overcome the cost problems in a not-for-profit environment.

Although it incrementally improves the regulatory and reimbursement framework which currently influences hospital decisions about the composition of their facilities, the bill does not aid hospitals in comprehensively planning for community medical needs. Consequently, the proposal's effect upon total demand and supply will be negligible, and it will obtain only slightly better results in promoting efficiency.

1. Costs of Hospitalization

The aim of the Talmadge bill, S. 1470, is to hold down costs generally by fostering increased efficiency in individual institutions rather than by attempting to constrain revenue growth of the entire hospital industry. It is supposed that the establishment of categories and a limit on governmental reimbursement at 120 percent of the categorical average will encourage hospitals to economize. The use of categorical standards in evaluating hospital performance is worthwhile,

for it avoids diluting the incentive to economize which would exist in a scheme which evaluates performance according to a hospital's previous record; with categorical standards, an administrator would not be discouraged from exploiting present opportunities to reduce costs because a reduction in cost would not diminish his future latitude. The disallowance of costs which exceed 120 percent of the categorical average will indeed force high-cost hospitals to economize, since they cannot survive indefinitely with expenses surpassing revenues.[200] But the supposition that other hospitals will also economize and that this bill will accomplish significant cost reductions is questionable. Those aspects which cast doubt upon the bill's potential are its unjustifiable assumptions about hospital behavior, its focus upon only routine costs when non-routine costs are escalating faster, its encouragement of unjustified hospitalization by reimbursing according to per diem costs, and its unfeasible wage adjustment mechanism.

While the most costly hospitals will have to economize under S. 1470, significant results will be forthcoming only if the bill elicits economizing behavior from many more hospitals. These other hospitals will economize only if they prefer to endure the hardship of instituting efficiency measures in order to obtain discretionary funds rather than to continue to spend at existing levels. That such behavior would occur is doubtful, especially since it would contravene the frequent assertion that nonprofit hospitals seek to maximize the quantity and quality of care delivered.[201] Those who support the bill's use of a comparative incentive system respond with a Darwinian analogy: only the most efficient

---

200 The bill's impact is reduced because it does not alter the provisions of Pub. L. No. 92-603, § 223, which allows patients to be charged directly for the excess costs. Fifty percent of those covered by medicare have supplemental insurance which will diminish their incentive to avoid high-cost providers. Newhouse, *Inflation and Health Insurance,* in HEALTH: A VICTIM OR CAUSE OF INFLATION? 217 (M. Zubkoff ed. 1976).

201 *See* note 40 and accompanying text *supra.* In fact, the conventionally-accepted value system trivializes the prospect of systemic savings from all alternative fractional reward systems, *i.e.,* from incentive payments lower than cost reductions.

hospitals will have available discretionary funds to expand. However, such an analogy fails for three reasons. First, unless already operating below the mean cost for its category, a hospital which plans to accumulate discretionary funds to expand would have to cut twice the cost of the expansion from routine expenditures. Second, if the hospital is already operating efficiently and need not reduce costs to receive the bonus, spending the bonus will raise the mean categorical expenditure and allow higher reimbursement rates for high-cost providers. Third, the bonus recipient has only two uses for his surplus, both of which will cause systemic inefficiencies: either it can be committed to intensifying and thereby increasing the cost of per-patient services, or it can be spent on expanding hospital facilities. But without a simultaneous contraction by another institution, a greater expenditure on facilities will either increase the per-patient cost of a constant patient base or maintain a level cost by inducing increased use and heightened total expenditures. Thus, the penalties may only remedy the behavior of the relatively few high-cost institutions, and the injection of excess compensation will bloat both the direct recipients and the hospital system as a whole.

The actual cost structure of the hospital industry contributes to the reservations about the bill's effecting significant expenditure reductions. The bill is targeted toward controlling the costs of individual routine services, which are the items most susceptible to direct control by hospital management. But it is the aggregate cost of non-routine services which is escalating faster,[202] in part because of the rapid growth in the quantity and sophistication of ancillary services. Even if the bill's mechanism is extended to encompass non-routine costs, the bill will not restrain the proliferation of

---

202 CBO FOR HEALTH, *supra* note 4, at xix. Frequent references in the cost control literature to the rise in the cost of a hospital room, which has actually exceeded the overall increase in hospital costs during the past 25 years, are often misleading. Routine services were originally subsidized by higher charges in ancillary services, while charges for their use now more properly reflect true cost. R. WARD, *supra* note 30, at 67.

new services so long as the cost of each hospital's providing these services remains within its categorical cost range.

Indeed, the bill could yield greater savings by using different mechanisms to control the routine costs. Reducing the maximum level of reimbursement from 120 percent to 110 percent of the average categorical cost would nudge savings from $.4 billion to $.8 billion annually by 1982[203] and would impose substantial losses on institutions exceeding this narrow range.[204] A system of limiting reimbursement for any costs above the categorical mean to only a fraction of their actual amount would also be beneficial in that it would extend the impetus to economize to a larger number of hospitals.

The bill's reimbursement of hospitals on the basis of comparative per diem costs encourages medically unjustified, and thus inefficient, increases in hospitalization. Ironically, total expenditures for hospital care will rise because hospitals will reduce their average per diem cost by increasing their number of patients, in order to spread their fixed costs across a greater number of patient-days, and by unnecessarily extending the stays of patients who do not need extensive nursing care. A volume measurement relying in part upon the number of admissions, the formulation used by the Administration proposal to avoid this adverse reaction, is not workable when comparing costs between institutions. A per-admission measurement unit would require categorizing patients according to standardized diagnoses so that cost comparisons are made between equal amounts of service. Unfortunately, we currently lack the knowledge necessary to accomplish this task,[205] and the administrative problems of verifying millions of diagnoses would dampen the prospects for practical application of any conceptual breakthrough in

---

203 CBO FOR HEALTH, *supra* note 4, at 28. The same bias as suggested in note 135 *supra*, towards understating savings from this program, is probably included here.

204 *Id.*

205 Shuman, Wolfe & Hardwick, *supra* note 159, at 23, *citing* Lave & Lave, *The Extent of Role Differentiation Among Hospitals*, (Graduate School of Industrial Administration, Carnegie-Mellon University, Working Paper (1970)). The problem of incomparable case mixes is not present when a per-admission basis is used for intra-institution measurements, unless the patient mix significantly changes over time.

this area. The revenue ceiling discussed earlier avoids such difficulties because it measures a hospital's revenues against its own base year revenues. These two years are comparable because patient mix within a hospital remains fairly uniform in the short run.[206] But the patient variations between hospitals would frustrate any similar use of a per-admission formula in Talmadge's proposed interhospital cost comparison.

The wage adjustment scheme of S. 1470, unlike the Administration's proposals, will not permit uncontrolled wage increases and will not induce an inefficient combination of labor and capital, but it may be impossible to implement properly. The bill avoids putting pressure on hospital employee wages in localities with generally high labor costs by dividing each hospital's costs into wage and nonwage components, and the wage component is separately adjusted to account for the relative level of the area's general wage scale. Because hospital services must be produced at the point of use, consumers would not benefit from rewarding providers who locate in areas with low labor costs. But proper administration of this wage adjustment mechanism would require currently unavailable measures of intraregional labor market differences (*e.g.*, between each region's urban, suburban, and rural areas), because substantial variations between these subdivisions would cause serious error if the formula used a uniform regional wage rate.[207]

2. Supply of Facilities

S. 1470 will not reduce the excess supply of hospital facilities to a significant extent. Its reliance on HSA planning is misplaced; and while its reimbursement provisions remove some present barriers to a reduction of surplus supply, its overall scheme is not one that would achieve the bill's goal.

---

206 *Id.* at 23.

207 For example, metropolitan Massachusetts hospitals paid $11,808 per full-time equivalent (FTE) employee in 1976, while nonmetropolitan hospitals in the same state paid $9,260 per FTE employee. AMERICAN HOSPITAL ASSOCIATION, *supra* note 11, at 148-49.

However, allowing surplus hospital beds to be used for skilled nursing care is a step toward that goal.

The Talmadge bill discourages a hospital from proceeding with a project denied approval by its local HSA by prohibiting federal payment for capital and operating costs related to the project and by forbidding the institution from shifting these unreimbursed expenditures onto other payors.[208] Although it makes the penalties more consistent with the magnitude of the HSA order violated,[209] the proposal contains nothing that improves the planning decrees of the HSAs. In addition, sanctions without improvement in the quality of the underlying planning decisions will not solve the supply problems of hospital services. By virtually compelling compliance, the bill may further erode HSA planning and regulatory competence. The new penalties will draw heightened local pressure upon the HSAs to approve capital projects; without clear standards and without a limit on the number of permits which may be issued, the HSAs might follow "the regulatory path of least resistance" by increasing their rate of project approval.[210]

The bill eliminates the financial obstacles that may prevent institutions from independently evaluating and, if necessary, decreasing the existing supply of services. Reimbursement is provided for the outstanding debt of up to fifty hospitals that completely discontinue operations, and compensation is provided for hospitals which continue to operate but which incur increased costs or decreased revenues by converting underutilized facilities to approved uses.[211] Yet if cost efficiency is to result, the formula of the revenue reimbursement provision for discontinued and converted services must be altered. The bill's formula provides reimbursement for the total decline in revenue.[212] Inefficiency is encouraged because

---

208 S. 1470, *supra* note 123, at § 4.

209 *Id.* § 4(b).

210 Pauly, *The Behavior of Nonprofit Hospital Monopolies: Alternative Models of the Hospital,* in REGULATING HEALTH FACILITIES CONSTRUCTION 158-59 (C. Havighurst ed. 1974).

211 S. 1470, *supra* note 126, at § 3.

212 *Id.*

a hospital that closes a facility and offers fewer services will be reimbursed for the cost of operating the closed facilities. The bill should only compensate for the actual detriment to the hospital, *i.e.*, for that portion of decreased revenues allocable to non-operating costs.

S. 1470 also eliminates the existing impediment to using excess hospital beds to alleviate the shortage[213] of skilled nursing care facilities. An institution cannot currently receive federal reimbursement for skilled nursing care services unless they are provided in a physically distinct area.[214] This is especially disadvantageous for small hospitals which have the lowest occupancy rates[215] and which are not large enough to establish a separate nursing care wing. By abolishing this required separation, S. 1470 allows hospitals to provide skilled nursing services as a swing device to maintain an efficient utilization level during otherwise slack periods.

3. Demand by Patients

If high-cost hospitals exercised their option, left unimpeded by this bill, to charge patients directly for costs unreimbursed by the government,[216] patient demand would shift toward more efficient institutions. Even if hospitals did this, however, the magnitude of the shift would be minimized by the high incidence of supplemental insurance[217] and by a patient's tendency to abide by his physician's recommendation, especially when the doctor cannot treat him elsewhere because he lacks staff privileges at an alternate institution. Moreover, hospitals would only charge patients for the excess if they expected a positive effect upon net revenues; if

213 COUNCIL ON WAGE AND PRICE STABILITY, *supra* note 173, at 18. A study in a Berkeley hospital revealed that the unavailability of adequate skilled nursing facilities was responsible for two-thirds of the "environmental factors" (which accounted for 41.5% of the total factors) causing excess hospitalization. Restuccia & Holloway, *Barriers to Appropriate Utilization of an Acute Facility,* 14 MED. CARE 559, 567 (1976).

214 42 U.S.C. § 1395x(j) (1975).

215 AMERICAN HOSPITAL ASSOCIATION, *supra* note 11, at 18.

216 42 U.S.C. § 1395cc(a)(2)(b)(i) (1975).

217 Additionally, since only 16% of the medicare recipients are below the poverty line, most could afford the relatively minor hospital charge if it is passed through.

direct patient charges would be successful in altering consumer behavior, most hospitals would not pass on the excess costs. Alternatively, if the charge were levied, high-cost institutions might become the domain of private insurance patients, while those individuals assisted by public programs would be forced to cheaper hospitals in order to avoid the surcharge. The solution necessary to restrict the development of such a two-tier system is to extend the reimbursement limit to all cost payors, so as to put government and private insurance beneficiaries on an equal footing.

V. INTEGRATION OF THE PROPOSALS

Neither an industry-wide revenue ceiling nor an incentive system based on hospital cost comparisons will individually ameliorate the twin elements of the hospital cost problem: an excessive amount of hospitalization delivered in an inefficient, and thus unnecessarily expensive, manner. Both proposals attack the problem in piecemeal fashion, generating adverse side effects as the market compensates for restraints in one area by expanding in other areas. For example, an incentive system based on a per diem measurement will reward those hospitals which are particularly efficient, but will swell the overall system by encouraging the extension of hospital visits and the wasteful expenditure of the reward payments. The government may counter such untoward reactions only by constructing an ubiquitous regulatory structure which seeks to contain the secondary effects. In this vein, S. 1391 imposes an administratively complex and innovation-retarding capital allocation scheme in order to prevent the revenue ceiling from causing hospitals to shift from the delivery of important patient services to the purchase of unnecessary equipment.[218]

An integrated measure which simultaneously deals with both the total cost and the efficiency aspects of the hospital cost problem would establish a comprehensive regulatory

---

218 CBO FOR HEALTH, *supra* note 4, at 55.

structure that eliminates the pitfalls inherent in each of the two proposals, thereby making governmental intervention into particular hospital planning decisions unnecessary. A measure of this sort would incorporate a modified version of the Administration's revenue ceiling and a timetable for the rapid introduction of interhospital cost comparisons. Its effect would be to bring the determination of the amount of resources to be devoted to hospitalization under deliberate social regulation and to make its proportional allocation among the various types of facilities, principally a matter of efficient health planning, respond to the dictates of medical need and private institutional competition. An integrated plan would also render the stopgap direct capital expenditure controls unnecessary.

From its inception, the combined measure should contain guideposts which stake out the structure for permanent hospital reimbursement reform. Approaching the problem, as does the Administration, with a transitory measure designed primarily to provide immediate results[219] will not generate fundamental changes in the outlook of hospital managers and staff physicians. Instead, the temporary measure would delay basic alterations in hospital operations while time is spent attempting to make its program operational. Imposing an exacting temporary regime also wastes goodwill between the government and hospitals that is essential for the effective functioning of any future program. Moreover, the indefinable and self-regulatory nature of hospital quality[220] demands that hospital administrators be accorded a degree of certainty in their planning, that they be treated as partners rather than as servants subject to the vagaries of an obscure future. So, while the initial details of the program will

---

219 President Carter, in April 1977, said that the rapidly rising cost of hospitalization requires quick adoption of a transitory containment program (originally scheduled to commence operation October 1, 1977). It was planned that the Secretary would take advantage of the respite from rising costs to formulate permanent reforms. 35 CONG. Q. WEEKLY REP. 810 (1977).

220 State accreditation standards guarantee a minimum level of quality but are incapable of ensuring, without institutional cooperation, the standards to which the public has become accustomed. A. SOMERS, HOSPITAL REGULATION: THE DILEMMA OF PUBLIC POLICY 109 (1969).

have to be chosen with less than an optimum amount of information and will be subject to revision in the future, the regulatory structure itself should be designed for continuity.

A. *Costs of Hospitalization*

A refined version of the Administration's industry-wide revenue ceiling should be the backbone of any permanent plan to slow the diversion of social resources to the hospital care sector. The formula used to adjust the revenue ceiling should immediately reflect the annual increases in the cost of hospital inputs,[221] which have risen faster than prices in the economy as a whole. Otherwise, intensity growth will be held below the formula amount in the first year, a period when maximum leeway is necessary to accomodate the hospitals' adjustment to the new regime. A variation of the American Hospital Association's measure of hospital supply costs[222] could be used instead of the GNP price deflator. It is also possible, by using currently available information, to adjust a hospital's annual ceiling increase in order to disallow that portion due to excessive base-year costs caused by unusually low utilization rates.[223] This adjustment would prevent hospitals with extreme excess capacity from annually benefiting from their past spending excesses.[224] Also, the base-year standard should be adjusted for institutions that

---

221 AMERICAN HOSPITAL ASSOCIATION, *supra* note 11, at xiii.

222 The index is known as the Hospital Input Price Index and was compiled from data reported by 500 hospitals since 1968. *Price Indexes in the Hospital Industry*, 51 HOSPITALS 38 (1977).

223 For example, by adopting an estimate of marginal cost, the Secretary can compute what the cost per patient would have been at a minimum level (*e.g.*, 60%) of occupancy. A hospital's revenue ceiling increase could then be limited to that amount to which it would be entitled if its average cost were at the hypothetical level.

224 As the long implementation period for the Talmadge bill demonstrates, immediate disallowance of increases attributable to operating inefficiencies is not practical. This is a result of the differential, at times up to 50%, between average costs of service among institutional categories and nonuniform cost accounting systems. AMERICAN HOSPITAL ASSOCIATION, *supra* note 11, at xvi-xvii. Much of the cost differential between categories is reasonably attributable to different services and their capital and staff requirements. Altman & Eichenholz, *supra* note 163, at 29.

A more drastic step than those contained in Talmadge's bill would be to follow

can demonstrate a significant increase in the population-to-bed ratio of their service area between the base year and the initiation of this program. Such a change, caused by population ingress or the closure of another institution, is not subject to manipulation by those petitioning for the exception and so would not provide an opportunity for evading the revenue regulation. This adjustment to bring the base-year revenues current with the effective date of the revenue ceiling is needed in order to allow hospitals to increase the amount of care that they can offer when such expansion is dictated by a rapidly growing community.

The revenue ceiling can be designed to account equitably for wage increases for non-supervisory personnel, while simultaneously avoiding the inflationary effects of a wage pass-through. This can be accomplished by dividing each hospital's total revenue increase into a wage and nonwage component and then annually adjusting the wage portion upward by the actual national hospital percentage wage increase, with further adjustment for an institution's current number of employees. This would simultaneously free employee wages from constraints intended only to control other hospital costs and retain internal hospital incentives to restrain wages. The mechanism does not affect or respond to the actual wages paid by any particular institution. Instead, it assures to the hospital's administration the funds to raise employee compensation commensurate with the national average of similarly employed individuals (whose wages have recently been rising faster than those in the economy as a whole),[225] yet it does not destroy management's incentive to resist unbridled employee demands because normal internal hospital budgetary trade-offs are retained. This adjustment mechanism, which is computed for each hospital as a percentage of its current wages, maintains the normal differential

New York's lead by reducing the base level of reimbursement by the costs attributable to excess capacity. Feldstein & Goddeeris, *Payment for Hospital Services: Objectives and Alternatives,* in 2 HEALTH CARE MANAGEMENT REV. 15 (Fall 1977). One should first determine if the effects upon institutional performance warrant the demoralization and inequity caused by such an alteration in the reimbursement rules after capital has been irrevocably committed.

225 INTERSTATE AND FOREIGN COMMERCE REPORT, *supra* note 45, at 54 (Table C-4).

between high- and low-wage regions. By severing reimbursement from the individual institution's cost, it has the additional advantage of securing the hospital management's ability to choose the most efficient combination of capital and labor, undistorted by the ability to automatically pass all wage increases on to the consumer.[226] An exception to this provision need be included only for institutions which justify "catch up" increases because their base-year wages were substantially below the national hospital employee average (when corrected for the differences in its prevailing local wage scale). The most significant drawback to this provision would be its inertial resistance to conforming with rapid changes in the general economy. However, should severe economic modulations cause too large a differential, Congress could enact a one-time adjustment in the annual change allowed in the wage fraction of the revenue ceiling. While depending on remedial congressional action is an imperfect corrective mechanism, it would rarely be necessary and, when required, it would only be in response to significant deviations that should prompt action.

The automatically declining character of the Administration's proposed revenue ceiling ought to be retained in order to deter the hospital industry from delaying revisions of the statute[227] and to prompt Congress to establish permanent guidelines expeditiously. The added pressure is necessary to force Congress to take the politically difficult step beyond this initial regulation and toward genuine planning, that is, to determine the growth rate of hospital service that our society

---

226 The revenue adjustment for wage increases should be made according to the number of current (not base-year) employees so that decisions about increasing a hospital's labor force stand on the same basis as decisions about augmenting capital.

227 The American Hospital Association originally objected to federal action. 35 CONG. Q. WEEKLY REP. 2129, 2130 (1977). Representatives from the Federation of American Hospitals, the investor-owned hospital trade association, have testified against the House version of the Administration's bill. Not surprisingly, they support Senator Talmadge's efficiency incentive payments. STAFF OF THE HOUSE SUBCOMM. ON HEALTH OF THE COMM. ON WAYS AND MEANS AND SUBCOMM. ON HEALTH AND THE ENVIRONMENT OF THE COMM. ON INTERSTATE AND FOREIGN COMMERCE, 95TH CONG., 1ST SESS., SUMMARY OF TESTIMONY RECEIVED ON THE HOSPITAL COST CONTAINMENT ACT OF 1977, at 5-6 (1977); 35 CONG. Q. WEEKLY REP. 790 (1977).

desires.[228] Empirical studies may provide guidance to congressional resolution of this central issue of the hospital cost problem, but the determination of the socially desired level of spending is ultimately a matter of political consensus.

Integrated with the revenue ceiling should be an extended version of the Talmadge proposal's interhospital cost comparisons; that is, there should be a system of rewards and sanctions, under the aegis of third-party payors, for routine and specialized services whose costs vary significantly from their categorical averages. Limitations on available data restrict the form of the initial comparisons to a timetable for actual implementation as the necessary categorical information is compiled. If accompanied by a definite schedule of sanctions, the incomplete form of the comparisons should not significantly reduce their economizing effect upon hospital administrators, who will economize now in anticipation of the sanctions becoming effective.

Both experience and theory suggest the desirability of penalizing violators by refusing to reimburse costs which too far exceed the categorical mean. The original experimental program in Connecticut, which used incentives but no penalties, had virtually no, or even an adverse, effect on hospital costs;[229] and conventional assumptions about nonprofit institutional objectives cast doubt upon the ability of a fractional incentive system to change hospital administrators' behavior.[230] Granting rewards for spending below the categorical average should be part of the regulatory scheme, as a tribute to the exercise of restraint. And by concurrently restraining revenues with a ceiling on growth, the integrated proposal will not totally reimburse a hospital when it later spends its reward, unless the institution has otherwise extraordinarily restrained its growth. Thus, by preventing the automatic recycling of reward

228 The revenue ceiling in Rostenkowski's version of H.R. 6575 lacks logical justification. It advances at 150% of the inflation rate, an advance which has absolutely no relationship to a planned intensity growth factor. There is no reason to want the amount of real hospital services to change with variations in economy-wide prices.

229 *See* note 90 *supra.*

230 *See* note 201 *supra.*

payments in the form of higher costs, the bill will require the hospital to continue its efficiencies in order to re-earn the bonus and thereby preserve its pool of discretionary funds.

Another benefit of an integrated proposal is the elimination of hospital evasion that would destroy the effectiveness of per diem cost comparisons. A hospital which reacts to the comparison by reducing its average cost of service through increasing either the number of or length of patient stays would quickly exhaust its revenue ceiling. By increasing its volume a hospital would also eliminate its opportunity to increase per-patient intensity without a loss in revenues, an opportunity which is available to hospitals under the Administration bill during the first 10 percent reduction in their patient load. Thus, integrating the proposals internalizes disincentives for acts which could evade the individual bills; and it appears to be the only workable method of instituting cost comparisons, since there is presently no alternative to a per diem volume measurement for use with cost comparisons.

Once categories of hospitals have been refined by regulatory experience, they can be combined with the revenue ceiling to eliminate the inequalities caused by the industry-wide imposition of a uniform percentage revenue ceiling adjustment. The adjustment could be changed to permit the hospital to increase its total revenues (as measured per unit of volume) by the dollar amount corresponding to the allowed percentage increase of its categorical mean. The new formulation would restrict total industry-wide revenue increases to the target level and would prevent past inefficiencies from being rewarded because the revenues of the more expensive hospitals in each category would increase by a lower percentage. Furthermore, it would administratively simplify the system by replacing each institution's individually-determined ceiling increase with a single dollar-denominated revenue adjustment per category.

B. *Supply of Facilities*

Once a revenue ceiling and an interhospital efficiency measure are instituted, a capital expenditure limitation would provide no demonstrable benefit. Its operation would

not reduce patient expenditures, and government supervision would not improve the cost-effectiveness of capital projects. Instead, the effect of combining the revenue ceiling and efficiency incentives will be to internalize incentives for each institution to plan properly its services so that they fit within the overall community need for hospital services.

Because a capital expenditure restriction does not significantly affect the availability of funds which a hospital has to spend,[231] it will merely divert, rather than reduce, total expenditures. A reduction in the number of certificates-of-need for capital projects will cause a shift in spending from restricted capital projects to unrestricted capital projects,[232] more intensive use of personnel, and higher salaries.[233] As a result, a capital expenditure restriction will add nothing to the consumer savings effected by a revenue ceiling set at the level in the Administration bill.[234] Moreover, there is no reason to believe that spending in the unrestricted areas is a more efficient use of health dollars than spending for

---

231 A minor reduction in inflow might occur due to decreased borrowing and the inability of a charitable donor to earmark his gift for unapproved purposes. However, charitable contributions have been declining recently and now account for only 10% of an average hospital's construction outlay. Fifty-four percent of 1976 construction expenditures were projected to be from tax-exempt bonds and 25% from private financing. CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 20, *citing* Kelling & Williams, *The Projected Response of the Capital Markets to Health Facilities Expenditures for the Years 1976-1981* (paper presented at the Conference on Capital Formation for Health Facilities, University of Pittsburgh, 1976). These inflows might continue at their present levels by being diverted toward less expensive capital improvements.

232 Alternative projects may become even more attractive as borrowing costs decrease, because total outstanding hospital debt increases. Salkever & Bice, *supra* note 53, at 207-09.

233 A study of five state certificate-of-need programs operating between 1968 and 1972 revealed the growth in the number of beds to be 9%, less than otherwise predicted, but total hospital assets were not affected. The hospital utilization rate declined 4.8% from original predictions, but per capita expenditures did not decline. These facts suggest that there was no change in aggregate hospital expenditures but merely a shift in their composition. Data for the twenty states which subsequently adopted certificate-of-need programs for the years 1971 to 1974 show no decrease in number of beds and an increase in assets per bed. A further analysis of the first five certificate-of-need programs shows a possible 3.1% savings. CONGRESSIONAL BUDGET OFFICE, *supra* note 5, at 32-33, *citing* Salkever & Bice, *Impact of State Certificate of Need Laws on Health Care Costs and Utilization, Final Report on Contract No. HRA-106-74-57, HEW;* Havighurst, *supra* note 39, at 1218.

234 *See* text accompanying notes 33 to 34 *supra.*

restricted capital assets, if the new assets were to be used to capacity.

An integration of a revenue ceiling and an interhospital efficiency measure, with penalties, will also assure that hospitals will only acquire facilities and equipment for which there is a high patient demand, so that the rationing of capital expenditure permits and the government supervision of institutional expenditure plans will no longer be necessary. Cost comparisons will automatically prevent full reimbursement for any equipment whose cost-per-patient exceeds its cost-per-patient at other hospitals because its rate of use is inadequate to have justified its purchase. As some hospitals discontinue operation of above-average cost facilities, and as other hospitals which project inadequate demand for those facilities refrain from purchasing them, the average utilization rate of facilities will rise and the mean categorical cost of service will decline, thereby amplifying the cost savings and systemic rationality.

While this integrated program will achieve the full cost reductions of the Administration's proposal and will limit expansion to equipment and facilities that will be highly demanded and used, it will not protect against hospital expenditures for highly-demanded but medically unjustifiable facilities. Nothing suggests, however, that the HSAs or any other governmental body would be more adept at making this sort of health benefit evaluation than professional hospital administrators.[235] Indeed, if the HSAs are not to yield to the influence of local institutional providers, they must suddenly acquire heretofore undemonstrated technical competence and the ability to place medical considerations over political expediency. Their record impugns their ability to make adequately the social and economic class trade-offs that are required by a deliberately induced shortage of capital expenditure permits. HSAs frequently have the most difficulty when they must decide between approving the acquisition of

---

235 Harrington, *Forecasting Areawide Demand for Health Care Services: A Critical Review of Major Techniques and Their Application*, 14 INQUIRY 254, 263-66 (Sept. 1977).

high-technology equipment or approving the renovation of an inner-city hospital facility.[236] An "improper" decision between these choices would work a significant hardship on the affected community. Such problems are eliminated under the integrated proposal by simply relieving the government of this scrutinizing task and, instead, letting medical professionals proceed, within the mandated revenue limits and efficiency constraints, with those projects that they consider beneficial to the health of their communities.

Furthermore, requiring every capital project to obtain one of the stringently rationed certificates-of-need involves the risk of curtailing competition, innovation, and needed replacement. The predicted $9.5 billion decrease in capital spending in 1982, under a $2.5 billion per year capital limit, is projected to be comprised of $5 billion in construction and modernization, $3.2 billion in new beds and associated facilities, and $1.3 billion in equipment.[237] These estimates portend relatively little impact upon high-technology acquisitions and lend credence to critics of the Administration's proposal who question, without evidence of the actual need for replacement, whether the capital expenditure ceiling is sufficient to permit repair of normal deterioration and replacement of obsolete facilities.[238]

The rejection of a capital expenditure ceiling does not prevent the integrated scheme's retention of the HSAs, which may competently serve as controllers of new bed construction in hospitals not affiliated with HMOs, as clearinghouses for regional planning information, and as facilitators of interhospital coordination. Unlike other capital items, the appropriate number of beds for an area may be derived from a relatively stable and precise formula,[239] with exceptions made only for the few health centers which draw their patients

---

236 CBO FOR HEALTH, *supra* note 4, at 45.

237 *Id.* at 40.

238 *Id.* at 41.

239 Proper information for detailed clinical supervision often does not exist. Mechanic, *supra* note 185, at 253. The criteria used by health planners to determine the proper number of CT scanners vary by 300%. AMERICAN HOSPITAL ASSOCIATION, *supra* note 7, at 65-66.

from throughout the nation. The relative ease of administering these guidelines and the fact that low occupancy rates serve as an accurate indication of failure have allowed HSAs to be particularly successful in regulating bed supply.[240] Furthermore, the excessive supply of beds constitutes a particularly important factor in the hospital cost problem, because the beds generate demand not only for their own use but for the use of all ancillary hospital services as well. Additionally, the retention of HSA approval as a requirement for major capital projects other than those which will expand the bed supply, though without restriction on the total value of certificates-of-need which may be issued, will ensure that even institutions with otherwise lax managerial practices are forced to analyze and are able to justify publicly projects before committing their capital. The HSAs will also become a repository of each institution's plans and objectives. With just a little effort, this area-wide collection of data could become a focal point for individual hospitals coordinating their services for maximum local benefit and the basis of a valuable regional exchange of planning techniques.

The rigorous application of cost comparisons will also force the removal of surplus beds without the politically difficult task of singling out institutions for decommission.[241] Excess beds cause low occupancy rates, which result, *ceteris paribus*, in higher than average costs. Consequently, institutions with a significant amount of excess capacity will receive partial reimbursement, which affords only incomplete recapture of invested capital and prevents renewal as the facility depreciates.[242] Government grants to retire outstanding debt will hasten closures and conversions to facilities for which there is greater demand, and will minimize the hardship to individual hospitals inherent in the systemic contraction.

---

240 Cartaya & Curran, *A Model Certificate of Need Statute*, 2 HEALTH CARE MANAGEMENT REV. 31, 35 (Fall 1977).

241 The Province of Ontario recently discovered that hospital beds can be eliminated without political reaction if budgeting restraints, rather than legislative directive, dictate such cutbacks. Lewin, Somers & Somers, *State Health Cost Regulation: Structure and Administration*, 6 U. TOL. L. REV. 670 n.60 (1975).

242 New York has reduced excess capacity by reimbursing hospitals according to the higher of expected or a minimum occupancy. *Id.* at 670.

By forcing high utilization rates, this proposal will expand present experimental sharing of expensive hospital equipment and apportionment of special-purpose wards among facilities in close proximity.[243] In addition to reducing costly duplication, having fewer technologically sophisticated facilities will increase each facility's rate of use and the expertise of the attending practitioners and will thereby improve patient recovery rates.[244] Legislation cannot alleviate the doctor's inconvenience in having his patients at multiple locations, but it can remove an obstruction to his ability to admit patients to whichever hospital provides the needed services. Hospitals are currently hindered from adopting regional or interhospital staff privileges[245] by malpractice liability for errors committed by staff members.[246] This deterrent should be statutorily removed for institutions which comply with approved interhospital staff regulations.

Unlike a forced centralization scheme, this integrated proposal seeks to lower the legal barriers which encumber the preferred dispersion of services, thereby permitting a balancing of the costs as well as the benefits. A regulatory board which presides over centralization is more likely than those who work daily within the institutional structure to focus upon the easily quantifiable savings of construction and operating costs resulting from concentration. It is also more likely to neglect the equally important, but more abstract, costs of increased transportation time, the medical consequences of reduced visitor accessibility, and the harms of having to transfer patients to another hospital upon discovery of an unanticipated treatment need. On the whole,

---

243 At least one group of four hospitals jointly owns a CT scanner as a substitute for individual acquisition of the instrument, which costs upward of $400,000 and requires about one-third as much per year to operate. AMERICAN HOSPITAL ASSOCIATION, *supra* note 7, at 14, 51-52; COMPTROLLER GENERAL OF THE U.S., *supra* note 155, at 109.

244 Bloom & Peterson, *Patient Needs and Medical-Care Planning*, 290 NEW ENG. J. MED. 1171 (1974).

245 *See* AMERICAN HOSPITAL ASSOCIATION, *supra* note 7, at 69.

246 Darling v. Charleston Community Hosp., 33 Ill.2d 326, 211 N.E.2d 253 (1965). Many state statutes now impose similar liability. R. WARD, *supra* note 30, at 60.

the integrated proposal's internal incentives are preferable to forced centralization.

C. *Demand by Patients*

An integrated measure will produce the combined reductions and shifts in demand which are produced by its component elements applied separately. That aspect of total patient demand which is spurred by physician encouragement of, or willingness to provide, treatment of questionable value will be reduced by imposing upon doctors and administrators the need to remain within the revenue ceiling. Similarly, by ending the unlimited availability of hospitalization, the measure will heighten awareness to, and exploration of, medical alternatives for treating particular ailments. The categorical reimbursement limits will have the same effect as they would operating alone-shifting patient preferences to lower-cost institutions, but their influence will continue to depend upon the tendency of hospitals to charge patients directly for excess costs and upon the response of patients to price disparities between hospitals.

D. *Future Directions*

Experience administering the proposed regulatory program will yield an improved system of hospital data collection and a sophisticated uniform cost-accounting system. Efforts can then commence to improve upon pioneering studies which have constructed elementary multiple regression models of hospital costs.[247] These formulas, if perfected, would yield a cost of service standard for each hospital based on its total characteristics so that sharp discontinuities between classifications, caused by the necessarily limited number of discrete categories, could be eliminated. This methodological improvement, by minimizing the impact of any single change in a hospital's operations upon its cost allowance, will discourage hospitals from selectively adding

247 Shuman, Wolfe & Hardwick, *supra* note 30, at 60.

medically unnecessary facilities or removing valuable services in order to manipulate their categorical placement.[248]

The addition of computer-assisted regression models would make regulation much more exact, but unfortunately, it would continue the system of compensation based on cost. Reimbursement based on the end-product of hospital treatment is the ultimate long-run solution to the hospital cost problem.[249] Such a system would internalize incentives for quality care and efficiency and would discourage excessive services without involving detailed governmental supervision. However, its implementation would require the ability to diagnose with exactitude[250] and to measure the fine divisions between degrees of treatment success—capabilities which remain many years distant.[251]

Recent studies indicate that systematic evaluation of the health benefits from currently accepted medical practices could trim hundreds of millions of dollars per year from hospital expenditures.[252] Legislation insulating physicians and hospitals from liability for acting in accord with certified guidelines, as now exists for PSROs,[253] is needed. Immunity would permit a physician to treat his patients according to scientific evidence and his best medical judgment, rather than to cater to the fear of malpractice liability by practicing

---

248 The Province of Saskatchewan was forced to abandon its point system of grouping hospitals after only one year because hospitals added services of no use to the community in order to increase their reimbursement. *Id.* at 18.

249 A capitation payment system, *i.e.*, a single fee per person for total services, is the same concept. A constant fee is possible because patient variations average out when the total load is considered. A capitation program achieves the same result (except for a weaker internal quality control) as the concept discussed in the text and does not require additional knowledge to implement. It is restricted, however, to the limited situations where the provider is precluded from refusing to treat high-cost patients.

250 R. WARD, *supra* note 30, at 68.

251 Shuman, Wolfe & Hardwick, *supra* note 159, at 23.

252 A recent study shows that patients who have suffered a myocardiac infarction and do not display complications by the fourth day of hospitalization may be discharged without adverse effect after seven days rather than the national average of 14 to 17. Adopting the shorter period of hospitalization nationally would save $360 million per year at 1977 costs. McNeed, Wagner, Ginsburg, Wallace, McCants, Conley & Rosatei, *Hospital Discharge One Week After Myocardial Infarction*, 298 NEW ENG. J. MED. 229-32 (1978).

253 42 U.S.C. § 1320c-16 (1976).

a more customary and unnecessarily expensive form of hospital treatment.

Conclusion

The persistent, uncontrolled escalation in hospital costs demands remedial action. The Administration's solution, a hospital revenue ceiling, implicitly rations hospitalization by forcing providers to make allocational decisions between the potential beneficiaries of their services. The proposal explicitly rations capital assets by delegating decisions about the composition of capital expenditures within a national limit to local HSAs. Senator Talmadge's proposal, on the other hand, is directed at reducing the federal contribution to inefficient hospitals and rewarding those hospitals which provide low-cost treatment.

A centrally imposed limitation on total revenue stands as the only effective surrogate for the market's normal rationing mechanisms. The Administration's revenue ceiling, with adjustments to make it better accommodate the characteristics of the hospital industry, should be adopted. In addition to bringing total hospitalization expenditures within social control, Congress should advance the complementary objective of encouraging efficient hospital operation. Integrating comparative categorical reimbursement provisions with the revenue ceiling will promote efficiency and produce the advantages of an explicit rationing of capital but without its rigidity and its stifling effect upon innovation. Health care providers will remain at liberty to conduct their own institutional planning, but they cannot expand their facilities faster than the revenue ceiling allows, and they will receive full reimbursement only for highly-utilized capital expenditures.

The current congressional proposals and the integrated concept proffered in this article feature primarily cost containment rather than long-term cost reduction. After inducing initial operating efficiencies, these programs will simply prevent wasteful procedures from reappearing and the industry from expanding excessively. Regulatory experience will lead to the perfection of categorical groupings and may

ultimately allow payment according to a predetermined rate per service. However, long-term savings depend upon altering the basic ingredients of the market for hospital care. Significant reductions in hospitalization will only follow development of a greater concern by the public for its own health and a more realistic evaluation of the potential benefits and hazards of hospital treatment.[254] Providers must be induced, either through education about the social alternatives or through a capitation payment system,[255] to consider the commonweal when making investment and operating decisions. Finally, advances in medical knowledge will allow prevention rather than expensive episodic treatment of more diseases.[256] However, these hopes for future accomplishments should not forestall congressional passage of the integrated remedy for the two presently redressable elements of the hospital cost problem.

---

254 Mechanic, *supra* note 185, at 252.

255 *See* note 249 *supra.*

256 Rushmer, *supra* note 1, at 60; COMPTROLLER GENERAL OF THE U.S., *supra* note 155, at 95.

BOOK REVIEW

HEALTH ASSOCIATIONS AND THE DEMAND FOR LEGISLATION: THE POLITICAL ECONOMY OF HEALTH. By *Paul J. Feldstein.* Cambridge, Ma.: Ballinger Publishing Company, 1977. Pp. 251, index. $18.00.

*Review by Joanna Lion**

Introduction

Paul Feldstein's *Health Associations and the Demand for Legislation*[1] is surprisingly seductive. A health care economist, Feldstein uses an economic model to explain the legislative interests and lobbying efforts of seven major nationally-based health care associations — the American Medical Association, the American Dental Association, the American Nurses Association, the American Hospital Association, Blue Cross, the Association of American Medical Colleges and the American Association of Dental Schools. He analogizes health associations to industrial organizations. If the health association is a profit-making one, increases in net income directly achieve its goals; if it is non-profit, increases in net income enable it to spend its income to increase its prestige and growth objectives. Like industrial organizations, these associations will realize increased revenues when faced with an increased demand for their members' services, restrictions on the supply of the services or substitutes for the services, lowered prices of inputs, and institutional factors that enable the associations to act as monopolists or in a discriminatory manner.

---

* Director of Information Services, Massachusetts Hospital Association. A.B. 1960, M.A. 1963, Ph.D. 1974, University of Chicago. Dr. Lion did research for the Illinois Hospital Association from 1960-1966, was a research associate with the Center for Administrative Studies, University of Chicago, 1966-1974, returning to association work with MHA in 1975. She is a study section member of the National Center for Health Services Research and is a visiting lecturer in the School of Public Health at Harvard.

1 P. FELDSTEIN, HEALTH ASSOCIATIONS AND THE DEMAND FOR LEGISLATION: THE POLITICAL ECONOMY OF HEALTH 15-17 (1977).

Stripped of its economic language, the premise is an indisputable one: namely, that these associations are all working in the self-interest of their members in their attempts to influence legislation and regulation at the national level. Where Feldstein may part company with much of the rest of his readership, however, is in assuming that this self-interest is wholly economic and self-serving in fairly narrow terms.

Actually, any professional organization has among its objectives the retention of complete control over its membership and will oppose interference with this control by any level of government. A second, related and highly salient objective is the preservation of professional status, which assures independent decision-making prerogatives for the group involved. These issues are much broader than economics and cut across a number of areas where the involvement of economic analysis is farfetched.

Feldstein's explanation of why the American Dental Association supports fluoridation of the public water supply illustrates his disregard for these non-economic factors. He constructs an elaborate argument which "proves" that fluoridation actually increases demand for dental care (and thus the income of dentists) by shifting that demand from low-paid restorations for children to more highly-paid preventive care which will build up a demand for dental care in adult life.[2] A non-economist would offer a more plausible explanation: the dentists' professional association supports fluoridation of the water because dentists are paid to know what they are doing in their own field and fluoridation is clearly a preventive measure which, at least in scientific terms, has unchallengeable benefits.

Another obvious example of non-economic motivation is the prescription of birth control pills by gynecologists. Certainly this will result in a reduction of business for both obstetricians and pediatricians. Feldstein wisely avoids this subject altogether. As these examples illustrate, there are

---

2 *Id.* at 81-84.

such factors as professional pride and professional standards to be considered, difficult as they are to quantify in any economic model.

If it is not apparent by now, I should state that Paul Feldstein and I differ on many basic issues about the delivery of health care and that my biases will undoubtedly be reflected in the discussion that follows. It will also be observed that I work for a state affiliate of one of the organizations under discussion. My strongest disagreement with Feldstein's underlying philosophy is that I do not believe that economic theory is particularly useful in explaining the exceedingly complicated machinations of lobbying efforts and of the health care regulatory system.

Within these limitations, however, Feldstein has produced a creditable book with a wealth of carefully documented information about the growth and functioning of the seven associations mentioned above. The subject is really too complex to have been covered in any one book, as witnessed by the fact that Feldstein is able to reference many books which have been written about only one of the seven groups. But he has managed to produce a large amount of readable information on a topic that would not initially appear to be appealing.

Rather than attempting to canvass the hundred or so carefully constructed arguments in the book, I have selected three issues which are timely, complex, and capable of more than one compelling explanation. These three are the role of proprietary hospitals as competition for the not-for-profit sector, community rating and service benefits as a way of attempting to give Blue Cross a monopoly over private insurance companies, and the push for college education for Registered Nurses as a means of limiting the supply of nurses and therefore forcing up wages. In his book, Feldstein explains the conflicts within each of these issues clearly, but *solely in terms of an economic model.* This review attempts a rediscussion using a more realistic and complex approach. Then I shall briefly discuss some of the other issues mentioned by Feldstein and finally note by way of contrast the health care systems in operation outside the United States.

I. PROPRIETARY HOSPITALS

Proprietary hospitals are hospitals managed for a profit, usually smaller in size than community or specialized government or university-related hospitals. The majority of the hospitals in the American Hospital Association are within the latter group. Following a strictly economic rationale, Feldstein argues that the American Hospital Association and Blue Cross are opposed to proprietary hospitals because they would prefer to maintain or increase the monopolistic status quo of the majority of their membership — the not-for-profit hospitals. Small proprietary hospitals represent unwelcome competition, in his thinking, because they force reexamination of the "inefficient" or at least non-competitive mode of operation of the not-for-profits.

This point of view presents a simplistic picture of hospitals as a business, with reinvestment of the profits entirely into increases in size, technology, and prestige rather than into payments to stockholders — a type of a not-for-profit department store. If you don't have the money, you don't buy. Many eager consumers of the hospitals' goods have no money or refuse to spend the money they have on hospital care. The State of Massachusetts is high on the list of such consumers since it disclaimed responsibility for the in-patient care of its 25,000 general relief recipients in December, 1975.[3] Emergency rooms open twenty-four hours a day attract a large number of people who are unable to pay; unlike department stores, however, the hospitals can hardly do other then administer the blood first and ask questions afterwards. Even patients who cannot pay, or cannot pay the full amount, and who are *not* emergencies cannot easily be transferred if there is no municipal hospital willing to accept them. In short, hospitals have a large number of customers who would not be welcome in department stores that judge the acceptability of customers by the potential contribution to the store's profits.

3 Reimbursement for almost all services for general relief recipients was restored on June 1, 1976, with the exception of in-patient hospital care. MASS. GEN. L. ANN. ch. 283, § 31 (West Supp. 1978), *amending id.*, ch. 118E, § 6 (West 1975).

Small proprietary general hospitals succeed in many parts of the country, particularly in areas such as California where regulation is still sparse and expanding population requires the quick establishment of new hospitals. Needless to say, there are few proprietary hospitals in Massachusetts (only 5 out of 117).[4] As is true of proprietary hospitals in the rest of the country, those in Massachusetts operate at a lower cost per patient day than not-for-profit hospitals.[5]

Although the latter point is appealing to an economist, it does not mean that competition from proprietary hospitals is necessarily beneficial for society. Obviously, a small hospital run like a business will avoid patients without insurance or the means of paying their bills and very sick patients who seem likely to run out of insurance. This type of hospital will also avoid running any "money losing services" if at all possible, including such items as emergency rooms and obstetrics units. Instead it will concentrate on skimming the cream of routine surgical patients, thus driving up the costs of the large hospitals with which it supposedly competes. The proprietary hospital is "efficiently" enough run to find the healthy young hernia patient with Blue Cross. The large not-for-profit hospital gets the patient with a strangulated hernia and a bad heart whose insurance has lapsed.

Another way of describing the situation in terms broader than economics is to note that while the role of a proprietary hospital may be to maximize its profits, the role of a not-for-profit hospital encompasses more than plowing its "profits" back into increased prestige, more beds, and more fancy equipment. The not-for-profit hospital encounters the very real problem of community service and community responsibility. Many crass and self-seeking motives are hidden under this rubric, but there are also some fairly altruistic and socially useful ones influencing daily decisions.

---

4 AMERICAN HOSPITAL ASSOCIATION, HOSPITAL STATISTICS 82 (1977).

5 In Massachusetts, the average per patient per diem expense for a not-for-profit hospital in 1966 was about $239.00, compared with an average per patient per diem for the proprietary hospitals of about $135.00. *Id.* at 83.

II. PRICING OF HOSPITAL INSURANCE

Just as Feldstein favors competition among hospitals, he also follows an economic model in encouraging competition in the underwriting of health insurance. The history of Blue Cross, which he clearly and accurately describes, is not, however, a particularly good argument for his theories from other than a very narrow economic point of view.

Blue Cross plans, which now comprise a loose federation of some seventy local units banded together on the national level as the Blue Cross Association,[6] began with two basic concepts of underwriting hospital insurance. One was community rating — each subscriber covered by the local plan paid the same rate regardless of risk — and the second was service benefits — the hospital was reimbursed either in full or as a percentage of its charges, rather than being paid a flat rate per day or per stay.

It should, of course, be noted that before the not-for-profit Blue Cross plans entered this area, the for-profit insurance companies were totally uninterested in insuring what they considered an unprofitable area of risk. It was only when Blue Cross was well established in the 1950's that the profit-making companies saw the possibilities involved in health insurance. Obviously, competing with Blue Cross on its own terms (*i.e.,* community rating and service benefits) would be quite difficult, since the private companies would have to be managed so much more efficiently than Blue Cross in order to return a profit to their stockholders. Rather, the private insurance companies developed two clever ideas which enabled them to capture a fairly large portion of the market over the next ten years. These ideas are experience rating and indemnity payments. Experience ratings base an individual's insurance premiums on the actuarial probability of his making a claim. (His health, age, family medical history and other factors are taken into account.) Contrast this to community rating, initially used by Blue Cross, which offers hospital

---

6 For a discussion of the Blue Cross Association, *see* S. LAW, BLUE CROSS: WHAT WENT WRONG? 18-25 (1976).

insurance to all members of the community at a uniform rate. Under an indemnity payment system, the insurer sets a fixed dollar amount to be paid per day or per period of hospitalization. Blue Cross plans usually give the subscriber assurance that his costs will be paid, with the insured paying only the deductible demanded by the plan.[7]

Naturally, a private insurance company can compete very effectively with Blue Cross if it insures only young, healthy employee groups with good medical records, leaving Blue Cross the old, the sick, and the less desirable. Also, by paying indemnity benefits, the insurance companies need not raise their premiums as hospital costs go up — the sick individual merely bears a higher proportion of the cost until an adjustment is made. The private insurance companies also developed cost-saving gimmicks, including denial of payment for pre-existing conditions and various other exclusions that were stricter than those used by Blue Cross.

Employer groups seeking to provide a fringe benefit at the lowest possible cost are naturally enthusiastic about private insurance. So, in fact, are individual subscribers attempting to save money on their premiums and comparing the cost of a private plan with that of Blue Cross. The only people unhappy are the patients who, when they are admitted into the hospital, frequently find that their stay is not covered at all or is covered for far less than its actual cost. During the 1960's it was common to find weeping patients in hospital admitting departments asking for a $30 room when the charge was actually approximately $80. Since most members of an employer group will not be hospitalized during the year, the feedback to the personnel office is usually not sufficient to alter most of the more onerous provisions of the insurance.

There is another group which is fairly unhappy with indemnity type insurance, with its exclusions and occasional initial deductibles in place of first dollar coverage. This group is, of course, the hospitals, which Feldstein dismisses rather lightly as "having a bad debt problem." The inability of

---

7 *Id.* at 12.

many privately insured patients to pay their full hospital bills not only results in such "bad debts" but also requires hospitals to be staffed with social workers and financial counselors. Thus, hospitals prefer the use of Blue Cross by their patients (especially by the "undesirables") in order to assure their own financial well-being, rather than for any of the nefarious motives such as collusion and restraint of trade that Feldstein suggests as their reasons for lobbying against a free market in the sale of insurance.

Many of the problems discussed above are rapidly becoming history. Due to competitive pressures, Blue Cross has adopted experience ratings and some Blue Cross plans have utilized an indemnity system. Medicare was in part a response to these insurance problems and has now altered the national health insurance system. Specifically, the main impetus for Medicare came when tens of thousands of old people could obtain no coverage from private insurance companies or were offered only indemnity coverage with such low payment rates that they owed the hospital much more than they could pay for out of pocket. These same old people could no longer afford the extremely high Blue Cross premiums, which began to be based on experience rating since lower risk employee groups and younger people could not subsidize them.

If the initial system of community rating could have been extended to non-group subscriptions rather than being vitiated by "competition," there might have been no need for the artificial mechanism of Medicare to subsidize the health care of people over age sixty-five through Social Security funds. While competition certainly led to a multiplicity of options for the consumer, it is not entirely easy to see that this was in anyone's best interest, least of all society's.

III. Educating the Nurse

In his chapter on the American Nurses' Association, Feldstein maintains that this group follows a deliberate policy of restricting the supply of nurses in order to create an artificial shortage and to force up wages. He sees their support of bac-

calaureate education as one of the main foundations of this argument.

Actually, nowhere does Feldstein mention that there is a large supply of nurses available already — almost half as large as the number currently working. These, of course, are the men and women who have completed their nursing training but who, for various reasons, are not practicing their profession. Many are women who have decided to devote their full time to their families. At any given time, 30 percent of the persons holding a nursing license are not employed as nurses.[8] Obviously, it is impossible to prevent these nurses from returning to practice as the wages and their own personal preferences warrant it. With an ailing economy and smaller families, this is happening more often, which is certainly one of the explanations for the termination of a shortage of nurses in many parts of the country. If the American Nurses' Association really desired to limit the supply of nurses, it could press for relicensure by examination after a certain number of years of inactive status. The Association has been very unwilling to go this far, although the membership of the ANA is almost entirely composed of working nurses and receives little funding from inactive nurses. Mild continuing education requirements are only now taking hold and can be attributed at least as much to the desire to enhance professional status as they can to a scheme to restrict practice opportunities.

Although the chapter on the ANA is otherwise thorough, there appears to be no thought given to *why* the nurses' association would prefer to have diploma schools phased out and replaced with baccalaureate programs, except for the previously mentioned "supply" question. Nursing school programs average three years, but a nurse who graduates from a

8 For example, in Massachusetts in 1972, there were about 18,000 licensed nurses who were not working, compared with 36,000 who were employed as nurses. Even among those working, a substantial proportion, probably about a quarter to a third, worked only part-time. In addition, a substantial but unknown number of those trained as nurses allow their licenses to lapse or do not reapply for licenses when they move from one state to another. These nurses represent a greater source of supply than the graduating class of new nurses. AMERICAN NURSES' ASSOCIATION, FACTS ABOUT NURSING 13, 24 (1974) (figures estimated from data).

three year hospital diploma school rarely has the equivalent of three years of college credits. In order to obtain a baccalaureate degree, even in nursing, the nursing school graduate must repeat much of the three years' work. This situation has continually contributed to the extreme shortage of nurses at the college-educated level or beyond. Yet it is only from those levels that the faculty of nursing schools and the administrative staff of hospitals traditionally have been drawn. Having only a non-academic diploma, then, has kept the nurse in a subordinate role and prevented a natural progression into higher management.

The American Nurses' Association has favored, in addition to baccalaureate programs, associate degree programs, which are mentioned only in passing by Feldstein. These programs require only two years, are less expensive to the student than the hospital-based programs (because they are state funded at the junior college level), and, most importantly, provide the first two years of college credit. Thus, the most able students can progress naturally by transferring into the baccalaureate program without repeating any of their courses. They can also finish their education part-time, while at the same time working as fully qualified R.N.'s.[9]

There is much nostalgia associated with the old diploma school of nursing, particularly among alumnae and the immediate community, but the truth of the matter is that they have usually been money losers for the hospital, a point of which Feldstein may be aware but which he avoids in presenting his financial information. Twenty years ago when there *was* a nursing shortage, proprietary hospitals did not operate nursing schools. They simply took advantage of the losses incurred by the not-for-profit hospitals in performing this service and then hired their graduates. As the nursing shortage has become less acute and, in fact, has turned into a surplus in many parts of the country, hospitals have become much less interested in maintaining their diploma schools. In fact, twenty-two diploma schools in Massachusetts have closed

9 Although that is the way the programs work in theory, in practice many universities are reluctant to accept transfers from the weaker associate degree programs.

since 1965, leaving only twenty-eight still in operation; ten of these are in the process of phasing out.[10] At the same time, thirteen advanced degree programs have opened since 1965 in the state, making a total of eighteen such programs operating as of 1976.[11] Yet to read Feldstein's book one would scarcely guess that the associate degree programs exist, not to mention that they are supplanting the diploma programs.

IV. Other Issues

The three previous issues have been discussed in detail because of the magnitude of the problems they present and because it will be many years before these problems are resolved. There are, however, a number of smaller issues or interesting items of history which Feldstein also thoroughly discusses. While I cannot quarrel with his scholarly work, again the same problem of using an economic interpretation when the situation demands a more complex explanation arises frequently.

For example, Feldstein reviews the regulations promulgated under the Hill-Burton Act,[12] now history since this program has not been funded for the last several years. It is his thesis that hospitals were in favor of Hill-Burton only when federal funds could be used to build new hospitals that were not in direct competition with existing ones. This is inaccurate. The history of Hill-Burton is replete with hospitals being built in the service areas of other hospitals since these service areas are almost never limited to one town.[13] Sound planning would indicate that an area already adequately served by an existing hospital should not be forced to support another one, but the rural interests in Congress in the 1940's were not always swayed by this argument. As a result

---

10 Adapted from National League for Nursing, State Approved Schools of Nursing - R.N. 22-24 (1976) and Macro Systems, Inc., The Role of Beverly Hospital in Nursing Education Exhibit III (1970).

11 *Id.*

12 Hospital Survey & Construction Act, 42 U.S.C. §§ 291a-291o (1976).

13 *Hill-Burton Hospital Survey and Construction Act: History of the Program and Current Problems & Issues, Hearings Before the Subcomm. on Health of the Senate Comm. on Labor & Public Welfare,* 93rd Cong., 1st Sess. 17 (1973).

we now have a large number of half-filled small town hospitals which have difficulty in attracting doctors and which face competition from nearby larger hospitals.[14]

Eventually there came a saturation point at which there were no more small towns in which to build hospitals. At this point, Hill-Burton turned its emphasis to renovating existing inner-city hospitals.[15] Pushed by the burgeoning Civil Rights movement of the 1960's, Congress was concerned with equal access to hospitals for ghetto residents. Feldstein seems to feel that proprietary hospitals should also have been eligible for Hill-Burton funds, although there were no strings attached to these funds in terms of community service. I am not convinced that this is a sensible use of tax dollars, but then I am not as hooked on free enterprise in the health care system as he is.

Another issue which Feldstein discusses in a sophisticated manner is the opposition of professional groups to competition from other practitioners whose services are less costly. This opposition usually takes the form of encouraging legislation which restricts the entry of these practitioners into the members' traditional fields. Feldstein has compiled a good set of illustrations, including some which had not occurred to me — dentists versus laboratory technicians who make dentures and who want to sell them directly to the public, for example. While I am not qualified to comment on task overlap among professionals, I would like to discuss briefly the connection between two groups Feldstein discusses — hospitals and nursing homes.

Feldstein argues that it is in a hospital's best interests to keep nursing home costs high so that patients will use more hospital care and the hospitals will not lose business to the nursing homes. He cites as evidence for this a Medicare regulation which required three days' stay in a hospital prior to being admitted to a nursing home when Medicare is paying

---

14 For a discussion of this problem *see* J. LAVE & L. LAVE, THE HOSPITAL CONSTRUCTION ACT: AN EVALUATION OF THE HILL-BURTON PROGRAM 1948-1973 38-39 (1974).

15 *See* Rose, *Federal Regulation of Services to the Poor Under the Hill-Burton Act: Realities and Pitfalls*, 70 NW. U. L. REV. 168 (1975).

the bill.[16] The argument is, again, a strictly economic one which is plausible but grossly oversimplified. The Medicare requirement was designed to prevent families from dumping perfectly well but senile old people into nursing homes once Medicare was willing to pay the bill.[17]

Under most circumstances, hospitals are extremely anxious to release their elderly patients and would like to see nursing homes increase in number and become more accessible. Under conditions of high hospital occupancy, which prevailed until relatively recently and still occur at certain times of the year and in certain hospitals, the presence of old people awaiting nursing home beds prevents the admission of patients for elective surgery. Furthermore, it is demoralizing to hospital staff to be caring for a number of people who are not really sick enough to require acute hospital care. Hospital social work departments sometimes must call thirty or forty nursing homes before finding one that will take an especially difficult patient. An added incentive in Massachusetts for hospitals to release patients to nursing homes has been the refusal of the Department of Public Welfare to reimburse hospital for days of waiting time which are not medically necessary. Hospitals have litigated this issue several times and have partially convinced the Department of Welfare that they are not willingly keeping the patients, but that they cannot find placements for them and cannot put them out on the street.[18]

Pre-paid group practice is an area so complex that I could not do justice to it even if I devoted the entire review to this subject. Feldstein has done a good job of outlining their history and growth and some of the legal impediments to them. Certainly his economic analysis here is correct: there is no question but that pre-paid group plans are a threat to the fee-for-service physicians in the same geographic area, just as

---

16 20 C.F.R. § 405.120 (1977).

17 *See* S. REP. NO. 404, 89th Cong., 1st Sess. 30-31, *reprinted in* [1965] U.S. CODE CONG. & AD. NEWS 1943, 1971-72. *See also* Pippin v. Richardson, 349 F. Supp. 1365, 1367-68 (M.D. Fla. 1972).

18 *See, e.g., Massachusetts Hospital Assn. v. Commonwealth of Massachusetts,* No. 76-1972-M (D. Mass., filed May 19, 1976).

a large hospital outpatient department with salaried physicians is a threat. What Feldstein does not discuss is that there are reasons for the very slow growth of pre-paid group practices in addition to roadblocks in the enabling legislation. One elementary reason has been lack of consumer acceptance. Americans are very accustomed to having their "own" physician and have not always adapted well to the rotation of physicians in many of the pre-paid group practices. Americans are also accustomed to obtaining elective surgery on demand. The economic thesis that discretionary surgery results solely from *physicians'* desires to increase their business and profits neglects the fact that *patients* want surgery for a variety of reasons, both psychological and physical. If one surgeon will not perform an operation to relieve symptoms which are annoying but not incapacitating, another willing surgeon can usually be found.

Patients who are confronted with a pre-paid group practice, which is much less apt to do discretionary surgery, will quit this practice and go elsewhere, thus raising the fee-for-service rates for surgical admissions while helping to keep the pre-paid group practice rates low. In other words, this is an extremely complex issue that involves the basic question of American society's attitudes toward medical care.

V. Health Care Systems in Other Countries

Conspicuous by its absence in Feldstein's book is any attempt to describe how other countries finance and deliver health care. This would be beyond the scope of the kind of book that Feldstein has written, but it is of interest because of the points he persistently makes. While Feldstein would have the United States adopt a much more competitive and laissez-faire system, where the economic market place would insure efficiency, our system is already much less government-regulated than that of any other industrialized country.

In England, the national government owns almost all of the hospitals. The hospital specialists are salaried and the general practitioners are on a capitation system which pays them for the number of patients for whom they are responsi-

ble, rather than on a fee-for-service basis, although physicians do receive fees for certain services (maternity).[19] In Sweden, the local governmental units operate the hospitals and citizens participate in a compulsory health insurance plan similar to Medicare but covering all citizens, not just the aged.[20] The situation is similar in Canada, with the provinces controlling the health care system and with universal national health insurance. Japan is perhaps most similar to the U.S., in that the Japanese have a large number of proprietary hospitals, but even their payment through universal health insurance is through strict government regulations.[21]

An ironic sidelight of all of this is that the United States spends a far greater proportion of its health care dollars on medical and hospital care for the aged, while other industrial countries concentrate their expenditures on children, pregnant women, and the working age population, where mortality reductions are much more promising.[22] Most health care researchers who have noticed this phenomenon feel that beginning a universal health care program with Medicare contributes to a great upsurge in the use of services by the aged who previously could not afford optional health care. Had this been a matter of explicit public policy rather than a response to a failure in the private sector, it might have been preceded by substantial discussion of the alternative of underwriting other portions of the population, such as pregnant women and children. As it is, legislation resulting from the economic factors inherent in a free market philosophy has obscured a great many underlying social issues.

Conclusion

This discussion is not meant to suggest that a reading of Feldstein's book is unprofitable. The book is well worth reading for its discussion of health care policy regulation over

---

19 D. FULCHER, MEDICAL CARE SYSTEMS 85, 88-89 (1974).

20 *Id.* at 141-45.

21 *See generally* Newkirk, *Costs, Technology Highlight International Meeting,* 51 HOSPITALS 85 (1977).

22 O. W. ANDERSON, HEALTH CARE: CAN THERE BE EQUITY? 150 (1972).

the last thirty to forty years. Rather, this reviewer has sought to introduce a broader perspective to Feldstein's attempted explanations of health care regulation. Also, it should be noted that there is a great reservoir of irrationality in the system whereby legislation is proposed and implemented. It is greatly to Feldstein's credit that he has tried to make the process appear rational, by applying a relatively stringent economic theory to it. It is not a failure on his part, but rather one of human nature and the human condition, that any one set of theories is inadequate to explain some of the strange results that legislation engenders.

RECENT PUBLICATIONS

BIBLIOGRAPHY OF BIOETHICS — VOLUME 3. By *Gale Research Company, Dr. LeRoy Walters, ed.* Detroit: Gale Research Co., 1977. Pp. 348, indices. $24.00.

The dimensions of bioethical issues have multiplied in stride with the rapid advances of medical technology. Yet while physicians, biologists, psychologists, sociologists, philosophers, lawyers and legislators can usually identify a "bioethical problem" when it affects their professional practice, their approach to such questions is often narrowly focused and influenced by the discrete factual situation which created the bioethical dilemma.

Public attention to bioethical issues such as abortion, genetic engineering, the right to die, and access to health care delivery, has spawned a vast amount of literature in this field. Some of it is technical and directed towards members of a certain profession. Other writings are intended to increase public awareness of important questions that must be asked before granting carte blanche to certain scientific advancements. The *Bibliography of Bioethics* was designed to provide comprehensive, inter-disciplinary coverage of a variety of media on bioethical topics. Materials indexed include Supreme Court and lower court opinions, articles in law reviews and medical journals, government reports, and newspaper articles. The publishers anticipate provision of a series of annual volumes; Volume 3 covers 1512 documents from 1973 through 1976. Sixty reference works and seventy journals and newspapers were monitored for articles and citations falling within the scope of bioethics.

The *Bibliography* is comprehensive in scope — covering the traditional physician-patient relationship and access to health care; abortion, contraception, and genetic intervention; mental health therapies; human experimentation; death and dying; and international dimensions of biology and medicine (for example, biological warfare). Its map is a

"Bioethics Thesaurus," which cross-references key words for the user. These cross-references are identified as "broader," "narrower," or "related" terms. The *Bibliography* also contains a title and author index.

The core of the *Bibliography* is the "Subject Entry Section," an alphabetical listing of material included. The great advantage of these entries over similar entries in other indices is the degree of information given the user. Eleven pertinent data elements appear for each entry. The author, title, name of journal, volume and issue numbers, pages, date of publication, number of references, and number of footnotes are identified. Also included are "descriptors" and "identifiers." "Descriptors" summarize the content of each document; "identifiers" are proper nouns not listed in the thesaurus that refer to a particular person or political entity. For example, "descripters" used to illustrate the scope of the decision of *In the Matter of Karen Quinlan* are

> "allowing to die, brain death; competence; *constitutional law; criminal law; *decision-making; determination of death; diagnosis; ethics committees; extraordinary treatment; human rights; judicial action; killing; *law; legal aspects; legal guardians; legal liability; legal rights; medicine; moral obligations; *parental consent; parents; *physicians; *privacy; prognosis; prolongation of life; religious beliefs; Roman Catholic ethics; standards; state interest; *terminally ill; *withholding treatment . . . ." (at p. 287).

Asterisks indicate the most important concepts in the work.

It is difficult to criticize the selection or arrangement of the *Bibliography;* certainly the authors have undertaken a herculean task in attempting to organize and categorize subject matter that spans such a number of technical specialties. The *Bibliography* will be an asset for libraries and scholars in the field. However, since bioethics questions are effected by rapidly changing events, a reference volume published almost a year after its last entry is not always useful. It is hoped that once a cataloguing system is perfected by the authors that this problem can be overcome.

ETHICS IN MEDICINE — HISTORICAL PERSPECTIVES AND CONTEMPORARY CONCERNS. By *Stanley J. Reiser, Arthur J. Dyck, and William J. Curran, eds.* Cambridge, Ma.: The MIT Press, 1977. Pp. xii, 667, index. $19.95 paper.

Since the days of Hippocrates, ethics has been a significant focus of the medical profession. Modern technology and medical advances have made issues of life and death even more crucial to consumers and producers of contemporary health care. *Ethics in Medicine* is designed to meet those concerns. Endorsed by the Joseph P. Kennedy Jr. Foundation, the volume offers an anthology of readings and cases on medical ethics over the last 2000 years. Initially compiled for medical students at Harvard University, the book treats a medley of issues ranging from the physician-patient relationship to regulation, consumer protection, medical experimentation, patient rights, and provision of health care in the 1970s and beyond.

Do all have rights to medical care? On whom should we experiment? What are the rights of the handicapped? These are only a few of the questions which the book addresses. Essays by Joseph Collins, Hans Jonas, Sissela Bok and others present a variety of views from several disciplines on the aims of the medical profession, its failures and successes.

The book does not purport to give answers. Nor does it present a systematic theme or single point of view. It does present, however, a commendable and well-footnoted overview of ethical issues with far-ranging interest and application.

Among the more interesting aspects of the volume is its perspective on the intervention of lawyers and legislators in the medical world. While positing medical problems, the work points the way for legislative action in an area neglected to date because of judicial and legislative fear and ignorance in the medical field. Lawyers and legislators could well pay attention to ideas set forth in the essays. William F. May, for example, subjects the legal paradigm of contractual medical care to a thorough critique and suggestive analysis. Elsewhere in the book, authors such as William Curran,

Judge David L. Bazelon, and Philip Reilly discuss the growing need for judicial and legal intervention in medicine today.

That, in the end, there are no answers, no single right way is the theme if not the frustration of *Ethics in Medicine.* Its goal is to spur future leaders of the medical society to begin and continue to ask questions.

GENETICS, LAW, AND SOCIAL POLICY. By *Philip Reilly.* Cambridge, Ma.: Harvard University Press, 1977. Pp. 275, index. $15.00.

Eugenics and genetic screening legislation have only recently begun to emerge from a long travail in the intellectual and political wilderness to gain acceptance in the legal and medical communities. But legislation to assist genetic programs raises a host of troublesome issues related to personal autonomy, the right to privacy, and practical administration. In addition, such legislation has often served merely as a flimsy cloak or a crude rationalization for racial oppression. Philip Reilly recognizes the dangers of poorly drafted or wrong-headed legislation, but he believes that it is possible to draft legislation that will promote genetic health without harming the very individuals whom such legislation is designed to help.

Genetics, Law, and Social Policy provides a lucid and comprehensive discussion of the recent history and current status of genetic screening legislation in the United States. Reilly's discussion of the history of legislative attempts to control two of the better known genetic diseases — phenylketonia, a disease which can cause mental retardation, and sickle cell anemia — outlines the multitude of problems that have plagued screening legislation in the past: inadequate counseling to affected persons, lack of follow-up programs, inaccurate testing procedures, failure to protect the confidentiality of information obtained through screening. Nevertheless, Reilly cites the improvements in screening legislation and concludes that the funds spent on such programs are justified.

Although Reilly offers no detailed analysis of the constitutional considerations directly related to the special question of compulsory genetic screening legislation, his treatment of constitutional issues is far more adequate when he discusses the degree to which the state should use pre-marital screening laws as a means of discouraging couples with defective genes from procreating. Reilly contends that mandatory premarital screening tests would survive judicial scrutiny so long as the legislation did not require any action on the basis of test results and so long as the law provided for competent screening services, high quality genetic counselling for persons with positive test results, public education, and confidentiality of test data.

Reilly has carefully noted many perplexing questions raised by screening legislation. Unfortunately, the answers he proposes are not always so detailed. Although Reilly clearly does not purport to furnish any definitive legislative schemes, apparently intending only to frame the issues, many of his conclusions are sufficiently provocative to merit more comprehensive analysis. Nevertheless, the book highlights the central legal and practical problems in this area of legislation. The work is essential reading for anyone connected with the drafting, enactment, interpretation, or enforcement of legislation regarding genetics and eugenics.

BOOKS RECEIVED

AND THE DESERT SHALL REJOICE . . . CONFLICT, GROWTH AND JUSTICE IN ARID ENVIRONMENTS. By *Arthur Maass and Raymond Anderson.* Cambridge, Ma.: MIT Press, 1978. Pp. 447, index. $19.95.

ARBITRATION 1977 — PROCEEDINGS OF THE THIRTIETH ANNUAL MEETING, NATIONAL ACADEMY OF ARBITRATORS. Washington, D.C.: BNA Books, 1978. Pp. 387, index. $15.00.

BENTHAM'S THEORY OF THE MODERN STATE. By *Nancy Rosenblum.* Cambridge, Ma.: Harvard University Press, 1978. Pp. 169, index. $15.00.

THE CRIMINAL LAW REVOLUTION AND ITS AFTERMATH: 1960-1977. By the editors of *The Criminal Law Reporter.* Washington, D.C.: BNA Books, 1978. Pp. 292, index.

DEVELOPMENTS IN TENDER OFFERS FOR CORPORATE CONTROL. By *Edward Aranow, Herbert Einhorn, and George Berlstein.* New York: Columbia University Press, 1977. Pp. 411, index. $57.50.

THE FEDERAL SYSTEM IN CONSTITUTIONAL LAW. By *C. Herman Pritchett.* Englewood Cliffs, N.J.: Prentice Hall, 1978. Pp. 394, index. $7.95 paper.

HUGO BLACK AND THE BILL OF RIGHTS: PROCEEDINGS OF THE FIRST HUGO BLACK SYMPOSIUM ON "THE BILL OF RIGHTS AND AMERICAN DEMOCRACY." By *Virginia Van der Veer Hamilton.* Birmingham, Ala.: University of Alabama Press, 1978. Pp. 104, index. $8.00.

IMAGES OF THE URBAN ENVIRONMENT. By *Douglas Pocock and Ray Hudson.* New York: Columbia University Press, 1978. Pp. 181, index. $12.00.

INHERITANCE AND THE INEQUALITY OF MATERIAL WEALTH. By *John A. Brittain.* Washington, D.C.: Brookings Institution, 1978. Pp. 102, index. $7.95 cloth, $2.95 paper.

THE LESSONS OF WAGE AND PRICE CONTROLS — THE FOOD SECTOR. By *John Dunlop and Kenneth Fedor, eds.* Cambridge, Ma.: Harvard University Press, 1978. Pp. 344, index. $19.50.

A NEW GUIDE TO FEDERAL CABLE TELEVISION REGULATIONS. By *Steven Riukin.* Cambridge, Ma.: MIT Press, 1978. Pp. 314. $25.00.

NEW MEANS OF FINANCING INTERNATIONAL NEEDS. By *Eleanor Steinberg and Joseph Yager.* Washington, D.C.: Brookings Institution, 1978. Pp. 256. $11.95 cloth, $4.95 paper.

THE PAY BOARD'S PROGRESS: WAGE CONTROLS IN PHASE II. By *Arnold Weber and Daniel Mitchell.* Washington, D.C.: Brookings Institution, 1978. Pp. 454. $12.95 cloth, $5.95 paper.

POLITICS AND THE PROFESSORS — THE GREAT SOCIETY IN PERSPECTIVE. By *Henry J. Aaron.* Washington, D.C.: Brookings Institution, 1978. Pp. 185, index. $9.95 cloth, $3.95 paper.

THE PROMISE OF GREATNESS. By *Sar Levitan and Robert Taggart.* Cambridge, Ma.: Harvard University Press, 1978. Pp. 316, index. $5.95 paper.

PUBLIC POLICY AND PRIVATE HIGHER EDUCATION. By *David Breneman and Chester Finn, Jr., eds.* Washington, D.C.: Brookings Institution, 1978. Pp. 468, index. $16.95 cloth, $7.95 paper.

RECONCILING MAN WITH THE ENVIRONMENT. By *Eric Ashby.* Stanford, Cal.: Stanford University Press, 1978. Pp. 104, index. $7.95.

RICH AND POOR NATIONS IN THE WORLD ECONOMY. By *A. Fishlow, C. Dias-Alejandro, R. Fagen, and R. Hansen,* New York: McGraw-Hill, 1978. Pp. 264, index. $6.95 paper.

SCHOOL DESEGREGATION: SHADOW AND SUBSTANCE. By *Florence Levinsohn and Benjamin Wright, eds.* Chicago: University of Chicago Press, 1976. Pp. 216, index. $3.95 paper.

THE SENATE NOBODY KNOWS. By *Bernard Asbell.* New York: Doubleday & Co., 1978. Pp. 466, index. $10.00.

SOCIAL LIMITS TO GROWTH. By *Fred Hirsch.* Cambridge, Ma.: Harvard University Press, 1978. Pp. 208, index. $3.95 paper.

TRADE NEGOTIATIONS IN THE TOKYO ROUND — A QUANTITATIVE ASSESSMENT. By *W. Cline, N. Kawanabe, T. Kronsjö, and T. Williams.* Washington, D.C.: Brookings Institution, 1978. Pp. 314, index. $11.95.

WELCH'S GRAPE JUICE: FROM CORPORATION TO CO-OPERATIVE. By *William Chazanof.* Syracuse: Syracuse University Press, 1977. Pp. 407, index. $20.00.