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Why Does Health Care Regulation Fail?

ROBERT C. CLARK**

In the past two decades in the United States, the percentage of the gross national product that we have devoted to expenditures on medical care has nearly doubled, to about ten percent.¹ It is difficult to overstate the importance of this change. It is also difficult to identify the nature and amount of the benefits that society has thereby bought. During the same period, death rates in the American population changed only slightly.² Certainly, when compared to the enormous improvements in mortality experience during the 150 years before World War II and the introduction of modern medicine, the recent drop in death rates has been the merest blip on the graph; and in any event, it would be a brave statistician indeed who would attribute the change to improved medical care rather than to other determinants of longevity.

These facts are somewhat puzzling to many people. Equally puzzling is the fact that attempts to find that higher medical care expenditures have produced an overall improvement in specific measures of morbidity or health status—for example, in the number of individuals with serious hypertension—have failed, or have produced limited or unimpressive results.³ Most ordinary people, who tend to think of concrete experiences and examples and to be relatively unmoved by pallid statistical data, would find it hard to understand or accept the apparent

² Id. at 59, 70, 72 (table no. 104), 79.
implications of these facts. Surely everyone knows some relative or friend who had a heart attack or other serious condition and "would not be alive today" were it not for the superduper expensive modern intensive care unit at the XYZ Hospital. And we all read about developments, like microsurgery, that clearly do represent major advances, at least in a narrow technical sense. How then, can we make sense of statistical data that seem to say that our great increases in spending on medical care have not had an equally great impact on our health?

One approach to answering this question is to assemble particular studies that illustrate how it can happen that we can spend money on medical care and yet produce no impact, or even an adverse impact on health. For example, some researchers found that eighty percent of all doctor visits are for conditions that will get better by themselves or that can't get better as a result of any known medical treatment. Others have found that a very small percentage of all hospital patients account for a very large percentage of hospital costs, and that these people tend to have chronic or recurrent conditions that do not respond decisively to medical treatment. And the prestigious medical journal, The New England Journal of Medicine, recently carried two disturbing articles on the incidence of iatrogenesis, that is, on adverse conditions in patients that would not have occurred but for the failure to follow approved medical procedures. Put simply, the researchers found that iatrogenesis is not a little problem, but a very big one.

In the end, we will want to tote up the significance of studies of this sort and match them against the clear successes of modern medicine. It is still necessary to think in terms of aggregates, or total net effects, not just in anecdotes and particulars, in order to assess the modern system of medical care.

I think that one sensible conclusion to draw from all the evidence presently available is that in modern societies the marginal or incremental contribution of medical care to health status is very small. Doubling the amount a nation spends on medical care does not produce anything like a comparable gain in the health status of its people.

Some health care policymakers have long recognized this basic in-

5. Zook & Moore, High-Cost Users of Medical Care, 302 NEW ENG. J. MED. 996 (1980).
Virtually all policymakers have recognized the skyrocketing nature of health care costs. As a result, we have witnessed an enormous growth in health care regulation over the last decade or so. Massive regulatory systems have been introduced to control the entry of new capital equipment, to limit the use of health care facilities, and to set prices. Econometricians have done studies of these programs. The results have been meager and disappointing. The Professional Standards Review Organization (PSRO) law — the federal utilization review program — seems to have produced a slight drop in health care expenditures, but the savings have been matched by the direct costs of merely administering the program. The certificate of need laws, which regulate new capital expenditures, seem to have had little or no effect. Until very recently, studies indicated that the rate setting programs also had no effect. In the last year or so, however, several studies have shown that these programs have produced some positive results. But don’t start cheering: even in most states with effective rate setting programs, hospital costs are still rising much faster than the general rate of inflation.

8. For example, the National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 81 Stat. 2225 (codified at 42 U.S.C. § 300K (1976)), was in part created to check the growing cost of health care in this country. In apparent recognition that growing government subsidy of health care costs has been a major factor in driving up costs, the 1974 legislation was drafted with a twofold purpose in mind:
   (1) [To create] a single new program of State and areawide health planning and development which combines the best features of the existing programs; and
   (2) [To minimize] uneconomic duplication of facilities and highly specialized services; [to foster] cost control through improved efficiency and productivity, including promotion of cost effective preventive method health care services; and [to foster] more effective competition within the health system in order to improve consumer choices in the organizing, financing and delivery of health services.

11. See generally F. Sloan & B. Steinwald, Insurance Regulation and Hospital Costs (1980); Sloan & Steinwald, Effects of Regulation on Hospital Costs and Input Use, 23 J. L. & Econ. 81 (April, 1980).
13. See, e.g., F. Sloan, Regulation of the Rising Costs of Hospital Care (1980); Biles, Schramm & Athinson, Hospital Cost Inflation Under State Rate-Setting Programs, 303 NEW ENG. J. MED. 664 (1980); Coelen & Sullivan, An Analysis of the Effects of Prospective Reimbursement Programs on Hospital Expenditures, HEALTH CARE FINANCING REV. 1 (Winter, 1981).
Overall, a neutral observer would probably reach the conclusion that our system of health care regulation has failed. Here, by “health care regulation” I mean not only the new style programs but the entire set of laws and legally shaped institutions that bear on the financing and delivery of health services. Health care regulation in this broad sense has failed in that it has neither restrained rapidly rising costs nor insured an acceptable ratio of benefits to costs.

The question then arises: why has health care regulation failed? Many analysts have proposed answers to this question, and the answers tend to come in standard packages. Today I want to focus on one part of a complete answer. It is a part that I believe has been missed, underemphasized, or misconstrued in many analyses. My theme is this: health care regulation fails because as a society we do not know how to impose optimal social controls on professional power, and our awareness of this ignorance is so disturbing that we have adopted no significant external controls on professionals at all.

Of course, numerous analysts have noted that physicians make many of the key decisions in the medical world. Usually they find a troublesome side to this decision making role, and usually they attribute it to physician expertise. This common analysis is correct, but incomplete. What I want to emphasize, and to illustrate extensively, is the deference that our legal system pays to the judgments of the medical profession. I will then indicate the results of this deference, and suggest some things that might be done about it. But before I do this, I must issue a few caveats.

First, I am not trying to put forward a conspiracy theory, or even a regulation-is-a-form-of-cartel argument. Nor do I want to suggest that the legal system’s deference to the medical profession has been clearly reprehensible and that something else quite obviously ought to have been done. My view is that the question of the proper stance of the law toward professionals—any and all professionals—is a very deep and difficult problem. Indeed, it is one of the major problems of modern societies. The problem arises because it may not be wise for inexpert lay persons to regulate the expert actions of professionals. If regulation is done improperly, it may do more damage than simply letting the professionals do what they want. While I do intend to offer some regulatory recommendations, I want to admit at the outset the difficulty of the problem.

The second caveat is that analyses parallel to the one I shall give

might very well be made in the cases of lawyers, accountants, business managers, investment advisors, and other professionals. Indeed, a plausible case can be made that the United States has failed to regulate professional power generally, and therefore suffers from socially excessive amounts of professional services: too much litigation because there are too many lawyers drumming up business among lay persons who cannot accurately value the worth of legal advice; too much securities analysis (despite the many years' worth of "random walk" studies that refute its worth to the average individual investor) because there are too many investment professionals who have convinced clients that their work is esoteric expertise rather than mystical hocus pocus; and so forth.

Excuse me for not elaborating all of this; I can tackle only one problem at a time.

I. THE DEPTH AND BREADTH OF LEGAL DEFFERENCE TO THE MEDICAL PROFESSION

There appear to be many laws regulating health care professionals. In fact, most of them embody extreme deference to the medical profession. Consider a number of the more salient instances.

Malpractice law. The first is medical malpractice law. In an obvious sense, malpractice law is designed to control the conduct of practicing physicians, to make sure that it lives up to certain standards of quality. But more significantly, in all but a tiny fraction of the reported cases, the standard of care is "accepted medical practice" as defined by the actual custom and practice of physicians. Thus a defendant physician will usually win if he can find other doctors to testify that he followed customary medical practice. Even if he didn't follow customary medical practice, he may still prevail if he can obtain expert testimony that his treatment was within the range of what a "reasonable and prudent physician" might do, or, in some courts, what a "respectable minority" of physicians would do. Courts almost never impose a higher standard on physicians than actual customary practice or, at most, the prevailing notions of orthodox doctors as to what customary practice ought to be. There are some exceptions. In *Helling v. Carey*, the court

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did impose a higher, non-customary standard when it held ophthalmologists liable for failing to give a cheap and simple pressure test for glaucoma to a young patient. It is a notorious case precisely because the court did the unthinkable — for once, mere judges dared to place their profane hands on the Ark of the Covenant. But the facts of the case were special, other courts did not follow the decision, the state legislature reacted against it, and commentators often condemned it. In short, it is the exception that proves the rule. Far more typical is the attitude of the California Supreme Court in *Landeros v. Flood*, which considered whether a physician was responsible for knowing about emerging diagnostic criteria, specifically, whether he should have been able to recognize battered child syndrome. The court concluded that there should be expert medical testimony on the issue — that is, in effect, that the norm of practice should be determined by physicians themselves.

A few informed consent cases, like *Canterbury v. Spence,* form another exception to the rule that customary practice defines a doctor's standard of care. They hold that a physician's duty to disclose is based on the patient's need to know rather than on customary practice. But the exception is an insubstantial one, because many courts have not

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22. The glaucoma test was cheap, simple, effective, reliable, and free of adverse side effects. When glaucoma is discovered, there are clearly effective ways of treating it. When glaucoma goes undetected, it can lead to serious and irreversible damage to vision. The probability of getting glaucoma at various ages is known with fair precision. *Id.* at 518, 519 P.2d at 983. In view of all these characteristics — which certainly are not all true of many medical conditions — the court could view itself, not as assessing any particular medical procedure or custom on its medical merits, but as performing an almost textbook-like cost-benefit analysis of the sort recommended by modern commentators on tort law.


While this article does not mention the *Helling* case explicitly, Dr. Altschule contends that physicians are exposed to an excessively high risk of liability for malpractice and, as a result, must substitute the use of "defensive", often unnecessary laboratory tests for reliance on their own sound medical judgment. His "solution": "make evaluation of a physician's judgment and technical competence solely the duty of experts, and not of a jury of laymen, of a judge, or of a lawyer who puts the intention of winning a case above every other consideration." *Id.* at 297.


28. This need to know is for information material to a treatment decision and the test for determining whether a particular peril must be divulged is thus its materiality to the patient's decision. *Id.* at 786-87.
followed this approach,29 legislatures have reacted against it,30 and most malpractice cases simply do not raise the issue.31 Most important of all, the informed consent cases do not entail judicial evaluation of the efficacy or cost-effectiveness of customary medical procedures.32

Furthermore, in most malpractice cases accepted medical practice has to be established by the oral testimony of expert physicians. The court will not do its own survey and assessment of medical texts and journals. Of course, there are occasions when proof of negligence does not depend on expert testimony. For example, the physician may have left a sponge or clamp inside the patient he operated on, and even a lay person might conclude that this was improper. But the courts restrict the range of these cases to a surprising degree. Often they force the plaintiff to get expert testimony as to whether or not a clear mistake in following a standard medical procedure, for example, putting a stitch in a woman's kidney tube during a hysterectomy, should be considered negligence.33 To be sure, in cases alleging maladministration of drugs, courts nowadays may allow the manufacturer's recommendations as to proper usage to be substituted for expert testimony.34 In view of the substantial research on safety and efficacy that lies behind all such manufacturer's recommendations,35 to do otherwise would be patently irrational. But even here the courts allow physicians to plead and

32. Since almost any medical procedure entails some risk to health from the procedure itself, a rational patient trying to decide whether to undergo a recommended procedure would be quite interested in the procedure's true efficacy and, to the extent the patient is uninsured, in its cost-effectiveness.
33. Hart v. Steele, 416 S.W.2d 927 (Mo. 1967).
35. See 21 U.S.C. § 355(a)-(e) (1976). Under this section of The Federal Food, Drug, and Cosmetic Act, the introduction into commerce of any new drug (which is defined as one not generally recognized by experts as effective and safe, 21 U.S.C. § 321(p)(1) (1976)) is prohibited unless there is substantial evidence showing that the drug is safe and effective for its intended use. "Substantial evidence" is defined as:

- evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labelling or proposed labelling thereof.

prove excuses, based on their experts' testimony, for their particular acts of deviance from manufacturer's instructions.  

In sum, the touchstone of malpractice cases is accepted medical practice, as established by the testimony of individual medical experts, and as defined in autonomous fashion by the medical profession itself. The crucial significance of this state of affairs lies in what the law does not provide. It does not provide for judicial evaluation of conventional medical judgment with respect to diagnostic criteria and treatment procedures. More important — since judicial evaluation is not feasible — the law does not even provide process controls on the profession's development of norms of practice. There is no requirement that a specified authoritative body, whether in the government or in the medical profession, must have reviewed evidence of controlled clinical trials of the efficacy, much less the cost-effectiveness, of a medical procedure before it can be treated as acceptable medical practice. There is an analogous requirement with respect to drugs, of course: manufacturers must obtain FDA approval before marketing new drugs, and that approval depends upon submission of fairly rigorous scientific proof of the safety and efficacy of the drugs. And while many would criticize the particular design of these procedures and the performance of the FDA, I think most responsible persons would approve the basic idea.

Why is it that our society can bring itself to demand that drug companies prove the efficacy of their pills but not to demand that the medical profession prove the efficacy of surgical operations and other standard procedures? Surely the answer is not the supposed inability of a lay legislature to legislate wise controls over matters requiring expertise. That explanation would suggest no regulation in either context. The answer, I think, is simply that lay persons, including legislators, are conditioned to exhibit deference and submission to physicians.

*Physician education.* The second example of the legal system's deference to the discretion of the medical profession concerns the educa-

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37. Note that process controls can be designed to leave room for medical researchers to engage in true experimentation with untested procedures. But much current use of unproven processes is "experimental" only in the colloquial sense that the doctors are not sure what will happen. This "let's try it out" approach of the individual clinician is a far cry from executing a well-planned, well-designed, controlled experiment in which data about results will be systematically collected and processed in light of a pre-formulated hypothesis. The latter kind of experiment is far more likely to add to scientific knowledge and it deserves more solicitude than the traditional freedom of the clinician to act on intuition and on experience with small samples of cases.

tion of doctors. After the famous Flexner report on medical education in 1910, every state established standards for licensing doctors, either by statute or by the rules of state medical licensing boards, with the proviso that the boards consider only graduates of medical schools approved by the American Medical Association or the Association of American Medical Colleges. Later, in 1942, the Council on Medical Education of the AMA set up the Joint Liaison Committee on Medical Education to perform the accrediting function. The committee was to be physician-dominated; its members were to include six representatives of the AMA, six representatives of the Association of American Medical Colleges, two public representatives, and one representative of the federal government. All states delegated power to approve medical schools to this committee. In essence, the system thus created has continued to this day.

As commentators have noted, this delegation creates a conflict of interest: "The decision with respect to what is adequate training and an adequate number of doctors affects the pocketbooks of those who do the regulating as well as their closest business associates." With some exceptions, economists and students of medical history attribute a number of problems partly to AMA control of medical education—a serious restriction for several decades in the supply of physicians, an increase in the costs of physician services, overspecialization, and a serious gap between educational costs and tuition revenues, a gap that has led to substantial government subsidies of medical education. Moreover, many of the educational requirements of medical schools have never been shown by any sort of systematic study to relate directly to the quality of actual medical practice. Once again, the law does not provide for any significant outside evaluation of the profession's own standards of accreditation, nor does it contemplate any process

42. Kessel, Price Discrimination in Medicine, 1 J.L. & Econ. 20, 29 (October, 1958).
45. J. Goodman, supra note 44, at 34.
controls. There is no requirement that accreditation standards be justified by empirical studies. There is not even a requirement that accreditation standards conform to vague statutory principles or goals—for example, that the benefits of accreditation standards in terms of improved quality of patient care must be found to outweigh their costs. In the construction and regulation of medical curricula that are prerequisites to the lawful practice of medicine, there is virtually total deference to the medical profession.

Medical licensure. The third example of the legal system's deference to professional autonomy lies in the medical practice acts. In general, under these laws, only licensed physicians can practice medicine. The licensing procedure is carried out by state medical licensing boards. These boards are always made up solely or predominantly of physicians, most of whom have been nominated or approved by state medical societies. They base licensing decisions principally upon the results of examinations that are prepared nationally by one or another trade association group and, as I indicated before, upon successful completion of a course of study at a medical school approved by the Joint Liaison Committee. After surviving this process, the new physician is given an almost unlimited right to practice medicine and de facto lifetime tenure. The newly licensed physician with little training in surgery can nevertheless perform it legally; the nurse who has skillfully assisted at many operations of a particular kind may not do them. Requirements for license renewal and maintenance are weak and the technical possibility of license revocation for conduct harmful to the

46. E.g., Md. Ann. Code art. 43, § 122(a) (1980) ("No person shall practice medicine in this State unless he is licensed by the Board and is registered in accordance with the provisions of this subtitle.")). Section 123 also requires that an applicant be 18 years old, of "good moral character," and a graduate of a medical school whose standards are equal to those established by the Association of American Medical Colleges and the Council on Medical Education of the AMA or of the American Osteopathic Association. Various exceptions are listed in § 122.

47. The number of members can vary from "five reputable physicians of known ability" appointed by the Governor from a list submitted by the State Medical Society (plus one member representing the public), N.M. Stat. Ann. § 61-6-1 (A) (Cum. Supp. 1980), to 12 physicians (plus one citizen) appointed by the governor from a list compiled by the State Medical Association, Ga. Code Ann. § 84-902 (Cum. Supp. 1981).

Maryland's Board of Medical Examiners, officially established in Md. Ann. Code art. 43, § 120 (Supp. 1980), has ten members: eight to be currently practicing physicians, licensed by the state and elected by the "Medical and Chirurgical Faculty of the State of Maryland", plus two members of the general public appointed by the Governor.

48. For example, both Florida and Georgia require that their applicants be certified by passing the Federation Licensing Examination (FLEX). Alternatively, Florida accepts certification by the National Board of Medical Examiners, Fla. Stat. Ann. § 458.313(d) (1981), and Georgia, by any other National standardized examination which the board approves, Ga. Code Ann. § 84-913 (1979).
public or other specified reasons is rarely actualized, even in the case of seriously impaired physicians. On the other hand, medical licensing boards can be very active in litigation trying to exclude other persons from attempting to do things that constitute or resemble medical practice. Can ear piercing be done by cosmeticians, or only by medical doctors? May a corporation formed to operate a plasmaphoresis or plasma collecting clinic, which uses a routinized and highly structured set of procedures, legally allow its nurse employees to collect blood from donors, or may this only be done by physicians? May licensed chiropractors draw blood samples to send to licensed laboratories for testing, may they perform acupuncture and prescribe vitamins, or may these activities only be done by physicians? May midwives legally assist women in the delivery of their babies, or is childbirth a disease or medical condition that can be supervised only by licensed medical doctors?

All of these questions and many like them have been litigated vigorously. In the aggregate, the cases indicate that the medical profession has been quite successful in preserving, extending, and monopolizing its turf.

More generally, the organized medical profession itself fills in the content of the legal concept "practice of medicine" as it sees fit, and it uses the state licensing system as a vehicle for excluding others from the activities it puts into that concept. Whether this deference to professional autonomy is justified is a separate issue, of course. The orthodox view is that the licensing process is essential to upgrade the quality of medical care and to protect the public from charlatans and quacks. But no good empirical study has ever been made to verify the inference that medical licensure in fact has led to an improvement in the quality of care. A number of prominent economists have even argued quite


50. See Hicks v. Arkansas State Medical Bd., 260 Ark. 31, 537 S.W.2d 794 (1976) (Arkansas State Medical Board failed in its attempt to have ear piercing classified as "the practice of medicine or surgery").

51. See Mirsa, Inc. v. State Medical Bd., 42 Ohio St. 2d 399, 329 N.E.2d 106 (1975) (Court held that blood collecting procedures constituted the "practice of medicine").

52. See State v. Wilson, 11 Wash. App. 916, 528 P.2d 279 (1974) (Court held that galvanic acupuncture and the taking of blood samples constitute the practice of surgery and may not be performed by chiropractors or drugless healers; that chiropractors may not give or prescribe any substance for the purpose of treating disease; and that drugless healers may prescribe only those nonpharmaceutical substances authorized by statute).

53. See Bowland v. Municipal Court, 18 Cal. 3d 479, 556 P.2d 1081, 134 Cal. Rptr. 630 (1978) (statute's prohibition against unlicensed persons treating a "physical condition" found to encompass the practice of midwifery).
seriously that licensure reduces the quality of care administered to patients.\textsuperscript{54} In addition, there are the more conventional critiques that stress licensure's effects in raising the costs of medical education and of health care and in aiding the growth in the numbers of allied health personnel, like nurses, most of whom extend physician productivity while being firmly subordinated to physicians.\textsuperscript{55}

\textit{Nonphysician personnel}. The laws pertaining to nonphysician health care workers provide a fourth example of legal deference to doctors. The basic statutory pattern in every state is that the medical practice act defines the practice of medicine — that which only physicians can legally do — in highly general, all-embracing, residual terms.\textsuperscript{56} The licensing statutes for other kinds of health care workers, such as dentists, optometrists, and nurses, then carve out strictly limited areas of permissible practice. When there is an overlap of actual activities, as where both physicians (plastic surgeons) and dentists (oral surgeons) claim the right to do surgical repairs on fractured jaws, the courts seem quick to interpret the statutes to allow the physicians to do the job, even when the statutes appear to prohibit their doing it.\textsuperscript{57} With respect to many nonphysician personnel who work in health care, such as

\begin{itemize}
\item \textsuperscript{55} See generally Rayack, \textit{Restrictive Practices of Organized Medicine}, 13 \textit{Antitrust Bull.} 659 (1968).
\item \textsuperscript{56} Because state licensing boards are largely controlled by the American Medical Association, "society has in effect given considerable power to organized medicine to restrict the supply of physicians and to influence the patterns of medical care for the benefit of the medical profession." \textit{Id.} at 663-64. See also E. Rayack, \textit{Professional Power and American Medicine} (1967).
\item \textsuperscript{57} The language in the Maryland statute defining "practice of medicine" is typical: "Practice of medicine" means the exercise, whether for compensation or gratuitously, of the art of science and medical diagnosis, healing or surgery and includes:
\begin{enumerate}
\item Operating on, professing to heal, prescribing for or otherwise diagnosing or treating any physical, mental or emotional ailment or supposed ailment of another.
\item Undertaking by appliance, test, operation, or treatment to diagnose, prevent, cure, heal, prescribe for, or treat any bodily, mental or emotional ailment or supposed ailment of another.
\item Undertaking to treat, heal, cure or remove any physical, emotional or mental ailment or supposed ailment of another by mental, emotional or other process exercised or invoked on the part of either the physician, the patient, or both.
\item Assisting, attempting, inducing, or causing by any means whatsoever the termination of a human pregnancy.
\item Performing acupuncture.
\end{enumerate}
nurses, the statutes firmly place doctors in charge of them.\textsuperscript{58}

Perhaps the most interesting and illustrative examples of this last point are given by the physician's assistant statutes.\textsuperscript{59} During and after the Viet Nam War, it struck observers that many military personnel who had been trained as medical corpsmen and who were returning to the states could sensibly be employed to provide good medical care to civilians for a wide variety of fairly routine ailments. The concept of using them as physician's assistants was born. Virtually all empirical studies that examined the quality of care they render concluded that, within the spheres of activity to which they were assigned, the quality of care given by the PA's was as good as that provided by physicians.\textsuperscript{60} And yet PA's were far cheaper to train than doctors, and would do their tasks for far less money.\textsuperscript{61}

\textsuperscript{58} In Maryland, for instance, the only medical duties that nurses may perform must be delegated. Thus, they cannot practice medicine without such direction and supervision as the physician desires. See \textsc{Md. Ann. Code} art. 43, § 291(b)(2)(1980).

\textsuperscript{59} A representative physicians' assistant statute establishing the hierarchy between a physician and his assistant is that of Arizona: "Services by a physician's assistant shall be rendered under the direction of a licensed physician or, when required by good medical practices, under the supervision of a licensed physician."


\textsuperscript{61} \textsc{Cong. Budget Off.}, \textit{Physician Extenders: Their Current and Future Role in Medical
From the medical profession's point of view, the financial implications of these findings were not clear. One could imagine at least three scenarios. First, if PA's could operate independent practices within their spheres of competence — subject, perhaps, to a duty to refer complex or doubtful cases to a physician — and if aggregate demand for medical services was basically fixed by external forces, then PA's might act as competitors of physicians. The competition would benefit consumers, but it might reduce physician incomes and opportunities. Second, if PA's were not independent but were employed and directed by some physicians, and if aggregate demand for medical services is externally fixed, the PA's might extend the business-getting power and net income of those physicians, albeit at the expense of other physicians. Third, if PA's were to be employed and directed by physicians, but if physicians are able to induce demand for their services, most physicians might be able to extend their business and increase their incomes by use of PA's. The result would simply be even more sharply increasing health care costs — a loss to consumers, but a gain to physicians.

Given the uncertainty as to which of these (or other) scenarios captured reality, one might have expected the reaction of the organized medical profession to PA's to be somewhat erratic, even schizophrenic, and it was. Ultimately, though, the AMA settled for resolutions favoring regulatory statutes that would insure strong and multifaceted physician control over PA's — statutes that would reduce the likelihood that scenarios one or two would be realized. These resolutions strongly influenced legislation. Philip Kissam, author of a meticulously documented analysis of the state laws on physician's assistants and nurse practitioners, concluded convincingly that most of the statutes

*Care Delivery* 26-29 (1979) (training costs of more than $60,000 per medical student — excluding college, internship, and residency training — as against $11,900 for PA). Also, the per hour compensation of physicians is about four times greater than that of PA's. *Id.* at 14, 16.


were unduly restrictive in numerous ways. Many of them forbid independent practice entirely or limit it to a very narrow range of situations. They frequently forbid hospitals and other institutional providers of care to hire and supervise PA's and nurse practitioners, even when the institution would regulate their activities according to detailed and carefully constructed protocols. Although PA's are permitted to practice under the direct command and control of a particular physician, the statutes often limit the number of PA's a physician can have (to one or two, for example); they forbid the physician to delegate or limit his ability to delegate diagnostic and treatment functions to PA's, no matter how well specified or routine; and they sometimes forbid delegation of authority to prescribe drugs, no matter what the context. In short, they limit the ability of individual physicians to use PA's as means of taking away business from other physicians (although they allow doctors to use PA's to do their dirty work and to induce greater aggregate demand for medical services). This tendency of the laws is usually reinforced by other regulatory requirements: PA's must be licensed, and the licensing function is given to the physician-controlled state medical licensing boards. Associations of PA's, who also

66. Kissam, supra note 65, at 65 (conclusions); see id. at 29-59 (supporting analysis). Kissam notes that there are 38 PA statutes operating in 37 states of which 33 are termed by him as "PA Regulatory Statutes," or statutes which "provide explicitly for some form of administrative control over expanded medical delegation." Id. at 21 (Maryland's PA statute is listed in this category). The remaining five statutes are termed "PA Simple Authorization Statutes," or statutes which "consist merely of specific exemptions to state medical practice acts for services rendered by nonphysicians who work under a physician's 'supervision' or 'direction and control.'" Id. at 24 (footnotes omitted). Kissam concludes that, when carefully drafted, the Simple Authorization format provides a more effective model for the regulation of PA's and NP's (nurse practitioners). He notes that the formal training required by most regulatory statutes is lengthy and unnecessary because a supervising physician can often "supply the comprehensive knowledge that the nonphysician lacks." Id. at 39.

67. See note 59 supra; see also Kissam, supra note 65, at 21 (PA laws that authorize only physician-supervised practice do not allow independent practice by PA's).

68. See Kissam, supra note 65, at 55.


70. See Kissam, supra note 65, at 5 (concluding that "physical examinations, medical histories, diagnosis and treatment of common illnesses, minor surgery, and decisions to continue or modify prescribed treatment for convalescing or chronically ill patients generally have not been delegated").

71. See id. at 50-51. An example is the Virginia PA statute which forbids "delegated acts [including] the prescribing or dispensing of drugs." Va. Code § 54-281.4(a) (1978).

seek some of the attributes of professional status, have compounded the restrictions by lobbying for formal educational requirements that will increase the cost of training and the future incomes of PA’s but which, according to the empirical studies of PA’s performance, are not necessary to their effectiveness.\(^7\)

A very similar, though somewhat different, story can be told and documented about the regulatory statutes affecting nurse practitioners.\(^7\)

Why is it necessary for physicians to direct and control virtually all of the activities of physician’s assistants and nurse practitioners? And why is it necessary for the organized medical profession, through medical licensing boards, to control the ability of individual physicians to compete against one another by employing PA’s or nurse practitioners and delegating many tasks to them? The entire justification for these restrictions rests on the supposed assurances of quality medical care that these physician-manipulated controls will generate. Legislators have apparently bought this argument. And yet there is no good systematic empirical evidence that the physician-held controls are necessary to ensure quality.\(^7\) The studies we do have suggest they are not.\(^7\)

Why then was the quality assurance argument accepted? The answer is that in our society lay persons, including legislators, emit deference to physicians almost as a reflex response. Deferential behavior, and the associated suspension of critical judgment, comes as quickly as sneezing in the presence of pepper.

**Relationships between physicians and hospitals.** A fifth example of

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73. When physician’s assistants were first introduced, there was some concern that these individuals having relatively brief clinical training (PA’s normally complete a minimum of two years of special training in basic primary medical care) would not be able to provide good quality patient care, even when closely supervised by physicians. See, e.g., Miles, **Physician’s Assistants: The Evidence Is Not In**, 290 NEW ENG. J. MED. 251 (1974). However, Dr. Sox’s review of 21 controlled studies indicates that the quality of primary ambulatory care, i.e., initial care of patients not confined to bed, given by the physician’s assistants was indistinguishable from that given by physicians. See Sox, **supra** note 60. See also Cherkin, **Factors Influencing the Physician Market for Primary Care New Health Practitioners**, 18 MED. CARE 1097 (1980) (increased utilization of PA’s has the potential to increase the efficiency of the health care system by ensuring that expensive inputs (physician time) are not used to provide outputs (medical services) that could be equally well provided by less expensive inputs (PA time)).

74. Kissam, **supra** note 65, at 29-59, 65.

75. See Sox, **supra** note 60. (None of the studies in question analyzed solo care separately from care in which a physician provided consultation).

76. See, e.g., Newkirk, **Rural Emergency Department Coverage**, 71 J. ME. MED. A. 375 (1980). In this study PA’s were used in the emergency department without on-site supervision. Diagnostic algorithms and a list of treatment protocols were used in lieu of direct supervision. In the 564 cases studied, PA’s made no significant diagnostic or treatment errors.
deference to professional self-regulation appears in hospitals. According to the standards of the Joint Commission on Accreditation of Hospitals and an occasional state statute, medical staff by-laws should leave all "medical matters," whatever that might mean, in the hands of the medical staff rather than in the hands of the hospital's board of trustees. There is obviously a severe problem in trying to draw a proper line between matters appropriate for the business and managerial decision making authority of trustees and the professional medical judgment of the physicians. The decision to build or not to build a heart transplant unit obviously belongs to the trustees; the diagnosis of a particular patient belongs to his physician. But there is a wide variety of intermediate matters, such as whether the hospital trustees can impose, over the objection of the medical staff or of a particular physician, a flat rule that all patients with myocardial infarction will be sent home after one week in the hospital, absent the presence of certain clearly specified circumstances. (Such a rule would be based on published empirical studies indicating that a longer stay does not correlate with improved prospects.) Theoretically, these intermediate issues are quite problematic and ought to lead to extensive litigation and rule making. In fact, it is common knowledge that most such issues are negotiated peacefully, with the trustees generally deferring to the judgment of the medical staff.

Another facet of the hospital-physician relationship concerns admitting privileges. The considerable case law in this area demonstrates that established groups of professionals can decide who comes into their club, subject to no significant controls by hospital trustees or courts. Trustees routinely defer to the medical staff's decision whether to grant or renew admitting privileges to a particular physician. Courts also exhibit almost total deference to the institution's judgments about those matters, although in some contexts they impose due process re-

77. JOINT COMMISSION ON ACCREDITATION OF HOSPITALS, ACCREDITATION MANUAL FOR HOSPITALS 103 (1981); CAL. BUS. & PROF. CODE § 2392.5(c) (West 1974) (California code provision requiring that a hospital medical staff be self-governing with respect to the professional work performed in the hospital).

78. See, e.g., Hutter, Sidel, Shine, & DeSanctis, Early Hospital Discharge After Myocardial Infarction, 288 NEW ENG. J. MED. 1141 (1973) (for a patient with an uncomplicated myocardial infarction "there appears to be no additional benefit" from a three-week as compared to a two-week hospital stay); McNeer, Wagner, Ginsburg, Wallace, McCantis, Conley, & Rosati, Hospital Discharge One Week After Acute Myocardial Infarction, 298 NEW ENG. J. MED. 229 (1978) (found that it was feasible and ethically justifiable to discharge uncomplicated patients at one week after an acute myocardial infarction).

quirements such as notice and a right to be heard. Rarely are the staff's bases of decision struck down, and in any event the range of permissible criteria of decision are broad enough to permit all manner of things to go on under cover of vagueness. Since the due process attacks on staff decisions have proven unsatisfying, disappointed physicians have recently begun to attack staff decisions on antitrust grounds. But preliminary results from this wave of cases, which include holdings that the federal antitrust laws are inapplicable because staff decisions have no impact on interstate commerce, suggest that plaintiffs will fare no better than in the past. The deference by trustees and courts (and by legislators) persists even though, as a judge now and then points out, key members of the existing medical staff may reject an applicant because they regard him as a potential competitor, because they consider him racially, ethnically, or socially unacceptable, or because they disapprove of his unorthodox attitudes. Thus an applicant might be rejected because he believes in health maintenance organizations or prefers to emphasize primary care and preventive medicine. The lay persons following the rule of deference must have assumed that all actions tainted by such conflicts of interest or improper motives must be greatly overwhelmed by the decisions on admitting privileges that reflect only the staff's decision to maximize the public interest. Such an assumption requires a considerable act of faith.

Economic autonomy. A sixth case of deference — a whole complex of examples, actually — consists of the many rules and practices granting physicians economic autonomy — the right to determine unilaterally, rather than in a serious bargaining session or in an informed competitive market, how much they ought to be paid. Physicians in our country generally work on a fee-for-service basis. Moreover, even though hospital rates and revenues are being increasingly subjected to severe regulation, physician fees are not subject to any significant re-

strictions. The prototypical third party reimbursement formula refers to usual, customary and reasonable physician fees, which is code language for saying that (a) only a physician whose fees are wildly out of line with those of his peers will be questioned by third party payors, but (b) the physicians as a group may steadily move their average fees upward, as they see fit. Similarly, the use by payors of specific fee schedules usually reflects practice rather than shapes it. Despite the fee-for-service custom and the virtual nonregulation of the amount of fees, insurers and governmental programs generally accede to reimbursement of physician charges. The result, predictably, is continuing inflation in physician fees and incomes.

Moreover, there is very little outside evaluation and control over the "services" part of the fee-for-service system. The situation is reminiscent of malpractice standards: third parties do not independently evaluate the appropriateness of classes of medical procedures that are considered for inclusion in their health plans. Nor are there any significant process controls. Insurers do not routinely require, for example, that before a given type of surgery will be eligible for reimbursement under their plans, some authoritative national organization must have found, from examining empirical evidence, that the kind of surgery in question is (a) efficacious and/or (b) cost-effective. Basically, third party payors simply accept whatever happens to be customary practice as it has evolved through the cumulative decisions of the members of the medical profession. There are some heartening exceptions, such as the Blue Cross/Blue Shield "medical necessity" program, but they represent, as of now, a minor factor in the health care system. For the most part, potential conflicts of interest — physicians' incentives to favor those plausible, but not rigorously tested, procedures that happen to maximize their own income or sense of craft or other kind of utility — are simply ignored.

To drive home the point about the deference to professional discretion on the part of third party payors, I will quote the first section of the Medicare statute as it has been codified. You might think that the lead-off section of this historically momentous federal statute, which along with Medicaid caused a virtual sea change in the American

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87. In May, 1977, the Board of Governors of the Blue Cross/Blue Shield Association approved a resolution for a nationwide program of "medical necessities." This program was instituted to contain medical costs by requiring physician justification for the use of certain procedures. Telephone interview with J.S. Nagelschmidt, Director of Public Information, Blue Cross and Blue Shield Associations, Washington, D.C. (Oct. 14, 1981).
health care system, would say something about the great importance of providing equal access to effective medical care for the nation's older citizens. But it does not. It is entitled "Prohibition against any federal interference," and it reads,

Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or any employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.89

That certainly puts the federal government in its place!

The second section of the Medicare statute sets forth the principle that Medicare beneficiaries should have a guaranteed "free choice" among physicians.90 This is code language for saying that the federal government should not urge physicians to join closed panel health plans91 that might control program costs but reduce physician incomes. It is quite plausible, of course, to suppose that people prefer to choose their personal physicians. But it is doubtful that taxpayers value such choice so highly that they welcome the extraordinary cost of absolutely free choice—that is, that they have given informed consent to government programs that assure each beneficiary of the ability to choose any one among the thousands of doctors in a large city rather than any one of the fifty or one hundred doctors in a reputable prepaid group practice that he voluntarily joined. I doubt that the extreme value placed by the statute on "free choice" is supported by good evidence of taxpayer preferences. Once again, the law simply reflects uncritical deference to what the medical profession thinks is the proper way to structure its own business arrangements.

89. Id.
91. A closed panel plan is one in which subscribers who wish to have health services covered by the plan must obtain them, subject to certain exceptions (e.g., for emergencies and when certain specialists are needed), from a defined group of physicians with whom the plan administrators have contracted. Usually determined in advance is their method and rate of payment for giving services to plan subscribers. The number of doctors in the panel may be relatively small or large, for restricted size is not the key to the concept. "It is a key feature of such plans that" the doctors will have restricted their freedom to bill for services as they please.

Prepaid health plans, like health maintenance organizations, are often organized on a closed panel basis. In a sense, any provider agreement between an insurance company and signing physicians that makes these physicians more likely to be chosen by the insured parties is a closed panel plan.
Physicians' freedom from regulation. My seventh and final set of examples concerns the medical profession's surprising freedom from the massive waves of "new style" health care regulation that inundated our health care system throughout the 1970's. Consider the three major sets of regulatory controls: utilization review, certificate of need programs, and rate setting laws. The 1972 federal law establishing hundreds of Professional Standards Review Organizations\(^9\) in the United States directed them to review and evaluate all hospitalization decisions that would lead to payments under the Medicare and Medicaid programs. So stated, the law sounds as if it intrudes significantly into professional discretion. But the process turns out to be nothing more than local peer review that is basically undefined and unregulated by external authorities. By statute, PSRO's must consist solely of licensed physicians practicing in the area where the PSRO does its work.\(^9\) Moreover, a PSRO may delegate its reviewing functions to a committee in each hospital in its area, under certain conditions,\(^9\) and the great majority of hospitals have taken advantage of this.\(^9\) As for the standards of review, the statute says that the reviewers must make sure that the proposed institutional care (a) is "medically necessary," (b) satisfies professional standards of quality, and that (c) a cheaper but equally good alternative such as ambulatory care or in-hospital care of another sort is not feasible.\(^9\) To say the least, these standards permit of generous interpretation. (Is it "medically necessary" for a terminally ill cancer patient whose life may be prolonged for a few more weeks by extremely expensive therapeutic measures to undergo such measures?) Overall, the PSRO law is like putting a bunch of fat little boys in charge of a bottomless cookie jar, and telling them, "Don't let any one of yourselves eat a cookie unless the rest of you think that it's appropriate and that the cookie is up to your professional standards of good taste. (If necessary; Big Mommy will make sure that good quality cookies, however expensive, are put into the jar.)"

Federal law\(^9\) has made it practically necessary for almost all states\(^9\) to adopt certificate of need programs under which institutional health care providers must seek agency permission before they can

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95. Status Report on Professional Standards Review Organizations, 43 CONN. MED. 733 (1979). This report states that, as of 1979, at least 70% of the review functions of PSRO's had been delegated.
97. 42 U.S.C. §§ 300m, 300m-6 (Supp. III 1979).
98. Arizona is the hold-out. See ARIZ. REV. STAT. ANN. § 20-830 (1975).
make major capital expenditures. In general, these entry controls do not apply to the purchasing decisions of individual physicians and groups of physicians, regardless of how significant their expenditures might be. Finally, states have increasingly adopted rate setting laws applicable to hospitals and other institutional health care providers, and they have tended to make these laws stricter over time. But in general, they have not yet moved significantly against the fees and revenues of physicians.

Both hospitals and doctors in the United States operated in a bizarre, wildly inflationary world of third party reimbursements applied to a fee-for-service system of pricing. Yet only the capital expenditure and pricing decisions of the hospitals were subjected to public utility-type regulation. Why this difference? Could it be that lawmakers have determined, independently upon examination of relevant empirical evidence, that doctors are much better able to resist the conflict of interest inherent in a fee-for-service system than hospitals? One certainly doubts this, especially because most hospital costs, both in the utilization and in the capital-building context, are the result of decisions by doctors. The most plausible explanation is that lawmakers are simply afraid to regulate physicians.

Let me sum up this part of the analysis. The question is whether physicians as a group determine their own norms of practice exclusively — whether they and they alone determine what they do as doctors, how they do it, how they should be paid for it, and how much — or whether the norms of conduct governing them are created or at least evaluated by other groups of people or, failing that, whether the physicians’ norm-making process is somehow subjected to control and structuring by other groups. My analysis suggests that the medical profession enjoys enormous autonomy. Its determination of its own work is not significantly controlled by patients, acting as medical care...

99. The New Jersey statute is typical, applying such controls only to health care facilities, not to physicians:

    No health care facility shall be constructed or expanded, and no new health care services shall be instituted after the effective date of this act except upon application for and receipt of a certificate of need as provided by this act.

100. See Coelen & Sullivan, supra note 14.

101. Since the provider of medical services on a fee-for-service basis (a) often has some power or influence over the patient’s decision to purchase services (because of the patient’s inferior position of medical knowledge) and (b) has an incentive to provide ever more services (because more services mean more income), the provider experiences a continual temptation to recommend and provide services that may be excessive, unnecessary, or even harmful to the patient. There is, therefore, a pervasive conflict between the patient’s and the provider’s interest.
purchasers in something like a competitive market; nor by judges, in hearing malpractice cases; nor by the states, in their licensing laws; nor by hospital managers, in their institutional decision making; nor by other health care workers, through their competition; nor by insurers and governmental programs, through their reimbursement practices; nor by the modern health regulatory agencies, through their programs of utilization review, certificates of need, or rate setting. In very large part, the medical profession gives the law to itself, and all others defer.

II. Results

The key result of the system of widespread deference to professional power has been a socially excessive consumption of medical services. The system is characterized by realized conflicts of interest and mysticism about the value of customary medical practice. Physicians, having been given the incentives to do so, recommend and produce costly services that are only marginally valuable; and, since they are subject to strong financial incentives but little external criticism about matters within their areas of expertise, they are able, without any conscious deception or subjective bad faith, to convince themselves and lay persons of the value of clinical practices that are not really proven.

Professional power that is not externally regulated may be tolerable in some contexts. Perhaps the so-called "academic freedom" of college professors is an example. (More likely, such freedom is simply overvalued by interested parties like myself!) But in the medical sector professional autonomy operates in a huge part of the economy that is flawed in many ways. Consumers and insurers are unable to second guess conventional medical judgment in particular cases; society is ignorant of the true value of medical practices in general; insurance is widespread and generates moral hazards; massive government subsidies drastically alter private decision making; and the populace, often alienated from older sources of comfort like the church and the family, has developed a blind faith in salvation through medical care. These conditions are like the debris on a forest floor, and are themselves enough to support a spontaneous combustion; unhampered professional autonomy is like the wind that blows it into a raging fire.

102. "Moral hazards" refers to the tendency of a person who is covered by an insurance policy to incur greater risks and to run up the cost of compensating for realized risks precisely because he is covered by insurance and will not bear these costs himself. It does not refer only to policyholders who commit immoral acts like burning their insured homes, but also, and more frequently, to careless behavior such as taking a damaged and insured automobile to a very expensive repair shop. See Clark, Does the Nonprofit Form Fit the Hospital Industry?, 93 Harv. L. Rev. 1416, 1424 (1980).
III. What Can be Done?

The key problem, of course, is how — or whether — inexpert lay persons can control expert professionals without making things even worse than they are in a system of virtually complete professional autonomy. I will present again three reform suggestions that have long been in the air, in the hope that in the aftermath of my analysis they will take on new meaning and force. I will also propose a new look at two other paths of reform.

First, the laws relating to health care delivery and payment should be altered to change the economic incentives presented to doctors. The propriety of different kinds of economic incentives is not a subject about which the medical profession has special expertise. Courts might change their incentives by methods as conservative as employing antitrust principles to break down conditions that inhibit insurance companies from effectuating cost-conscious innovations in their plans and practices. This is one of the moves that Professor Clark Havighurst has in mind when he advocates unleashing the forces of competition.103 Economic incentives might also be changed by strategies as innovative as adopting a national health plan that favors health maintenance organizations in the manner of Alain Enthoven’s well-known Consumer Choice Health Plan.104 I strongly endorse efforts of this sort. After studying the depth of the legalization of deference to the medical profession, however, I feel constrained to express the suspicion that reforms of this sort are not enough. I doubt whether the problems of our health care system can be fully appreciated solely within the categories of economic analysis. Deference to professional power is a profound and basic fact of our society, and it must also be examined in psycho-

104. See A. ENTHOVEN, HEALTH PLAN (1980).

The primary elements of Enthoven’s Consumer Choice Health Plan are:

1. Universal health insurance independent of job status.
2. Public funds used equitably so that subsidies to people for health insurance would be based on the average cost of premiums in their medical risk categories.
3. Reform of the health care delivery system through incentives (competing organized systems).
4. Positive program on the part of the government to make the market work.
5. Design based on principles that have actually been applied successfully (competition, multiple choice, private underwriting and management of health plans, periodic government-supervised open enrollment, and equal rates for all similar enrollees selecting the same plan and benefits).

Id. at 115-19.
logical, social, and political terms. And the fact of deference must be dealt with not only by changing monetary inducements, but also by changing personal attitudes and structures of power and authority.

Second, the law should seek to create greater lay control of health care institutions and health care regulatory agencies. Such changes could make a measurable difference. For example, recent empirical work suggests that reimbursement levels are substantially lower when physicians are not in control of the boards of Blue Shield plans.  

Third, the federal government should sponsor or facilitate efforts to provide health education for consumers — to restore or create a greater measure of enlightened self-care, and a better appreciation of the true advantages and the true limits of modern medicine.

Fourth, legislators ought to reexamine and reduce some aspects of the legal system’s deference to professional power. In particular, they should support major studies of ways to reform and liberalize, if not abolish, health licensing laws. Because the medical practice acts and laws relating to nonphysician health personnel are state laws, and because substantial features of them have been static for many decades, they tend to be ignored at the national policymaking level — even when broad reforms like national health insurance are being assessed. This situation is understandable, but most unfortunate. Because of custom and our natural (but flawed) human psychology, many lawmakers and commentators focus, as journalists do, only on recent changes in the environment. They systematically ignore or slight the importance of long-existing structures in shaping the effects of new developments. Academics should help redress this imbalance.

Fifth, and finally, I think that the federal government ought to regulate norms of medical practice. In the first phase of this effort, it should gradually restrict reimbursement under governmental subsidy programs to medical procedures or "technologies" that have been formally determined to be (a) effective in producing the results intended and (b) worth their cost, as determined in a formal cost-benefit analysis.  

In the past few years, support for greater and more systematic ef-


106. For a good discussion of the nature and causes of chronic flaws in the layman's attempts to act as intuitive scientist, see R. NISBETT & L. ROSS, HUMAN INFERENCE (1980).

forts to evaluate medical practices has increased.\textsuperscript{108} With the creation of the National Center for Health Care Technology in late 1978,\textsuperscript{109} Congress took a step in the right direction. Among other things, the Center was to support (by grant and contract) assessments of health care technologies that take into account their safety, effectiveness, cost-effectiveness, and their social, ethical and economic impact. The concept of "health care technology" was defined very broadly, and would include most things falling under less trendy labels like "medical practices" and "procedures". The Center could make, and has made, recommendations to the Secretary of Health and Human Services (specifically, for the Health Care Financing Administration) on proper reimbursement policy. One recent study of four of the nonreimbursement recommendations estimates that they will have significant impact on health care costs.\textsuperscript{110}

But existing programs are in an incipient stage, and are far from perfect. Considering the magnitude of its tasks, the Center was severely underfunded\textsuperscript{111} — and recently was simply given zero funding. Moreover, there is generally no requirement by the government or other payors that providers supply data vital to the evaluation effort, nor is there even a good system for making sure that national norms of practice are being implemented in different regions of the country. Moreover, the Center's role is to recommend, not to make binding decisions, and its positive duties are not well specified.

In my view the federal government should restructure and greatly augment its attempts to regulate the practice of medicine. I lack the time to mention, much less discuss, the many issues of design and implementation that ought to be addressed. I will only suggest that two basic principles ought to guide the endeavor: the use of process controls and the use of countervailing professional power. My first principle suggests that the federal government might set up an independent regulatory commission — call it the Commission on Medical Technol-


\textsuperscript{110} CENTER FOR THE ANALYSIS OF HEALTH PRACTICES, HARVARD SCHOOL OF PUBLIC HEALTH, IMPACT ON HEALTH COSTS OF NCHT RECOMMENDATIONS FOR NONREIMBURSEMENT OF MEDICAL PROCEDURES (1981) (revised report submitted to National Center for Health Care Technology).

\textsuperscript{111} For the fiscal year ending September 30, 1981, $33 million were appropriated to fund the Center. 42 U.S.C. § 242n(i)(Supp. 1979). Dr. Relman states that $100 million in funding would be necessary for the center to begin "a proper" program for the support of technology assessment. Relman, \textit{supra} note 108, at 154.
ologies — whose full time commissioners would have the duty to evaluate both new and old common medical procedures in order to make binding, albeit alterable, decisions about their efficacy and their cost-benefit rationality. The statute would direct the commissioners to consider certain specified, economically significant procedures by a particular date. They would be bound each year to draw up a list of other economically significant procedures that have not yet been evaluated — a kind of "ten most wanted" list — and to evaluate them as soon as feasible. They would also be bound to render evaluation decisions upon request by third party payors (both public and private), providers (including groups such as medical societies), and consumer groups. They would approve or disapprove the procedures for reimbursement under government health care plans, and they might specify conditions of reimbursement, doing the best they could on the basis of available evidence. Failure to find affirmative, methodologically valid empirical evidence (for example, controlled clinical trials) of the efficacy of a procedure, whether in the published literature or in the reports supplied by interested private parties, would result in nonapproval, pending possible future receipt of acceptable evidence, and with exceptions for well designed experimental programs. If the clinical efficacy of a medical procedure were established, the procedure would then be subjected to a formalized cost-benefit analysis of the sort done by academic public policy analysts. All relevant assumptions would have to be specified and, where possible, supported by evidence.

The principle of using countervailing professional power is based on the notion that one can sometimes fight fire with fire. If it is dangerous to let lay persons regulate professionals, then we might try to arrange things so that different kinds of professionals impose cross-checks on each other. In particular, the members of the Commission on Medical Technologies should consist predominantly of nonphysicians who nevertheless have relevant professional expertise — Ph.D. training or its equivalent, and eminence in their profession. Thus, the commission members might include biochemists, biostatisticians and epidemiologists, economists, and public policy analysts. A minority of its members would be physicians who are not also practicing medicine and who are not members of any medical association or society. (Something akin to this suggestion appears in the statutory description of the composition of the National Council on Health Care Technology, but the guiding principle there appears to have been interest-group representation more than deliberate use of countervailing professional
None of the members of the commission would be able to have any financial interests in any kinds of health care providers or suppliers of medical goods and services. All would be appointed for long terms.

Once established, the decisions of the Commission on Medical Technologies could be put to many uses besides reforming the reimbursement practices of governmental health insurance programs. The state courts could be urged to consider determinations of efficacy or inefficacy in malpractice cases. Hospital boards of trustees could be given explicit authority and encouragement to take commission approval or nonapproval of procedures into account when laying down rules as to what kinds of procedures could or could not be followed within their hospitals, or as to what kinds of practitioners could be admitted to their hospitals' staffs. Licensing agencies might periodically test physicians to determine their familiarity with the decisions of the commission. Licensing agencies might consider licensing nonphysician personnel to perform selected approved procedures that they had found such personnel were trained to do.

To evaluate my proposal critically, to work out its details, and to implement it would be a sizable task. But it is a task well worth undertaking.

CONCLUSION

Professional power arises naturally in contexts where one person is engaged to perform services for the benefit of another and the proper execution of those services depends on a great accumulation of technical knowledge on the part of the provider. It arises in circumstances where the client is inherently at a disadvantage in dealing with the professional — where there is a profound informational inequality. It is precisely in this situation that society welcomes the adoption by service providers of a fiduciary attitude. It is no accident that doctors, lawyers, and other professionals spend a great deal of time developing codes of ethics and generating a sense of professional responsibility. This process — by which the professional is encouraged to internalize the welfare of the client rather than his own income as a norm of his action — is an important and valuable aspect of the process of adjusting professional power to the public interest.

Moreover, when the fiduciary spirit is allowed to express its full force in the life and actions of an individual professional, the results can inspire awe. Before preparing this Sobeloff Lecture, I was fortu-
nate to read the short biography of Judge Simon Sobeloff that was written by Michael Mayer.\textsuperscript{113} Reading about the career of that great jurist, I was struck by the surpassing moral beauty of a life that in its actions and effects was dedicated to advancement of the general good. I was moved, and personally humbled, by the account. I have felt a similar admiration in the presence of certain members of the medical profession whom I have been privileged to meet. Not surprisingly, then, I want to preserve the fiduciary spirit wherever it exists.

Nevertheless, observation of human nature in its more ordinary guises convinces me that no society can rely totally on self-generated ethical norms to assure that discretionary power is exercised for the general good. The fiduciary spirit, and even altruism, are real, but they need a boost from a social, economic, and legal environment that rewards them. No group of powerful men and women should be free of sensible external controls.

\textsuperscript{113} M. MAYER, SIMON E. SOBELOFF (Michael Mayer is Judge Sobeloff's grandson, and he prepared this pamphlet to acquaint younger lawyers and students at the University of Maryland School of Law with his grandfather's biography).