PRÁCTICE GUIDELINES FOR MEDICAL CARE: THE POLICY RATIONALE

CLARK C. HAVIGHURST*

I. INTRODUCTION: A POPULAR NEW INITIATIVE IN HEALTH POLICY

Unlike most other health policy notions currently in vogue in Washington, the idea of "practice guidelines" is acceptable to all the relevant interest groups. All the "major players," from the Physician Payment Review Commission (PPRC) to organized medicine, appear to agree on the need to increase research on the outcomes and effectiveness of medical care and to use the findings of this research to develop appropriate diagnostic and therapeutic measures for each medical condition. The American Medical Association (AMA), however, prefers to speak of the anticipated products of this research as "practice parameters" rather than as "practice guidelines," the term most commonly used. This difference over nomenclature signifies some difference of opinion over whether the object of the exercise should be to chart actual "pathways" for physicians to follow or only to set "bound-

* William Neal Reynolds Professor of Law, Duke University. Professor Havighurst was a featured lecturer at the 1989 St. Louis University Health Law Symposium. His lecture was sponsored by the law firm of Thompson & Mitchell, St. Louis, Missouri.


2. See, e.g., Office of the General Counsel, American Medical Association, Legal Implications of Practice Parameters 2 (draft, Feb. 1990) [hereinafter AMA, Legal Implications] (defining parameters as "strategies for patient management, developed to assist physicians in clinical decision-making").
aries" within which physicians would be free to choose their course. But no one expects practice guidelines to be anything other than advisory in form or to be so prescriptive as to usher in an era of "cookbook medicine."

Congress has recently embodied its hopes for practice guidelines in legislation. The FY1990 budget reconciliation act, passed in November 1989, created a new Agency for Health Care Policy and Research (AHCPR) within the Public Health Service and assigned to it a variety of research and demonstration functions. Although many of the AHCPR's research functions were previously performed by other agencies, the agency also includes a new, awkwardly named entity — the Office of the Forum for Quality and Effectiveness in Health Care (the Forum) — that is specifically charged with presiding over the development and maintenance of "clinically relevant guidelines" as well as "standards of quality, performance measures, and medical review criteria." Under the Forum's auspices, panels of physicians and consumers will either develop and update the guidelines themselves or oversee public and private nonprofit contractors enlisted for that purpose. The legislation authorizes substantial funding and earmarks some Medicare trust funds to carry out the effort. Thus the government's program to

3. See Meyer, Medicine Debates Parameters (Or Are They Guidelines?), AM. MED. NEWS, Dec. 15, 1989, at 36, col. 1 (giving flavor of debate within medicine). On the useful distinction between "boundary" and "pathway" guidelines, see Lewin & Erickson, Leadership in the Development of Practice Guidelines: The Role of the Federal Government and Others 3 (prepared for the PPRC's Conference on Practice Guidelines, Washington, D.C. Oct. 11, 1988) (revised April 24, 1989): "Boundary guidelines are used by payers to define the range of practice options within which physicians could act without incurring financial or other sanctions. Pathway guidelines are employed primarily by providers and serve as a beacon for clinical practice and a standard around which practice patterns should converge."


5. In particular, the AHCPR has primary responsibility for implementation of the Medical Treatment Effectiveness Program of the Department of Health and Human Services. The purpose of this program is "to improve the effectiveness and appropriateness of medical practice by developing and disseminating scientific information regarding the effects of presently used health care services and procedures on patients' survival, health status, functional capacity, and quality of life." Agency for Health Care Policy Research, Program Note (March 1990). See also Roper et al., supra note 1. This program supplements ongoing work in the assessment of new technologies.

6. Public Health Service Act §§ 912(a)(1)&(2). The statute also uses the term "practice guidelines." Id. at § 912(b)(3). As noted at a later point, these terms need not be understood as establishing rigid categories. In this article the term guidelines may often be read to include standards, performance measures, and review criteria.

7. The AHCPR's authorization for fiscal 1990 was $35 million, rising to $70 million for 1992. See Public Health Service Act § 926(a). The separate authorization
develop practice guidelines is well launched. Because the guidelines legislation was enacted with a minimum of controversy, it would be easy to conclude that the health policy establishment has finally hit upon a strategy with which no one can disagree. Who could object, after all, to obtaining and disseminating more and better information on how physicians can best help their patients? Nevertheless, the appearance of consensus has obscured a number of important issues. Some of these matters were finessed in the early discussions by participants who were content to see the research effort launched and to leave for a later day the debate over how its products would be designed and used. Although some of these issues are now beginning to surface, other issues exist at a deeper level, where they could easily remain as long as only the “major players” are consulted. Among other things, this Article seeks to identify the larger issues lurking in the guidelines strategy.

After some brief background, this Article presents three models of practice guidelines — or, more accurately, three basic conceptions of the proper locus of decision making about medical care — that have significantly different implications for how guidelines should be developed and used. Only two of these models, however, appear to be in the mind of anyone directly interested in the program. Moreover, although some differences between these two models are beginning to emerge in policy discussions, these differences are less important than the two models’ similarities, which distinguish them both from the third, neglected model. This Article argues that this third model of practice guidelines is superior, both conceptually and practically, to the first two. On this basis, it offers some crucial suggestions for administering the federal government’s new research and guideline-development program.

II. THE MOVEMENT TO SPECIFY BETTER STANDARDS FOR MEDICAL PRACTICE

The current consensus on the need for some kind of practice guidelines is directly traceable to the work of a handful of physician scholars who pioneered in the study of actual medical practice — what physicians actually do. These researchers demonstrated with striking evidence that physicians’ methods of treating many similar conditions vary widely for no apparent reason. Simultaneously, other researchers

---
8. See, e.g., Chassin, Brook, Park, Keesey, Fink, Kosecoff, Kahn, Merrick & Solomon, Variations in the Use of Medical and Surgical Services by the Medicare Popu-
were exposing the surprising weakness of the scientific support for many widely used methods of diagnosis and treatment. Together, the revelations by these researchers called into question the long-standing assumption that physicians, left to their own devices, gravitate toward uniform methods that reflect the best scientific understanding and a thoughtful weighing of the options available. Because many institutions and arrangements in the health care sector are founded on the belief that professional standards — essentially the norms and customs of medical practice — are the appropriate benchmarks for decisions regarding medical care, the discovery of the incoherence and unreliability of such standards was a significant, possibly portentous, event.

The emerging evidence suggesting possible shortcomings of professional standards has triggered a number of significant responses. For its part, the organized medical profession has generally accepted the need for increased research on the efficacy of clinical methods and for more collective effort to evaluate clinical policies and to assist physicians in making clinical decisions. Many professional organizations have begun serious efforts to develop practice guidelines and to re-educate their members in the appropriate clinical management of particular conditions. Much of this work has been in the best professional tradition,
representing an important contribution to improving medical practice.\textsuperscript{12} On the other hand, the effort being made also includes an element of damage control, necessitated by the threat posed by the new research to the profession's long-standing tenet that professional standards alone should guide spending on health services and the evaluation of physician performance. The profession's best hope for preserving the valued clinical independence of physicians against encroachment by government and corporate intermediaries probably lies in developing explicit professional standards to replace the customary ones that have become discredited.

Those involved in financing medical care, both publicly and privately, saw the new research findings somewhat differently than the medical profession. To them, the evidence suggested that their costs might be reduced by a new program of effectiveness research and guideline development. Although most of the researchers who criticized prevalent clinical practices and policies failed to investigate whether the dominant problem was overuse or underuse of resources, most payers viewed the new studies as confirming their belief that a great deal of medical care is unnecessary or inappropriate. These observers thus anticipate that better information, incorporated into practice guidelines, will result in reduced spending as quality improvements yield improved results at a lower cost and as some methods are discarded as inefficacious or as being no better than lower-cost alternatives.\textsuperscript{13} Payers also welcome the prospect of having clear standards, validated by a central authority, that they can employ in designing benefits, reviewing claims, and making payment decisions.

The movement to promote practice guidelines has been closely linked to physician payment reform in the Medicare program.\textsuperscript{14} Even

\textsuperscript{12} The extensive effort of the American College of Physicians known as the Clinical Efficacy Assessment Project is especially notable.

\textsuperscript{13} Physicians, however, when they hear talk of this kind, usually suggest that guidelines could easily call for more increases than reductions in expenditures. See also U.S. General Accounting Office, Quality Assurance: A Comprehensive National Strategy for Health Care is Needed 16-17 (Briefing Report to the Chairman, U.S. Bipartisan Commission on Comprehensive Health Care) GAO/PEMD-90-14BR (Feb. 1990) ("the use of some practice guidelines might actually increase expenditures over the long run by increasing the number of services and procedures that are not now provided as often as they should be").

though physician reimbursements are to be fixed arbitrarily by the use of a "resource-based relative value scale," there is concern that physicians will take countermeasures, such as reducing the content of each service for which a fee is set or providing additional services to each patient. These strategies are difficult to contend against not only because it is difficult to define compensable units of medical service with complete precision but also because, as things have stood, the payer must bear the burden of proving that a particular prescribed service is, or was, inappropriate under vague professional standards. Practice guidelines have seemed desirable to the federal government because guidelines can reduce the range of physicians' discretion and strengthen the government's ability to resist paying for inappropriate care.

Practice guidelines are also a potential aid to physicians seeking to live within the various utilization controls and budgetary constraints they are increasingly encountering. Among these cost-containment devices are the new "volume performance standard rates of increase" recently enacted for the Medicare program. Although the national volume standard to be adopted will be less directly punitive than the "expenditure targets" originally proposed by the administration, it could still evolve into a series of caps on the amount that can be spent within a prescribed period on medical care for some subset of Medicare beneficiaries. Proponents of this approach hope that the prospect of

15. See supra note 14.
16. Medical care can be paid for on the basis of each discrete service (which may be defined with varying degrees of precision and inclusiveness), each episode of illness (perhaps categorized by "diagnosis-related group"), or each patient or group of patients for whom responsibility is assumed (i.e., capitation). Each method of defining the compensable unit of service has particular advantages and disadvantages. Practice guidelines will have different uses depending upon the payment method employed and should be designed to assist in settings besides traditional insured-fee-for-service practice. Thus, in addition to facilitating payer determinations of appropriateness, they should also facilitate prioritizing where either/or (rather than yes/no) decisions are called for.
17. See supra note 10.
18. Social Security Act § 1848(f). These standards are to be used to adjust annual updates in the fee schedule. Id. at § 1848(d)(3).
19. The original proposal involved setting area-wide "expenditure targets" that would, in effect, have converted an area's physicians participating in Medicare into something similar to a health maintenance organization (HMO) of the individual-practice-association variety. Instead of being prepaid, however, the physicians would have been penalized as a group in a subsequent year for any failure to meet the target. See PPRC, supra note 1, at 207 (endorsing national expenditure target, with potential for localized targets later in order that "state and local physician organizations could play a larger role in attempting to affect practice through education and peer review"). This proposal was rejected by Congress in favor of the volume performance standard, which is national in scope initially but which may later be adapted to allow specific physician groups to elect to have a separate standard established for them. See Social Security Act § 1848(f)(4). Such groups might thus resemble, or actually be, HMOs.
penalties for exceeding the standard will affect doctors as a capitation payment would, inducing them to take collective action to control costs. In taking such actions, physicians should find practice guidelines helpful in improving outcomes, in obtaining comparable outcomes at lower cost, and in reducing spending at points where quality, measured in outcomes, would be likely to suffer least. Guidelines may provide a warrant for economizing moves that physicians have heretofore been reluctant to make individually, not only in public programs but in any delivery setting where spending constraints are encountered. In particular, guidelines might provide a degree of protection against malpractice suits premised on the omission of an arguably beneficial diagnostic test or therapy. In general, practice guidelines address a need for an objective standard of care for use not only in malpractice suits but in judging physician performance in other contexts, including disciplinary proceedings against physicians by Peer Review Organizations (PROs).

It is easy to see why some codification of good medical practice in practice guidelines has become a popular idea in many circles. Special interests aside, the concept holds much promise as a way of rationalizing medical care. Whether it will prove to be a magic bullet capable of hitting the target of optimal spending on health care in America, however, remains to be seen. Its success in this regard depends in large measure on how the concept is finally implemented, and many of the crucial issues bearing on this question have yet to be addressed. Although some tension is now detectable in the discussions surrounding who should develop practice guidelines and how they should be used, precise issues are still largely undefined. This Article aims at bringing these issues into the open in the hope that they will not be resolved without full discussion.

III. The Currently Contending Conceptions of Practice Guidelines

It is important that the general enthusiasm for practice guidelines not obscure the different visions of the medical care enterprise that are implicit in the support that the concept is receiving. Although two dis-


21. See, e.g., INSTITUTE OF MEDICINE, MEDICARE: A STRATEGY FOR QUALITY ASSURANCE ch. 10 (1990); INSTITUTE OF MEDICINE, CONTROLLING COSTS AND CHANGING PATIENT CARE? THE ROLE OF UTILIZATION MANAGEMENT (1989) [hereinafter UTILIZATION MANAGEMENT]. These reports express the need for practice guidelines for the purposes of, respectively, assuring quality and controlling costs.
tinct ways of thinking about guidelines dominate current discussions, these two views do not exhaust the ways in which guidelines can be viewed for policy purposes and implemented in practice. After outlining the two prevalent models of practice guidelines, this Article offers an alternative conceptualization of the guideline movement, noting the fundamental policy differences between it and the two dominant models.

A. The Traditional Professional Model

The extensive acceptance that the basic idea of practice guidelines currently enjoys within the medical profession is entirely in keeping with the profession's traditional ideology and perception of itself. Under the professional paradigm of medical care, a physician's practices should be judged only under professional norms and standards, which supposedly combine scientific knowledge with an overarching dedication to patient welfare. Professional dogma also supports a high degree of physician autonomy, on the theory that the physician is an expert, is closest to the situation, and is motivated only by a concern for the individual patient's health. The AMA's preference for describing guidelines as "parameters" reflects the profession's desire to protect practitioners' clinical freedom within professionally established limits. Thus there is nothing in the profession's basic attitude toward practice guidelines that departs from its traditional views concerning the proper locus of medical decisions.

The revelation by health services researchers that physicians' actual clinical methods frequently lack a solid scientific basis and often vary widely without reason might have been viewed as a telling indictment of the professional paradigm of medical care. But the ideal of independent, insured fee-for-service practice under the primary over-


23. See Havighurst, The Professional Paradigm of Medical Care: Obstacle to Decentralization, 30 JURIMETRICS 415, 419 (1990) (The source of this paradigm is a deep-seated belief, long fostered by the medical profession, that medical care is not a commodity, that its characteristics are scientifically determined, and that decisions concerning it must be entrusted exclusively to professionals'). Even though the medical profession originated the paradigm, it is not its sole custodian. Indeed, the organized profession is much less monolithic today than it once was and has updated its own thinking in many respects. Nevertheless, its original paradigm of medical care continues to dominate a great deal of thinking about health care, including that of many nonphysicians. "Residues of the professional paradigm can be found in many places but are particularly significant in the legal system." Id. at 421.
sight of the profession itself is so deeply entrenched that even hard evidence of disappointing performance has not dislodged it. Although revelations of dubious practice, including malpractice, have evoked concessions that there should be more direct professional control over physicians, few have drawn the alternative inference — that physicians should be primarily accountable not to their professional peers but to hospitals, health plans, and other intermediaries that are ultimately accountable to consumers and that can employ professionals to assist their efforts.24 Instead, most observers view the problems revealed by the new research strictly in accordance with the pure professional paradigm — as simply a rectifiable failure of scientific research, professional standard setting, and continuing medical education. Under this view, what is needed is simply more diligence by professional groups in determining what services work best and increased efforts to inform physicians of the conclusions reached. The assumption continues to be that, despite the demonstrated deficiencies of past performance, physicians left to their own devices with improved professional guidance will provide optimal care.

The professional paradigm implies that practice guidelines should take certain forms and not others.25 First and foremost, it prescribes that guidelines should be promulgated or validated by authoritative professional groups, especially the recognized specialty societies, thus ensuring that the guidelines will represent a consensus within the profession. Second, the guidelines should be, not hard and fast prescriptions, but “parameters” accommodating the full range of practices that the profession, tolerant of diversity, does not affirmatively declare unacceptable.26 As such, the profession’s guidelines would be used primarily for educational purposes to bring aberrant physicians back into the medical mainstream. Although they might also be used as screens for detecting the possible existence of quality problems or abuses of other kinds, they should not, under the professional model, be deemed bind-

24. Cf. Havighurst, The Changing Locus of Decision Making in the Health Care Sector, 11 J. HEALTH POLI., POL’LY & LAW 697, 703-05, 711-20 (1986) [hereinafter The Changing Locus]; Havighurst, Doctors and Hospitals: An Antitrust Perspective on Traditional Relationships, 1984 DUKE L.J. 1071 (arguing that antitrust issues in the administration of hospital staff privileges would disappear if the medical staff were properly subordinated to the governing board, contrary to the professional paradigm).


ing in any instance. Physicians would remain free to pursue their own judgment, subject only to scrutiny under a professional norm that expressly contemplates that physicians may sometimes deviate from guidelines in the interest of the patient.

The professional model finds support in the heavy scientific component in guideline development.27 Because practice guidelines must reflect sophisticated research on the outcomes and effectiveness of medical treatment, the work of developing them falls initially within the ken of medical scientists. Often, however, scientific studies cannot provide a complete picture, making it necessary to draw upon the collective wisdom of experienced practitioners. Not only may the organized medical profession appear to have a comparative advantage in enlisting the necessary expertise, but it is widely regarded as the exclusive translator of scientific findings into standards for patient care.28

For the foregoing reasons, many observers view the guideline movement through the lens of the professional paradigm of medical decision making and may not even appreciate that any alternative exists. But any claim that the medical profession should be exclusively responsible for guideline making can be contested on the basis that professional groups may be bent primarily on protecting their members from outside scrutiny and may be influenced in their judgments by the economic interest of physicians in maintaining demand for their own services. The profession’s authority can also be questioned on the ground that guideline development may not be only a technical endeavor. These reservations about the professional model of practice guidelines suggest some of the potential for controversy as guidelines are developed and used.

B. The Political Model

The main alternative to the traditional professional model of practice guidelines that can be detected in current policy discussions is a political one.29 The key element in proposals embodying this approach

27. Indeed, the professional paradigm of medical care got its initial foothold when the medical profession succeeded in establishing its scientific character in the early 1900s, especially in the famous Flexner Report: A. Flexner, Medical Education in the United States and Canada: A Report to the Carnegie Foundation for the Advancement of Teaching (Carnegie Foundation for the Advancement of Teaching, Bull. No. 4, 1910), reprinted in W. HEATLYE, THE POLITICS OF PHILANTHROPY: ABRAHAM FLEXNER AND MEDICAL EDUCATION (1988). See P. STARR, supra note 22, at 118-26.


29. For early advice of consultants largely treating guideline development as a
is the explicit inclusion of nonmedical interests in guideline development. The apparent hope is that putting representatives of various interests in a room to resolve their differences will yield guidelines that reflect appropriate concern for factors that profession-sponsored developers working alone would neglect. Cost considerations, for example, would be more likely to be given some weight under this model.

The recent guidelines legislation embodies the political approach. Specific guidelines are to be developed by or under the oversight of "panels of appropriately qualified experts (including practicing physicians with appropriate expertise) and health care consumers." These physician/consumer panels are to be created in consultation with "a broad range of interested individuals and organizations, including organizations representing physicians in the general practice of medicine and organizations representing physicians in [relevant] specialties." The law does not specify just who would represent "health care consumers" or whether anyone with a direct interest in the cost of care would be guaranteed a place at the table — and thus an opportunity to temper the enthusiasm for more and better services that beneficiaries of federal programs and some consumer advocates share with physicians. In general, however, according to the legislative history, "[t]he Forum structure is designed to accommodate and balance the growing interest of a broad range of parties and organizations in the development of guidelines, which interests sometimes have disparate perspectives."

Although the legislation, as drafted, does not guarantee complete balance in the panels it contemplates, the process it sets up for guideline development might be turned into a promising exercise in interest-group liberalism by giving a major role in the negotiations to employers and other representatives of the consumer's interest in getting value for money in health care. Indeed, one might have modest hopes for a bar-

political, consensus-building exercise, see Lewin & Erickson, supra note 3. These authors emphasize the need "to keep all of the parties communicating and working as cooperatively as possible to prevent the process from becoming overly fragmented and divisive." Id. at 9.

30. Public Health Service Act § 913(a)(2). The insistence on the inclusion of "practicing physicians" reflects organized medicine's concern that independent physician researchers and academics not control the process. See infra note 77.

31. Public Health Service Act § 913(c). This language was taken from a bill originally introduced by Congressman Waxman, chairman of the House Subcommittee on Health and the Environment. See H.R. 2601, 101st Cong., 1st Sess. (1989). The legislative history stresses the need for "objective, representative people of recognized authority and expertise." H.R. Rep. No. 101-247, 101st Cong., 1st Sess. 378 (1989). In addition, the panels, in developing guidelines themselves or reviewing guidelines developed by the Forum's contractors, are to engage in "appropriate consultations with interested individuals and organizations." Public Health Service Act § 914(b)(3)(A). In all these references, the words interested, representing, and representative are undoubtedly used in political senses, underscoring the political character of the task visualized.

gaining process that forced physician groups to work out the final guidelines in direct consultation with consumers and their agents, who together must pay for the care to be provided under them. Such hopes would be justified partly because the context in which the Forum's panels will function does not invite political bargaining in its purest form. Instead, the process directs the parties' advocacy toward technical and scientific issues, thus improving the chances for obtaining guidelines that appropriately balance the consumer's interest in the quality of care, measured by actual outcomes and patient satisfaction, with his competing interest in cost containment.

The drafters of the practice guidelines legislation apparently had some expectation that the political process it creates will ultimately yield an enforceable consensus on what medical care is appropriate for the American people. Although the guidelines produced will not have the force of law, the process employed in their development could confer on them enough apparent objectivity and political legitimacy to give them a great deal of de facto influence. It is anticipated, for example, that the guidelines will be used extensively in administering public financing programs such as Medicare and Medicaid.\textsuperscript{33} Private payers are also eagerly awaiting new standards to use in administering health benefits. Indeed, much of the enthusiasm for practice guidelines originates in the expectation that they will be available for bureaucratic uses, both public and private. In this respect, guideline development under the political model would be at odds with the professional model and could be quite threatening to physicians, who generally fear guidelines that have the specificity, the presumptive validity, and the legitimacy that payers need in order to use them in aggressive cost containment.

C. \textit{The Two Models Compared}

Because the professional and political models of practice guidelines differ with respect to the auspices under which guidelines would be produced, their products are likely to differ both in substance and in their practical utility to would-be cost controllers. These differences have po-

\textsuperscript{33} Indeed, the Secretary is expressly directed to commission three initial sets of guidelines that "account for a significant portion of [Medicare] expenditures," to "provide for the use of [such] guidelines . . . to improve the quality, effectiveness, and appropriateness of care provided under [the Medicare program]," and to make sure that the longer-term priorities set for the guidelines program "appropriately reflect the needs and priorities of [Medicare]." Social Security Act § 1142(a)(3)(A)(i)(I), (A)(3)(B)(b)(3). \textit{See also infra} note 46. As things now stand, however, medical reviews are done by Medicare's various carriers using criteria that each develops on its own. \textit{See} Hirshfeld, \textit{Medically Unnecessary Denials: Where the Standards Come From and How Physicians Can Participate}, 262 J.A.M.A. 3187 (1989). Given this administrative mechanism, it is not yet clear just how practice guidelines would be incorporated into Medicare payment practices.
tential significance for the future of the guidelines movement and give rise to some of the tensions that are beginning to appear as the federal guidelines program is implemented. On the other hand, the two models share some common ground that also needs to be observed.

The substance of practice guidelines will directly reflect the interests that participate in their development. The medical profession, for example, would be inclined to set relatively permissive standards. Because professional groups view the purpose of guidelines as curbing egregious underservice and overutilization and catching a few aberrant professionals — the proverbial "bad apples" — any guidelines they promulgate will tend to exclude only practices in which no competent, informed, and responsible physician would engage. The professional tradition is to consider only safety and efficacy — and not benefit/cost ratios — in treatment decisions and to honor the art as well as the science inherent in day-to-day medical practice. For this reason, a professional group is unlikely to disapprove any practice unless there is convincing affirmative evidence that it is unsafe, inefficacious, or inferior to some alternative. The combination of physicians' concern for their own autonomy and their self-interest in maintaining the demand for lucrative professional services naturally leads physicians to impose heavy burdens of proof on those who would limit their clinical freedom. Guidelines prepared with input from cost-conscious consumer interests, on the other hand, would be somewhat more likely to resolve a doubt in favor of doing less rather than more and to base a judgment on a comparison of costs and benefits.

Professional interests would also prefer guidelines that defy easy use in denying payment or disciplining a physician. Guidelines produced under their auspices would therefore be liberal not only in the lines they draw but also in their receptivity toward physicians' claims of exceptional circumstances. Profession-sponsored guidelines would not shift the burden of proof away from the party challenging a physician's transgression, nor would they be easily translatable into rules

34. For a discussion of the profession's antipathy to benefit/cost comparisons and the tendency of professional bodies to consider only safety and efficacy and to err on the side of doing more rather than less, see Havighurst & Blumstein, Coping with Quality/Cost Trade-Offs in Medical Care: The Role of Professional Standards Review Organizations, 70 NW. U.L. REV. 6, 8-9, 20-30, 38-68 (1975). Cost and quality considerations, however, do not always point in opposite directions. Indeed, efficient practice is that which yields good results, and poor practice can be costly. Nevertheless, there are many instances in which the expected incremental benefit of a test or procedure will not be great enough to warrant incurring its cost. Because addressing such trade-offs is morally difficult, physicians and others have been disinclined to admit their legitimacy. But it would be a mistake to ignore them in the belief that health care can be made affordable simply by eliminating sheer waste. See generally Schwartz & Joskow, Medical Efficacy versus Economic Efficiency: A Conflict in Values, 299 NEW ENG. J. MED. 1462 (1978).
having *prima facie* effect. On the other hand, an important objective of consumer representatives in shaping guidelines under the political model would be to make them as useful as possible in making and enforcing standards with regard to payment, physician discipline, and other matters.

Although the professional and political models of practice guidelines differ in the foregoing significant respects, they have one important thing in common. Both are based upon the assumption that health care should be governed by a single set of standards. Although they differ over what standard-setting mechanism should be entrusted to speak for society as a whole, it is unlikely that proponents of either model would regard as normal or tenable a situation in which more than one set of guidelines purported to govern some area of medical practice. Under both views, the *raison d'être* of practice guidelines is simply to provide an improved set of standards to which society — physicians, payers, courts, and others — can look for authoritative guidance on the appropriateness of treatment. These views in turn reflect a regulatory mentality that is very widespread in the health care field. Indeed, for a long time, the crucial issue in health care was whether the medical profession or government would exert the dominant regulatory

---

35. The Council of Medical Specialty Societies (CMSS) recently held a conference specifically dedicated to developing "a process for resolving conflicts that may arise when practice policies of specialty societies differ." Report of Proceedings, CMSS Conference on Resolving Conflict in the Design and Implementation of Practice Policies, Chicago, Ill., March 4-5, 1990, at 1. The main thrust of the focal presentation by David Eddy, M.D., Ph.D., was toward reaching principled resolution of conflicts occasioned by poor analysis of available evidence, and he reportedly counselled against pursuing objectives such as "increased income, personal gain, extend [sic] turf of a subspecialty, increased use of an exciting new technology, etc." *Id.* at 3. During discussion, "it was pointed out . . . that if a conflict [between] two different policies is not resolved, a third party (e.g., government) could step in and choose either one or the other option for a variety of reasons (e.g., financial)." *Id.* At this point the audience agreed to the need to develop a strategy to resolve conflicts . . . ." *Id.* at 2.

Although Dr. Eddy is correct in wishing to see the scientific rationales for inconsistent conclusions tested, the reconciliation of intraprofessional disputes is not necessarily in the public interest. Indeed, if two organizations were to unite behind a single conclusion, the apparent consensus could conceivably be questioned under the antitrust laws. Thus, it has been argued that agreements between independent professional organizations not to produce inconsistent opinions on commercially important issues should be subject to antitrust scrutiny as agreements denying consumers the benefit of competition in the production of information. Havighurst & King, *Private Credentialing of Health Care Personnel: An Antitrust Perspective* (pts. 1 & 2), *Am. J.L. & Med.* 131, 263, 295-300, 311-25 (1983). Efforts to pursue the CMSS initiative described above should be closely scrutinized by antitrust authorities, who should find in the instant article — and in the attitudes revealed at the CMSS conference itself — reason enough to be concerned about the suppression of competition in the development of practice guidelines.
influence. Even today, many things — from payers’ obligations to malpractice liability — still tend to turn on standards established by central authority, not in the give-and-take of market transactions. As the remainder of this Article will show, it is not inevitable that the guidelines movement must be mounted on the regulatory premise that underlies both the traditional professional and the political models of practice guidelines.

The common assumption that the guidelines movement should produce only a single set of guidelines for general use is traceable in part to the force of the egalitarian ideal in health policy. Even though society has seen fit to accept neither the heavy tax burden nor the stringent rationing that would be necessary to ensure truly equal access to health services, the egalitarian ideal still inspires a powerful entitlement mentality that affects most thinking about medical care. The belief that everyone is entitled to the same care accounts in some measure for people’s general willingness to have their health care governed by professional norms and standards and, together with the scientific component of guideline development, supports the professional model of practice guidelines. The egalitarian ideal also underlies the political model. Indeed, even though advocates of the political model dislike having to rely on organized medicine as the main source of standards, the egalitarian imperative leaves them little alternative. Thus the guidelines legislation was conceived as a way to modify the profession’s top-down standards, not as an opportunity to assist consumers and their agents to develop standards of their own.

There is an irony in adhering to the egalitarian principle in this context. Despite the ideal, neither the professional nor the political model of practice guidelines is capable of yielding a single, fixed standard of medical care for use in administering health care to all citizens. As noted previously, the professional model contemplates “parameters” leaving a wide range of acceptable practices. And the political model would narrow the range of acceptable practice only slightly more. There is simply nothing to compel those participating in political guideline making to reach a consensus on precise rules for allocating medical resources. Not only would physicians engaged in such bargaining resist

36. See infra note 42.
37. See infra note 10.
38. A tenet of professional ideology is that each physician should render the same care to all, without regard to ability (or willingness) to pay. This ethical commitment of the individual physician has been subtly converted, however, into the notion that there should be only one, scientifically determined set of standards to guide all medical practice and that neither consumer choice nor taxpayer parsimony should be allowed to dictate different standards. This social policy position serves the medical profession well by keeping pressure on the political system and private payers to underwrite very expensive technology and to respect physicians’ clinical freedom.
surrendering their clinical freedom, but the other participants would lack a common set of preferences that would enable them to settle upon a single standard of medical care, even as a negotiating position. In addition, inevitable differences in the availability of physical, human, and financial resources and in the circumstances under which care must be given necessitate recognizing a range of acceptable practices.\textsuperscript{39} For these reasons, practice guidelines produced under either the professional or the political model would not provide a specific prescription for doctors to follow unless there was no room for scientific or other debate. Establishing boundaries rather than marking pathways,\textsuperscript{40} they would have little utility in defining the precise entitlements of the patient or the precise obligations of the physician in particular health care programs or physician/patient relationships.

None of this is to say that guidelines delineating a range of acceptable practices would do no perceptible good. Such guidelines could improve outcomes by ruling out some poor practices and could save the cost of some services that yield no significant benefit. But there should be no illusion that practice guidelines developed under either model examined here will answer any of the hard questions that lie in the “quality/cost no-man’s-land” where the battle for efficient resource allocation must ultimately be fought.\textsuperscript{41} As the following discussion shows, the full potential of practice guidelines can be realized only if they are produced under a rationale that does not assume the desirability or inevitability of centralized decision making.

IV. AN ALTERNATIVE CONCEPTION

Even though the two models of practice guidelines embraced by “major players” in the guidelines movement each aims at creating a single set of standards for the governance of all medical practice, it is an important and still unresolved issue whether guideline development should build toward a society-wide consensus. Even though practice guidelines may seem attractive as a vehicle for deciding and declaring collectively what medical care is and is not appropriate, they should not be allowed to take this essentially regulatory form without a clear policy decision to scrap the decentralization strategy that has been pur-

\textsuperscript{39} The most obvious differences exist between urban and rural practice and between “uncompensated” and fully compensated care. See, e.g., Greene v. Bowen, 639 F. Supp. 554 (E.D. Cal. 1986) (PRO sanctions against rural physician); Hall v. Hilburn, 466 So. 2d 856 (Miss. 1985) (modifying “locality rule” in medical malpractice cases). For the view that practice guidelines should be localized, but with “national benchmarks,” see Lewin & Erickson, \textit{supra} note 3, at 16-19.

\textsuperscript{40} See \textit{supra} note 3.

\textsuperscript{41} On the “quality/cost no-man’s land,” see Havighurst & Blumstein, \textit{supra} note 34, at 15-20. See also \textit{supra} note 34.
issued with some success in recent years. Some observers still believe, after all, that decentralized decision making, allowing different persons and groups to choose the level and nature of their investment in personal health care, offers society the best hope of ultimately achieving efficiency in the allocation of resources to and within the health care sector. Even though the federal guidelines program is more likely to pursue the one-right-way chimera, there is an alternative approach under which the promise of informed consumer choice might finally be realized.

42. The issue raised here concerning practice guidelines connects this recent innovation with the larger issues in health policy in the last two decades:

Until [the late 1970s], little in the health policy debate challenged the prevalent assumption that the health care system must operate under prescriptive standards of acceptable care and appropriate spending. Instead, the issue debated was whether the medical profession alone should define these performance limits or whether government should exert an influence. When the advocates of competition entered the discussion, however, they rejected both professional self-regulation and government command-and-control methods as mechanisms for resolving medical-economic issues. Their scenario opened the possibility that consumers would have a chance to decide for themselves in the marketplace what standards of medical practice best suited their preferences and pocketbooks. In essence, the market reformers contemplated that decision making responsibility could be shifted to the numerous actors on the demand side of the market and that consumers could safely be encouraged to do business with health plans and providers whose practices departed from accepted norms. In particular, procompetition strategists anticipated that cost considerations would be given greater weight in medical decision making if those paying the bills were given a wider range of choice.

Havighurst, Decentralizing Decision Making, supra note 10, at 22. The 1980s saw the market strategy become dominant as the federal government renounced its regulatory ambitions, making public and private purchasers of health care responsible for controlling their own costs, and as the antitrust laws were enforced to remove private restrictions on private initiative. See Havighurst, The Changing Locus, supra note 24.

43. See, e.g., A. Entovien, Theory and Practice of Managed Competition in Health Care Finance (1988); Havighurst, The Changing Locus, supra note 24. Although a serious adverse-selection problem presents itself whenever consumer choice among competing financing plans is allowed, it could probably be managed by techniques still being developed. A. Entovien, supra, at 75-118. Otherwise, there are two substantial but surmountable obstacles to achieving efficiency through consumer choice. The major conceptual obstacle is the professional paradigm itself, with its assumption that anything departing from professional norms is suspect, not only in physicians' eyes but legally as well. See Havighurst, supra note 23; Havighurst, Decentralizing Decision Making, supra note 10, at 29 ("In place of the prevalent assumption that change can occur legitimately only by altering professional standards across the board, [market] theorists welcome the prospect of diversity and deviations from professional consensus."). The second obstacle, which has heretofore prevented effective challenges to the professional paradigm, is the practical difficulty of effectively specifying an alternative to the professional standard of care — a difficulty that practice guidelines, as conceived here, could eventually overcome.
A. A Nonregulatory Rationale for Practice Guidelines

Conventional economic theory supplies a third way to think about and approach the development of practice guidelines. Indeed, the most powerful justification for public sponsorship of outcomes and effectiveness research and guideline development is simply that these governmental activities address two distinct and important market failures. The first problem is familiar. The second one is less so, and its recognition in particular opens up new vistas on what guidelines can contribute to the evolution of health policy.

1. Practice Guidelines as a Public Good

The simplest way to conceptualize government support for the development of practice guidelines is as a public investment in the production of information. Because information, as a so-called "public good," is not consumed when it is used and can therefore be widely shared, free riders can make extensive use of it without contributing anything to the cost of its production. The resulting difficulty of marketing information profitably to everyone to whom it is potentially valuable makes its underproduction inevitable in a free market. Public subsidies are therefore necessary if society is not to incur the greater costs of avoidable ignorance.

The high cost and potential benefit of doing biomedical research and thorough clinical trials make the medical sector already an important focus of public investment. The research effort has heretofore been driven, however, largely by incentives and professional imperatives that have not ensured adequate attention to projects that might reduce the cost of health care or improve "effectiveness" — that is, the system's ability to translate exotic technologies into better outcomes. Given the large amounts that government and the private sector spend on health services, there is little danger that society will invest too much in investigating the wisdom of that spending. Indeed, because government programs can internalize much of the saving anticipated from guideline development, it may not even be necessary to invoke the public good rationale to justify the projected level of investment. It would be regrettable, however, if government were to view the guideline effort only as a way of lowering the cost of its own programs. Guidelines are also a good public investment because they can improve the quality of pub-

44. For a brief discussion of it in a related context, see Havighurst, supra note 22, at 348-51.
45. See supra note 33. If the guidelines program evolves, as it should, into a research and development program benefiting the private sector as well as government programs, the case for diverting substantial funds to it from the National Institutes of Health (or explicitly instructing the NIH itself to engage in outcomes and effectiveness research and guidelines development) would be very strong.
licly financed care and because they provide vital, otherwise unobtainable information to private-sector decision makers.⁴⁶

If the research agenda were driven exclusively by a public-good, market-failure rationale, one might expect it to focus only on effectiveness and outcomes research and not to include the generation of actual guidelines — on the theory that independent decision makers should finally decide what the evidence means and should not be given actual prescriptions. Nevertheless, even putting aside the government’s direct interest in guidelines for use in its own programs, a strong market-failure case can be made for public support of practice guidelines for private use. Because it is extraordinarily difficult for anyone, let alone a busy practicing physician, to synthesize the teachings of numerous, usually conflicting studies of uncertain scientific validity into a reliable basis for each clinical decision, a public investment in such syntheses could pay substantial social dividends. Although professional organizations are already making important, largely uncompensated efforts to supply needed clinical guidance to their members, a publicly supported effort, supplying independent advice and guidance to payers and consumers, as well as clinicians, would also be worthwhile.

If the federal government’s research and guideline-development effort were to be launched solely under a market-failure rationale, its nature and products would be strikingly different from what is contemplated in the professional and political models. Grants and contracts would be awarded solely on scientific merit and responsiveness to the public’s specific information needs; the political representativeness of the organization doing the research or promulgating the finished guidelines would count for nothing. Practice guidelines would be explicitly presented not as rules but as research findings, revealing rather than glossing over any uncertainties or weaknesses. Even with such caveats included, however, guidelines produced under this rationale could feature much more specificity and prescriptiveness than appears to be contemplated in the professional and political models. They could also take explicit account of nonscientific considerations that prospective users might find relevant to their needs — particularly relative cost-effectiveness, relative riskiness, and benefit/cost ratios.

Most importantly, it would be no cause for concern under this rationale if there were several inconsistent sets of guidelines outstanding at any one time. Indeed, this third approach to guideline development calls for explicitly encouraging different groups and researchers to de-

⁴⁶ Although the legislative history of the guidelines legislation does emphasize the utility of guidelines in public programs, see 135 Cong. Rec. H9581 (daily ed. Nov. 21, 1989), this emphasis should not obscure the value of guidelines to the private sector or induce the Forum to concentrate only on Medicare’s needs. See supra note 33, infra note 58. Later discussion suggests that, even with a limited budget, the private sector’s needs can be met without neglecting the needs of the the Medicare program.
velop practice guidelines that have significant areas of overlap and that reach possibly different conclusions on debatable issues. Not only would a multiplicity of guidelines give physicians and the consuming public the benefit of a variety of considered judgments about the scientific evidence and about the desirability of additional spending on marginal services, but, as the following discussion shows, the availability of competing guidelines would also yield another, potentially crucial benefit.

2. Guidelines and Transaction Costs

The availability of a variety of reputably prepared, relatively precise practice guidelines would help to overcome a second kind of market failure. Heretofore, any effort to contract for medical services meeting any standard other than the medical profession's own would have entailed prohibitive transaction costs. In order to specify an alternative standard of care effectively, a contract would have had to resemble a medical textbook, with prescriptions for virtually every medical contingency and with each prescription customized to reflect the priorities and resources of the consumers or patients affected.47 Not only would such contracts be nearly impossible to write, but, without uniformity between contracts, they would be extremely difficult to administer in most practice settings.

As a direct consequence of these transaction costs, consumers and patients have been generally unable to contract with payers or physicians for a different standard, or style, of medical care than is customary in the community.48 Instead, contractual relationships between pay-

47. See Havighurst & Hack Barth, Private Cost Containment, 300 New Eng. J. Med. 1298, 1300-03 (1979) (observing both the desirability and the difficulty of writing highly selective insurance contracts). For another way of contractually modifying the standard of care, see Havighurst, Altering the Applicable Standard, supra note 10, at 270-72. This source suggests clauses authorizing reasonable and prudent departures from customary practice and limiting the kinds of expert testimony that could be used to establish medical negligence. Such clauses would be helpful, however, only in reducing exposure to malpractice suits, not in defining payment obligations. Their greatest utility would be in an HMO context. See note 48 infra.

48. Perhaps the nearest approximation to contracts altering the applicable standard of care is found in group-practice or staff-model HMOs. The physicians participating in such a closed-panel HMO may practice a different style of medicine than is found generally in the community, so that their patients receive a different, more economical brand of medicine than other consumers. See Havighurst & Hack Barth, supra note 47, at 1303 ("plans that rely on provider selection to control costs embody implicit benefit limitations, in that the chosen providers' benefit-cost decisions have the practical effect of limiting coverage"). Nevertheless, physicians practicing in such plans are likely to be held to community standards in malpractice cases, as courts reject the argument that consumers, by accepting the group's services, voluntarily accepted any different standard of care than prevails in the community as a whole. Cf. Emory University v. Porubiansky, 248 Ga. 391, 282 S.E.2d 903 (1981) (invalidating on public-policy grounds contractual waiver of liability given in return for low-cost health care).
ers and physicians on the one hand and consumer/patients on the other have always implicitly incorporated the norms and standards of the medical profession. Thus, private health plans customarily undertake to cover all physician and hospital services that are "medically necessary" — a criterion that can be applied in ambiguous cases only by consulting profession opinion. Public programs have, for the most part, defined beneficiaries' entitlements in similar terms. Courts determine the obligations of physicians to patients in malpractice cases in comparable fashion — by consulting medical experts concerning professional custom. But even though the infeasibility of implementing alternative standards of care may have made it efficient for public and private health plans and doctor/patient relationships to adopt professional standards, it does not follow that professional standards are themselves efficient or well suited to the needs of the parties in every case. On the contrary, if alternative standards could be defined, many health plans, physicians, and consumers might find it in their mutual interest to adopt them.

The practice guidelines movement has the potential not only to define alternative standards of medical practice but also to supply them

But see Bovbjerg, The Medical Malpractice Standard of Care: HMOs and Customary Practice, 1975 Duke L.J. 1375 (suggesting that the legal standard of care might reflect customary practice in different practice settings). In any event, such success as an HMO might have in departing from community standards would result in part from the implicit character of the departures. If the same departures were provided for explicitly by contract, courts might well invalidate them. In addition, the HMO context helps to ensure that the physician will not end up as the patient's ally against the plan in court.

49. See generally Annot., What Services, Equipment, or Supplies are "Medically Necessary" for Purposes of Coverage under Medical Insurance, 75 A.L.R.4th 763 (1990). Although health plans can limit their coverage in a variety of other ways, most such exclusions are highly categorical and affect only peripheral services, rarely services at the core of medical practice. The appropriateness of routine medical services is frequently reviewed, however, by peer reviewers or utilization managers. See generally Institute of Medicine, Utilization Management, supra note 21. Nevertheless, such "managed care" programs are dedicated, at least in theory, to applying professional norms, not plan-specific contractual standards. Thus, they frequently do not reveal their operating rules to physicians, believing that to do so would facilitate "gaming" the system. Because such rules are not contractual, the utilization manager's legal position is unclear, and its standards might not be upheld in litigation concerning the payer's obligation to pay. Nevertheless, its ability to withhold payment allows it to influence physician behavior with some assurance that the matter will not come to court. Cf. Wickline v. State, 192 Cal. App.3d 1630, 239 Cal. Rptr. 810 (1986) (utilization reviewers were sued unsuccessfully after patient who was discharged after further hospitalization was not authorized suffered injury; physicians had failed to bring all facts to reviewers' attention).

in forms that facilitate their practical use. Indeed, because independently developed guidelines could rather readily be incorporated by reference into specific contracts between payers, physicians, and consumers, their availability would eliminate many of the transaction costs that have hitherto necessitated the health care system’s reliance on professional norms and standards. Whereas practice guidelines that attempt to express a society-wide consensus will often specify only a range of acceptable practices, guidelines that are developed for possible voluntary use could be quite specific, perhaps taking the form of protocols prescribing the actual diagnostic and treatment methods to be routinely followed. Such guidelines would probably never be comprehensive or clear enough to resolve all questions, nor should they be so rigidly enforced that exceptional circumstances could not be accommodated. But guidelines that charted actual pathways instead of merely setting outer boundaries would give health plans and consumers an unprecedented ability to specify the level of health care they wish to purchase on a prepaid basis. Although providers and patients would be free to agree on any additional services they deemed desirable, consumers would no longer be bound, as if by regulation, to pay (through their health plans) for everything authorized under professional norms and standards. Public programs, too, would benefit from being able to specify the precise services to be provided to their beneficiaries without embracing the collective standards of the medical profession.

If selected guidelines were used to specify their obligations to patients, both physicians and private health plans should enjoy substantial protection against legal liability for not providing or financing (as the case may be) the last measure of possibly beneficial care. Thus, if contractually specified guidelines were treated as the legal standard applicable in a particular relationship, there would be less reason for physicians, fearing liability for malpractice, to practice “defensive medicine,” and malpractice law would be generally easier to administer. Utilization management would also be easier, and less hazardous


52. See generally Havighurst, supra note 20. Defensive medicine is care that is provided out of an excess of caution by a physician seeking to avoid a charge of malpractice. Under a contractual regime, however, a physician might be protected in withholding services to which the patient was not entitled under the plan. Liability might be appropriate, however, if the physician, knowing of a patient’s need, failed to advocate her case with the plan. Cf. Wickline v. State, 192 Cal. App. 3d 1630, 1645, 239 Cal. Rptr. 810, 819 (1986) (dictum) (“the physician who complies without protest with the limitations imposed by a third party payor, when his medical judgment dictates otherwise, cannot avoid his ultimate responsibility for his patient’s care”). Failing in such an appeal, the physician might also have a duty to inform the patient of the need for
legally, with explicit standards.\textsuperscript{53} Although much would depend upon whether courts perceived the guidelines selected for use in a particular situation as legitimate and objective, there would often be powerful arguments for enforcing them as \textit{ex ante} contractual limits against patient plaintiffs in \textit{ex post} lawsuits. Later discussion suggests how the federal government's guidelines program could supply much of the legitimacy that courts will probably require before relaxing their vigilance on behalf of individual patients.

It seems probable that the health care sector's universal reliance on professional norms and standards — to the exclusion of independent choices by consumers and their agents — has resulted more from practical necessity arising from transaction costs than from universal agreement on the optimality of those standards. Yet, even though professional standards enjoy their current dominance only because of the difficulty of developing and specifying alternatives, they currently have nearly the same force in practice (in litigation, for example) as government regulations formally adopted in the public interest. The regulatory function of professional standards is also confirmed by the conventional models of practice guidelines and by the guidelines movement itself, which is currently proceeding as if the only goal is to improve the standards by which the industry as a whole is governed. But practice guidelines could also serve as tools for deregulating American health care. If developed with extensive public assistance in a pluralistic environment, competing guidelines could ultimately bring about the decentralization of crucial decisions about medical care by giving consumers both an unprecedented opportunity to choose among alternative standards and the means of specifying their choices with enough particularity to make them enforceable in practice. Once consumers have the means of exercising meaningful choice, there is no reason why the market for medical care, supplemented by public subsidies for low-income persons, could not finally "work" — that is, allocate scarce resources efficiently to health care uses.

The potential of practice guidelines to lower transaction costs, and

additional treatment at the patient's own expense. It would be inappropriate to impose liability on a physician for not providing a costly treatment for which the patient would or could not pay.

53. Currently, if coverage issues are raised in litigation, courts have no source other than professional norms and standards to consult for guidance on the legitimacy of a particular refusal to pay. See supra note 49. Contractually specified practice guidelines would give a more precise point of reference. New computer technology would seemingly facilitate implementation of competing guidelines in medical practice by giving physicians and hospitals clear information on the coverage limits applicable to particular patients. It remains to be seen, however, whether providers could be comfortable applying different standards to different patients under their care. Specialization in the use of particular guidelines — in treating subscribers of a single health plan, for example — would probably be common.
thus to make possible the exercise of real consumer choice, has not
previously been recognized. Although inertia and the limited supply of
guidelines make this only a long-range market-reform strategy, the op-
pportunity to facilitate informed, enforceable consumer choices among
alternative, highly specified benefit packages should not be missed. No
regulatory program could do as much to impose discipline on the medi-
cal care industry as a fully realized strategy of promoting pluralism in
the development and use of practice guidelines.

B. Centralization Versus Pluralism

The practice guidelines movement has yet to confront the issue of
pluralism versus centralization. Indeed, there may be considerable con-
fusion on the point. Most professional organizations and most individ-
ual physicians have insisted that guidelines should preserve ample room
for clinical judgment, thus preserving pluralism of a sort. Flexibility
allowed in a single set of guidelines is not the same thing, however, as
the pluralism that would result from the ability of users to choose
among a number of competing guidelines each expressing a slightly dif-
ferent (but internally consistent) valuation of medical care and degree
of risk aversion. Although the medical profession may define pluralism
solely in terms of physicians' independence, a more dynamic model of
the market for health services would allow each competing health plan
to choose — from a variety of reputably prepared guidelines, some of
which are more prescriptive and confining than the profession's own —
the one set that is best tailored to the preferences and pocketbooks of
its subscribers. This vision of how guidelines might be used opens new
possibilities for competition under conditions of informed consumer
choice.

The prevalent tendency to approach guideline development as a
search for a medical or societal consensus originates in a variety of
conventional perceptions and attitudes about medical care, all of which
seem to contraindicate a pluralistic approach. First, there has been a
tendency to think that the only considerations relevant to determina-
tions of "appropriateness" are technical ones; under this scientific view,
some disagreement and uncertainty are inevitable, but there is ulti-
mately only one right answer to every question asked. Second, wide-
spread aspirations for egalitarian distribution of health care also rein-
force the view that what is needed is a single standard to govern the
care of all citizens — or at least to define their theoretical entitlement.
This conviction is further confirmed by the tendency to focus only on
the specific needs of existing public financing programs, which do re-
quire uniform rules and which some view as simply forerunners of a
wider system of social insurance in which uniform guidelines would be
a vital component. Finally, many payers may strongly wish that hard
choices could be made for them by some central authority.\textsuperscript{54} Not wanting to be caught between pressures to economize and the potential legal and customer-, employee-, and public-relations consequences of denying desirable (but not necessarily appropriate) care, these payers are greatly attracted by the prospect of objective standards.

Despite these reasons for assuming that a single, definitive set of practice guidelines is the appropriate goal of public policy and professional endeavor, there are strong policy arguments for promoting pluralism and decentralization by encouraging the development of competing practice guidelines. To begin with, the scientific character of guideline making, far from implying a need for centralized decision making, points toward a need to air issues openly. Reasonable minds can, and do regularly, differ over scientific and technical matters, and there is no necessity or good reason for allowing such issues to be definitively resolved behind closed doors or to be committed, in predictably permissive guidelines, exclusively to the discretion of individual physicians.\textsuperscript{55} Moreover, decisions about health care are not exclusively technical. They also involve difficult value judgments and trade-offs between benefits and costs. Because practice guidelines produced under professional or political auspices will be aimed only at setting upper and lower limits, they will give consumers and their agents little help in choosing the precise standard of care that best fits their preferences and circumstances.

To expect consumers and their agents to make more particularized choices within authoritative "parameters" is unrealistic. As noted above, it is practically impossible to specify, in binding private contracts or in coverage rules in public programs, the precise standards to which physicians are bound to adhere; this is essentially the task of guideline writing itself. Moreover, even if consumers' agents — employers, insurers, HMOs, and so forth — could write their own internal guidelines, they would run severe legal and consumer-relations risks if,

\textsuperscript{54} Private insurers and health plans are fearful of being seen to economize, for many reasons. Their customers, mostly employers, are likewise reluctant to make hard economizing choices, even responsible ones. \textit{See infra} note 87.

\textsuperscript{55} Of the four possible outcomes of a conflict between guidelines of different professional organizations noted in Report of Proceedings, \textit{supra} note 35, at 4 — namely, reconciliation, "arbitration," "street fight," and "agree[ment] to disagree" —, only the latter two are clearly lawful under the antitrust laws. \textit{See supra} note 35. But even though independent professional organizations may be prevented from agreeing on a common position, professionally developed standards for the presentation of guidelines might clarify the differences for the benefit of decision makers. Thus, Dr. Eddy's recommendations for "agree[ments] to disagree" amount to standards for the presentation of guidelines that would greatly improve the quality and quantity of information received by consumers and their agents and would thus be a procompetitive improvement over the "street fight" outcome. As suggested in this article, the federal guidelines program may also provide this public service.
in order to reduce costs to manageable levels, they elected not to cover
care that was deemed appropriate in the prevailing government-spon-
sored, technician-developed guidelines. Physicians would probably not
be able to rely upon contractual or other coverage limits to excuse de-
partures from professional norms in the event an injury triggered a
malpractice charge. These practical and legal obstacles to rational con-
sumer choice would be greatly reduced, however, by a guidelines pro-
gram that generated alternative specifications of appropriate care, each
developed by conscientious researchers and physicians under the over-
sight of government-sponsored panels. Any departures from profes-
sional standards introduced by these means would be much easier for
the payer or the physician to defend in court, in the media, or
otherwise.

The main policy objection to a pluralistic approach to practice
guidelines would probably be that adopting it requires acknowledging
that different people might have different entitlements to health care,
with lower-income persons likely to have the less extensive claims. But
egalitarian distribution of health services is only an aspiration — and
one that becomes increasingly difficult to realize as the cost of state-of-
the-art health care (which many people insist on purchasing for them-
selves) rises faster each year than national income. Not only is the
egalitarian ideal increasingly unrealistic, but clinging to it in making
practical health policy can be highly counterproductive. The legal sys-
tem, for example, perpetuates costly inefficiency by threatening to pe-
nalize as “malpractice” all economizing that departs from the custom-
yary professional standard of care and thus seems to undercut the
ideal. 56 In addition, the legal system’s probable hostility to contracts
that seem to authorize a lowering of the standard of care provided has
meant that health insurance is priced out of the reach of over 30 mil-
lion Americans. At the same time, the theoretical commitment to mak-
ing the very best care accessible to all raises the cost of, and thus de-

56. See Moreim, Stratified Scarcity: Redefining the Standard of Care, 17 LAW,
MED. & HEALTH CARE 356 (1989) (thoughtful discussion of “whether we must aban-
don or substantially modify our traditional insistence that physicians owe all their pa-
tients a roughly equal minimum standard (quality) of care” and “why stratified scar-
city will force us to confront an enormous jurisprudential challenge”); Moreim, Cost
Containment and the Standard of Medicare Care, 75 CAL. L. REV. 1719 (1987). See
also Havighurst, supra note 20; Havighurst, Altering the Applicable Standard, supra
note 10, at 266-70; Havighurst, Decentralizing Decision Making, supra note 10, at 24
(“such rigorous enforcement of adherence to prevailing standards is unwise because
customary practice is distorted by third-party financing, a mode of payment that en-
courages practitioners systematically to discount the cost consequences of their treat-
ment decisions”). These latter sources argue the virtues of private contracts that alter
the legal rules applicable in defining and redressing malpractice. See also Symposium,
Medical Malpractice: Can the Private Sector Find Relief?, LAW & CONTEMP. PROBS.,
Spring 1986, at 1, 143-320.
ters, doing anything for these same deprived persons, whom the ideal is intended to assist — a grim instance of the best being the enemy of the good.\textsuperscript{57}

The gap between the egalitarian ideal and the reality of inequality in health care is reflected in the inability of either the professional or the political model of practice guidelines to produce practice standards that would truly equalize (even on paper) the health care of all citizens. Instead, both models would pay lip service to the egalitarian ideal by setting a single standard under which a wide range of practices are deemed acceptable. The theory is apparently that, because everyone can at least hope to receive the very best care, no “right” to desirable health care has been denied. And, indeed, under practice guidelines embodying this peculiar form of egalitarianism, a few poor persons might occasionally get the very costliest care — thus preserving the myth that nothing is too good for persons of limited means. Also under this approach, a rich person who received very marginal care could not claim a legal right to anything better than the guidelines’ minimum, again protecting the system against the charge that ability to pay gives some persons a greater entitlement. But \textit{de jure} egalitarianism is nothing to be proud of when \textit{de facto} inequality is so pervasive.

It will be noted that adhering to the egalitarian ideal keeps many consciences clear, even in the face of substantial inequality in the actual distribution of services. Custodians of “rights” — mostly politicians, lawyers, and judges — do not have to apologize for this reality because they can say that, in addition to advocating some form of national entitlement, they have done their part by not recognizing anyone’s legal or contractual claim to be treated better than someone else. But merely setting aside a few tickets in a health care lottery for poor persons is hardly a worthy societal accomplishment. If purely symbolic egalitarianism and fastidiousness about seeming to ratify any degree of inequality in health care in law or public policy together impair implementation of the guidelines strategy recommended here, it will cost society a great deal — specifically, the chance to give consumers of

\textsuperscript{57} A much-publicized effort by the State of Oregon to prioritize medical practice — to facilitate a wiser allocation of limited resources and the expansion of coverage under the state Medicaid program — illustrates the difficulty that public programs have faced. See generally Special Report, \textit{National Debate Sparked by State Plan to Expand Access to Health Coverage}, 17 Penn. Rep. (BNA) 725 (April 30, 1990); Crawshaw, Garland, Hines & Anderson, \textit{Developing Principles for Prudent Health Care Allocation: The Continuing Oregon Experiment}, 152 \textit{Western J. Med.} 441 (1990). Without a method, other than reference to professional norms and standards, of setting limits on what particular services the state will pay for, states had to control Medicaid costs by limiting individuals’ eligibility and underpaying providers. The Oregon experiment should at some point link up with the practice guidelines movement, either by adopting guidelines prepared by others or by promulgating guidelines of its own.
health care reliable, particularized advice about what to purchase, allowing them finally to control their spending on marginally beneficial services. It would be a consummate irony if the egalitarian ideal, which the nation is unwilling to implement because it would cost too much, is costing society anyway by precluding strategies that would allow the nation to economize rationally in purchasing health care.

V. Building Pluralism into the Federal Guidelines Program

It is most probable, of course, that the federal guidelines program will be implemented simply as a search for authoritative standards for medical practice and not as an aid to independent decision making. Even though Congress located the Forum for Quality and Effectiveness in Health Care in the Public Health Service (PHS) rather than in the Health Care Financing Administration (HCFA), the Forum is more likely to cater to the Medicare program's need for definitive standards than to serve the information needs of the decentralized private sector. 58 Certainly, the agency has no affirmative reason to question the assumption, common to both the professional and the political models of practice guidelines, that their purpose is to clarify and improve the prevailing standard of care, not to facilitate independent efforts to define alternative standards. Finally, the Forum's funds are not nearly sufficient to address all of the many technical issues demanding costly, systematic study, let alone to finance overlapping or competing studies in any particular area. 59 These circumstances all suggest that each set of practice guidelines will be expected to be definitive in its respective field.

It is still possible, however, that the Forum could be persuaded to become just what its name implies, a forum for the expression of many opinions, rather than a formulator of rules to be given near-regulatory

58. Although the placement of the program in the PHS might suggest interpreting its mandate more broadly, Congress was mostly concerned that the budgetary imperatives of the Medicare program not override quality-of-care considerations. See supra note 46. Moreover, like the congressional leaders who urged this placement, see supra note 31, the PHS bureaucracy is basically comfortable with regulatory, top-down approaches to all health problems. Indeed, the PHS is probably more wedded to the professional paradigm of medical care than is the HCFA itself, the leadership of which in recent years has been particularly supportive of the policy of decentralization. See Roper et al., supra note 1 (top HCFA officials advocate practice guidelines specifically as an aid to decision making at all levels).

59. See supra note 7. Even if they were deemed desirable in theory, competing guidelines are most likely to be seen as a luxury unlikely to be affordable anytime soon. And indeed it is hard to quarrel with the idea that a few well-executed projects would be preferable to frittering away funds on numerous half-baked ones, whether overlapping or not. Nevertheless, later discussion shows how economies of scale can be realized in research and development without foreclosing decentralized decisions.
force in the health care system as a whole. After all, a facilitative, information-generating role is more consistent with the research mission of the Forum and its parent agency, the AHCPR. Moreover, the Forum’s mandate to oversee the formulation of guidelines based on findings from the research it sponsors also fits comfortably under the traditional public-good rationale for publicly subsidizing the production of information. Finally, there is nothing in the guidelines legislation itself that precludes this interpretation of the Forum’s mandate. Although Congress may have assumed that definitive guidelines would result from the Forum’s efforts, that expectation did not reflect a policy preference so much as unthinking acceptance of the professional paradigm of medical care. In any event, the statute as written does not mandate definitive guidelines. The plural term guidelines need not be read as singular even though Congress, not recognizing the potential virtues of competing guidelines, may have so used it.

Although it is difficult to tell what precise hopes Congress had for

60. In a recent statement, the Forum has revealed a degree of receptivity to the notion that inconsistent guidelines might coexist and compete in the “marketplace of ideas”:

[W]e would like to see a set of guidelines accompanied by assessments of the strength of the scientific evidence and professional consensus attached to specific statements. If another group has developed conflicting guidelines or if scientific evidence and expert opinion conflict, the areas of conflict should be described and the rationale given for the guidelines in question.

AHCPR, Provisional Listings of Attributes of Good Practice Guidelines (attachment to letter to Robert H. Hodge, American College of Physician Executives, from Stephen H. King, Director, Office of the Forum for Quality and Effectiveness in Health Care, (Mar. 9, 1990)). See also Report of Proceedings, supra note 35, at 6 (Dr. King “was asked if his agency could serve as a judge in certain cases of interspecialty conflicts . . . [and replied] that at this point his governmental agency would not actively seek a role as a judge in such cases.”).

61. It is hard to argue that a policy of encouraging competing guidelines would, in addition to perhaps surprising Congress, also violate congressional intent. Congress’s primary purpose was to provide better, more scientific guidance for physicians, and competing guidelines would seem to offer significantly more precise guidance than a single set of guidelines produced under either the professional or the political model. It is true that Congress defined guidelines in a way that implied that only practitioners and educators would use them — as the professional model contemplates. See Public Health Service Act § 912(a)(1) (referring to “clinically relevant guidelines that may be used by physicians, educators, and health care practitioners to assist in determining how [to treat patients]”); but see id. at § 912(b)(3) (anticipating guidelines’ use in “reviewing quality and appropriateness”). However, the legislation is also pregnant with the expectation that the Medicare program will make extensive use of the guidelines, directly or indirectly, in defining the scope and limits of its own obligations. There is no reason why other payers, public and private, should not benefit from the research and development effort in the same way. Thus, the Forum would not be violating any congressional preference in encouraging the production of a multiplicity of guidelines, etc., that could be incorporated by reference in private contracts or otherwise used by different payers and organized health plans to govern physician behavior.
the guidelines program, a pluralistic approach might accomplish more than an approach premised on the professional paradigm. A single set of professionally validated guidelines in a particular field would achieve no congressional objective other than facilitating the identification of intolerably bad quality on the one hand and certifiable waste on the other. Even guidelines developed under the political model would paper over many significant disagreements, labeling many divergent, debatable, and cumulatively expensive practices as acceptable until more conclusive evidence is adduced. Paradoxically, therefore, guidelines developed to serve as a uniform standard for medical care would leave individual physicians wide discretion. Moreover, as to all practices not deemed inappropriate, a presumption favorable to physicians would be raised against any payer seeking to control costs and any plaintiff alleging malpractice. Such guidelines would thus bear out the well-supported hypothesis that public regulation is more likely to benefit producers than consumers. A strong case can therefore be made for construing the Forum’s mandate as something less radical than the setting of exclusive practice standards for all American medicine.

There are a number of ways in which the federal guidelines program, without incurring appreciable additional costs, could be administered with the primary object of generating high-quality information and advice for health care decision makers of all kinds. Specifically, the Forum’s strategy in selecting its oversight panels and contractors, its requirements concerning the presentation of research results, and its attitude toward independent developments could together ensure that the program’s products are neither offered nor received as the final word on how medicine should be practiced. Although the Forum does not currently intend to publish regulations explaining its implementa-

---

62. See supra notes 34-40 and accompanying text. The legislative history of the guidelines legislation acknowledges that definitive pathways will not always be feasible:

The Forum should not consider itself compelled to come up with the single best approach to a patient problem or condition, if consensus cannot be reached on a single approach but there is agreement that care can be improved through the use of a set of guidelines. In such circumstances, the Forum can provide for alternative approaches, with appropriate commentary on which ones appear to be preferable under various circumstances.


64. The program’s object — which is unlikely to be achieved without conscious effort — should be to avoid sending an unwarranted signal that, because the government and the experts have spoken, consumers and their agents are bound by their conclusions concerning which physician practices are appropriate or inappropriate, as the case may be. The Secretary could do his part in preserving the program’s pluralistic character in appointing the Advisory Council for Health Care Policy, Research, and Evaluation provided for in the Public Health Service Act § 921.
tion of the guidelines program, 66 regulations could be helpful in shaping the program to dispel the impression that guidelines are definitive on every issue they address. Because the Forum is widely expected to generate definitive determinations of what is socially acceptable in medical care and not merely to increase the quality and quantity of information and advice flowing to independent decision makers, the Forum should seize every opportunity to reiterate the public-good and transaction-costs rationales for its research and development (R&D) effort.

A. Selecting the Oversight Panels

In establishing panels of experts to preside over guideline development in each specialty area, the Forum will have the opportunity to determine much of the program's character. Because the legislation does not contemplate that the Forum will itself promulgate guidelines as government policy, 66 the panels themselves will apparently determine what is published under the program's auspices. Under the legislation, the panels may either develop guidelines themselves or review the development work of contractors selected by the Forum. An obvious danger is that the panels will view themselves as the final arbiters of what may and may not be regarded as appropriate or inappropriate medical practice. Although the Forum might instruct the panels otherwise in formal regulations and in other ways, it can also exercise influence over the panels by the manner in which it selects their members.

The guidelines legislation itself, by attempting to ensure that the oversight panels are constituted in a politically acceptable manner, may strengthen the impression that the panels are intended to make final decisions and not to act merely as overseers of a pluralistic program of R&D. 67 Nevertheless, even though Congress may have anticipated that the panels would perform quasi-regulatory roles equivalent to the self-regulatory functions of the medical profession under the professional paradigm, it did not specify that only one set of guidelines should be promulgated for each area of medical practice. Moreover, the same manner of appointing members would be appropriate if the panels were to serve, not as arbiters of medical care, but only as certifiers of guidelines meeting the Forum's minimum requirements. 68 If the Forum

---

65. The Forum is charged, however, with establishing formal "standards and criteria" to guide its panels and contractors. Public Health Service Act § 914(b). For the advice of a committee of the Institute of Medicine to the Forum on structuring its program, see INSTITUTE OF MEDICINE, supra note 1.

66. "[N]o one in the Forum or the Department of HHS would have any authority to review, modify, approve or disapprove the guidelines developed by panels or contractors." H. Rep. No. 101-247, supra note 31, at 378.

67. See supra notes 30-31 and accompanying text.

68. See infra text accompanying notes 80-85.
wishes this latter interpretation of the panels' function to prevail, it should assign panels' duties accordingly69 and select panel members who have such diverse interests that pluralism will come naturally to them.70

B. Selecting Contractors

In selecting contractors to perform the necessary research and to develop the guidelines themselves, the Forum may be naturally inclined to favor prestigious professional organizations, particularly the medical specialty societies. But even though such organizations are the traditional source of professional standards and are likely to be first in line for grants and contracts, a strong case can be made for bypassing them. Such professional bodies do not have a monopoly on the necessary technical expertise, much of which is found in research organizations and academic medical centers. Moreover, the clinicians who dominate the specialty societies may not always interpret evidence objectively when the value of their services is in question. Certainly the few skeptics within a specialty are unlikely to be nominated to the committees convened to consider such matters. Finally, guidelines produced by broad-based professional societies are likely to be quite permissive, if only because they must accommodate all respectable opinions and practices within the specialty. The most obvious reason for preferring researchers who are not associated with organized medicine is that they are usually more objective, more insistent on valid evidence of safety and efficacy, more skeptical of unsupported expert opinion, and more willing to be prescriptive when the evidence permits and when other

69. Contrary to what some have assumed, the statute does not contemplate that each panel will be responsible only for producing a single set of guidelines rather than for overseeing all the Forum's guideline activities in a discrete clinical field. The more restrictive model might be adopted by default, however, because the Forum's initial assignment is to generate guidelines in three discrete areas — each presumably the province of a single panel — for use by the Medicare program in a kind of pilot test of the concept. See supra note 33. In time, however, the panels should evolve into standing committees that oversee an entire area of practice. Their permanence is implied in their being charged with "periodically reviewing and updating" guidelines and with adopting guidelines that might, at any time, be submitted by others. See infra note 84. The Forum could guard against the initial panels' being perceived and treated as ad hoc rather than standing committees by the nomenclature it uses. For example, the panel it is planning to convene to oversee a study of prostatism treatments could be called something like the "Panel for Guidelines in Urology." The physicians appointed to these panels should not include only experts in the particular condition under study.

70. For example, it should include employers and other persons with differing perspectives among the consumer representatives and should select a disproportionate number of physicians representing closed-panel HMOs, the providers with the greatest interest in legitimizing different styles and methods of medical practice. The statute requires that the Forum director "seek to appoint physicians reflecting a variety of practice settings." Public Health Service Act § 913(c).
factors dictate that choices must be made. If they are in error or are too demanding in these respects, professional organizations will have ample opportunities to discover, publicize, and correct their mistakes.

The inclination to commission the dominant specialties to write their own practice guidelines originates in large measure in the belief that practitioners are more likely to follow guidelines that enjoy affirmative professional approval.\(^1\) Although professional efforts to improve clinical practice should be encouraged, it would be a mistake to administer the guidelines program on the basis that the only way to change the behavior of physicians is by attracting their voluntary allegiance. For one thing, there are reasons to doubt that physicians respond readily to voluntary guidelines even when they do respect their source.\(^2\)

More fundamentally, there are other practicable and acceptable ways to affect physician behavior — specifically, by strengthening the signals that are transmitted to physicians, through various middlemen, from the demand side of the market.\(^3\) The guidelines movement will make more policy sense, and will have a greater impact, if it is conceived, at least in part, as an effort to equip government and consumers and their respective agents to contest debatable collective judgments of the medical profession more effectively. Instead of simply conferring on such collective judgments even greater stature and influence than they naturally enjoy, the guidelines program should seek to develop, and raise the credibility of, alternative perspectives on the evidence.

For the foregoing reasons, the federal government should use its limited resources primarily to sponsor guideline development by researchers and other experts who are not accountable to organized medicine. Even if only one study could be launched in any given field, the cause of pluralism would still be well served. The guidelines produced by independent experts under the Forum's auspices would have enormous visibility and credibility and could not be ignored by profes-

\(^{71}\) See, e.g., PPRC, supra note 1, at 227 ("Guidelines that are developed by the medical community are more likely to be used by physicians in their practices. For this reason, the medical profession should take much of the responsibility for developing them"); Lewin & Erickson, supra note 3, at 6 (specifying as a criterion of good guidelines that they must be "supported by the profession").


\(^{73}\) Some of the belief that physicians must be appealed to as a group represents a holdover from the days when physicians employed boycotts to suppress or frustrate innovations that they did not like. See generally Havighurst, Professional Restraints on Innovation in Health Care Financing, 1978 DUKE L.J. 303. Today, antitrust law clearly prohibits professionals' collective resistance to efforts by payers to give effect to consumers' cost concerns. See FTC v. Indiana Fed'n of Dentists, 476 U.S. 447 (1986).
sional groups. The debates that would naturally ensue would be highly beneficial to consumers in revealing options and inviting economizing choices. Indeed, differences of opinion would often stimulate the promulgation of alternative guidelines by interested professional organizations, thus providing the public with competing guidelines at little additional public expense. By concentrating on funding independent researchers, the Forum could avoid using its limited resources to subsidize guideline development by professional organizations whose economic and other interests would ensure their active involvement in the field in any event. Such a policy would increase not only the quantity and variety but also — through competitive advocacy and criticism — the quality of information available to potential users.

It would be inappropriate, however, for the Forum absolutely to exclude broad-based professional societies from competing for contracts to develop practice guidelines. Indeed, there will often be more than one professional body with an interest in a given problem, so that a degree of competition in the "marketplace of ideas" could be obtained even if one looked for guidelines only to professional organizations. Moreover, professional groups often bring a high level of scientific expertise and commitment to their advocacy for important patient interests and might provide access to outcomes and other data that independent researchers could not easily obtain. To reduce problems of bias, professional organizations might be required or encouraged to participate through joint ventures with reputable independent researchers. On the other hand, joint ventures between professional organizations that are capable of acting independently should be discouraged in order to preserve as many independent sources of guidelines and critical viewpoints as possible. At the very least, the Forum's criteria for selecting contractors should stress the importance of an applicant's independence and objectivity. It would also be helpful if they stated that

74. The federal legislation expressly provides for the Forum's panels formally to adopt, perhaps with modifications, guidelines developed by entities not participating in the federal program. See Public Health Service Act § 914(b)(3)(B). See also infra text accompanying notes 84-85.

75. For example, the consortium recently formed by The RAND Corporation, the AMA, and several prestigious medical centers would seem to be a good candidate for funding. For a report on the organization of this consortium, illustrating the difficulties of getting professional organizations to cooperate with independent researchers, see Meyer, AMA, Rand, supra note 25. See also infra note 77.

76. It has been argued that the antitrust laws can and should be construed to pose a barrier to joint ventures between professional bodies that threaten to monopolize the provision to consumers of commercially significant information. Havighurst & King, supra note 35, at 295-300, 311-25. Although this legal theory is unlikely to catch on in administering the antitrust laws, a recognition of the virtues of decentralization and diversity should influence the administration of a government program to generate information and informed opinion on technical issues.
representativeness, a virtue in political institutions, is not a desirable characteristic in a scientific, informational enterprise.

C. Other Tactics for Promoting Pluralism

There are still other ways in which the federal guidelines program might encourage pluralism. One approach would be for the Forum to use its limited resources to commission separate studies that would build the scientific base in each field but that would stop short of producing actual guidelines. A number of smaller contracts could then be let to different groups to reduce the research findings to guidelines of different kinds. It is quite feasible, and perhaps even desirable, to separate the task of developing knowledge concerning effectiveness and appropriateness from the task of converting that knowledge into prescriptions of clinical practices to be employed in particular circumstances.\(^77\) Such a strategy would give the highest priority to developing the analytical techniques that are needed to reach supportable conclusions on medical issues and to apply those techniques to particular problems. Actual guidelines based on the new knowledge would follow in due course, with the Forum ensuring that they carry forward its primary mission of linking medical practice more closely to effectiveness and outcomes research.

An alternative approach would be to couple the initial guidelines projects mandated by Congress\(^78\) with a statement of the Forum's intention to award several smaller contracts to review the results of each project once it is complete. One express purpose of these subsequent contracts should be to produce alternative guidelines by modifying the initial set.\(^79\) The adaptations might reflect different substantive conclusions on the appropriateness of particular measures, or they might merely change the format to make the guidelines more useful to different users, such as payers, organized health plans of various kinds, and parties desiring to contract for a particular standard of care. Especially if the initial guidelines took the form of "parameters" stating only ranges of professionally acceptable practices, the modifications might be simply for the purpose of being more prescriptive. At this stage, explicit benefit/cost judgments might be introduced. One could imag-

---

\(^77\) The Memorandum of Agreement of the Clinical Appropriateness Initiative of the AMA, The RAND Corporation, and the Academic Medical Center Consortium (no date) (see supra note 75) provides that the latter two parties will "have responsibility for research on and development of appropriateness criteria" and that the AMA "will facilitate development of practice parameters by the national medical specialty societies based on the appropriateness criteria."

\(^78\) See supra note 33.

\(^79\) The statute supplies ample authority for contractors to borrow and modify the guidelines of others. Public Health Service Act § 914(b)(3)(B); see infra notes 84-85 and accompanying text.
ine, for example, a consortium of HMOs undertaking — perhaps in collaboration with independent researchers — to establish specific protocols for their own internal use. Without costing very much, such independent reviews and modifications would diminish the program’s centralizing tendencies and ensure that different users’ needs were met.

Perhaps the greatest single step that the Forum could take on behalf of pluralism would be to conceive of itself as, among other things, the overseer of a certification program. In many areas of the economy and throughout the health care industry, the private development of standards and private certification of compliance therewith serve useful informational purposes. Private certification of products, private accrediting of educational programs and other institutions, and private credentialing of technical personnel are generally encouraged by public policy and are viewed favorably under the antitrust laws as long as they retain their procompetitive, informational character and do not employ sanctions that convert them into anticompetitive private regulation. In the instant situation, the Forum should see its role as one of appointing and, in effect, accrediting expert oversight panels that in turn provide the valuable service of certifying privately produced “guidelines, standards, performance measures, and review criteria.”

80. See generally Havighurst & King, supra note 35, at 134-50.
83. Consumers have difficulty in relying on privately conferred certifications because they are uncertain concerning the integrity of the certifying organization, the legitimacy of the standards it employs, and the evenhandedness of its administration. Because broad-based professional organizations enjoy a great reputational advantage over other bodies that might engage in these activities, they are in a good position to dominate the standard-setting function — and have generally done so in the health care field. See id. at 138-50, 264-95. Government, however, could offset this tendency of certain groups to control information in their respective fields by itself accrediting certifiers, thus giving consumers needed assurances concerning alternative sources of information and advice. This article visualizes the Forum doing just that for its oversight panels, thus putting them in a position credibly to certify, in turn, privately produced guidelines for the benefit of consumers and others. Elsewhere in the health care industry, the task of certifying certifiers, etc., is performed by organized medicine itself, with the result that consumers hear only what the profession approves. See id. at 281-95. The guidelines program offers an opportunity to help consumers escape from their dependence on the organized medical profession for critical advice.

For a government program to accredit accreditors in the field of education, see 45 C.F.R. § 149 (1980); see also Finkin, Reforming the Federal Relationship to Educational Accreditation, 57 N.C.L. REV. 389 (1979) (criticizing the program for, among other things, fostering accrediting monopolies in particular fields).
A vast array of pronouncements purporting to be the equivalent of practice guidelines already exists, and the Forum would perform a useful service if its panels assisted practitioners, payers, and other users in identifying those that meet reasonable expectations with respect to the use of scientific methods. Although such a certification effort would probably employ only minimal standards in its initial searches for the best of a mixed lot, those standards could be raised substantially as the state of the art of guideline making improves under the Forum’s auspices.

The guidelines legislation can easily be construed to support administration of the Forum as an R&D-cum-certification program. In addition to instructing the panels to oversee the work of the Forum’s various contractors, it expressly provides for their “adoption” of guidelines that were originally prepared under auspices other than the Forum’s own. Such adoption may occur with or without modification of the guidelines by the panel itself or by a contractor. The panel must ensure only that the statute’s minimum requirements are met, not that the guidelines are the best possible ones or better than those produced by someone else.

It is probable that Congress gave the Forum’s panels and contractors the authority to adopt independently produced guidelines primarily to prevent duplication of effort — that is, to allow the Forum to fill gaps in its guideline set with guidelines that have already been developed by professional groups or that may be developed by them in the future without federal help. But the Forum could easily instruct the panels to use this authority to certify any guidelines that meet minimum standards. Such a policy would allow many more groups, including even individual HMOs, to have their guidelines reviewed and formally accepted by the Forum’s panels. Full use of these powers would add greatly to the program’s scope (though not to its cost), would protect the public against ill-conceived guidelines, and, most importantly,

---

84. See Public Health Service Act § 914(b)(3)(B). Although the legislative history states that “the Forum can put its imprimatur on guidelines developed by other appropriate groups,” H. R. Rep. No. 101-247, supra note 31, at 378, the statute contemplates adoption of such guidelines, “with or without modification,” by the oversight panels or contractors, not by the Forum as such.

85. The panels should evaluate guidelines on the basis of whether they are grounded in the best science available, were responsibly adopted using reasonable procedures and appropriate independent experts, and provide proper documentation and justifications of the conclusions reached. The substantive merits of the guidelines would not be an issue as such. For discussions of appropriate methodologies in guideline development that would be helpful in developing “certification” standards, see James Bell Assocs. & Lewin/ICF, A Taxonomy and Critical Review of Methods for Developing Clinical Practice Standards, Contract No. HHS 100-88-0006, (Oct. 1988); D. Eddy, Methods for Designing Guidelines (Oct. 1988). Dr. Eddy is reportedly working on a new book to assist guideline developers and evaluators.
would give pluralistically created standards a degree of credibility and legitimacy that should facilitate their voluntary use by independent health plans, both public and private.

Another way in which the Forum might ensure that the guidelines program fosters pluralism is by specifying the manner in which the results of the research and development effort should be presented. The primary object should be to ensure that more than bottom-line conclusions are given. Thus, the precise findings and methods of any research should be fully revealed, and each specific guideline or other recommendation should be accompanied by a detailed discussion of the pros and cons, including an express statement of the degree of confidence with which it is offered. It should be clear, for example, whether recommendations are based on outcomes and effectiveness research or have weaker support. When alternative practices are recognized as acceptable — as in "parameters" — information relevant to choosing between them should be provided to the extent possible.66 Indeed, in the initial stages of the guidelines program, the research findings and the explanations should be treated as more important than the guidelines themselves, which, as noted above, should be considered merely as candidates for adaptation and modification by others. Constant emphasis on the public-good rationale for the program would keep the program from slipping into a political mode in which bottom-line conclusions are all that matter.

Rather than requiring cost considerations to be taken into account in reaching conclusions on appropriateness, the Forum should expressly direct that researchers and guideline makers provide only explicit data on the various factors that would be relevant to a benefit/cost comparison. Such factors include the probable cost of various possible treatments, probabilities of various improvements in the health status and quality of life of different categories of patients, and the incremental benefits of using one treatment over another. The program should make clear that it anticipates that, in some instances, different persons would reach different conclusions concerning the practices to be followed.67

---

66. See supra note 62 (congressional sentiment to the same effect). Significantly, however, the House committee report anticipates such commentary only when the guidelines are unspecific, not where they reach a definitive conclusion. The Forum, however, has emphasized the importance of "disclosure" as follows: "[W]e expect that the procedures followed, the participants involved, the evidence used, the assumptions and rationales accepted, and the analytic methods employed will be meticulously documented and described. This ensures that those not involved in any given process of guidelines formulation can systematically and independently assess their soundness." AHCPR, supra note 60. The emphasis thus placed on the program's informational function stands in heartening contrast to the House committee's apparent view of the program as a political "black box" that need not give reasons for its definitive rulings.

67. Beyond leaving customary room for the exercise of physician judgment and patient preferences, the federal guidelines program should expressly acknowledge that
By not factoring cost considerations into the guidelines themselves but including information useful to cost-conscious decision makers, the program would avoid the implication that the guidelines are the final word and would give developers of alternative guidelines and other independent decision makers both the information and perhaps some of the courage they need to make their own judgments.

A final question is how far the Forum should go in specifying the form of practice guidelines themselves. Given the variety of possible uses and users, it would be a mistake to force all activities into the compartments of a single typology. Indeed, rather than attempting to define more precisely the several statutory terms — that is, "clinically relevant guidelines . . . [,] standards of quality, performance measures, and medical review criteria" — the Forum might eschew the drawing of bright-line distinctions and adopt a single generic term to cover everything that falls within its mandate. There are, after all, many other names — e.g., "parameters," "protocols," "algorithms," "norms," "criteria," and "standards" — for the kinds of things that the federal program could usefully provide to physicians, payers, and other users. Because the common denominator of the entire exercise is the need for a stronger scientific base for medical decision making of all kinds, the program should define its objective as being simply the production of "systematic, scientifically grounded statements to assist decision making with respect to medical care." By placing the emphasis on functional utility rather than on form, this terminology would avoid the implication that individual physicians are the only audience for practice

consumers purchasing health benefits through sophisticated agents may choose different styles and possibly lower standards of medical practice in the coverage they elect. Legitimizing such economizing choices will help to overcome the difficulty that arises when a consumer, having become a patient, regrets having assumed (in the prior capacity) a particular risk. Effective cost containment, yielding real efficiency in health care spending, can occur only if decisions that were in the consumer's interest ex ante cannot be easily revised ex post. See Havighurst, Decentralizing Decision Making, supra note 10, at 38-42. An express object of the guidelines program should therefore be to assist consumers in particularizing and making enforceable their understandings with each other — and with their health plan and physicians, their agents for carrying out these understandings — as to what will and will not be paid for out of the common fund.

Although the point is recognized too infrequently, a payer's refusal to pay is not a medical decision. Instead, the payer may only be enforcing an earlier decision that, for any of a variety of medical and nonmedical reasons, the plan should not pay for a particular treatment, leaving the doctor and the patient to make the final medical decision with the cost in view. Cf. Wickline v. State, 192 Cal. App. 3d 1630, 239 Cal. Rptr. 810 (1986) (payer not liable for injury from nontreatment occasioned in part by its refusal to pay); Association of Am. Physicians and Surgeons v. Weinberger, 395 F. Supp. 125 (N.D. Ill. 1975), aff'd, 423 U.S. 975 (1975) (rejecting argument that restrictions on public reimbursement for physician-prescribed care interfere with medical practice). Certain HMOs may render medical care as such, but should be held to contractual standards, not professional ones, unless no other standard is specified.
guidelines. The program outlined here would ensure that other constituencies— including employers, insurers, HMOs, utilization managers, PROs, the HCFA, and state Medicaid programs— could reasonably hope that their particular needs would also be served.

Despite the attractiveness of the certification model proposed here, the federal guidelines program might proceed in a somewhat different manner to strengthen pluralism in American health care. Although setting as its objective the production of only a single set of guidelines for each area of medical practice, the federal Forum might expressly require in its criteria and standards that such guidelines be presented in a form that would allow different health plans to specify different levels of benefits. Although the art of guideline making is still in its infancy, the leading experts in this art subscribe to neither the professional nor the political model of guidelines and view their task, realistically, as providing useful information, not prescribing what is appropriate for all citizens. Thus, they advocate rating procedures in terms of their probable utility for each of a large number of carefully defined classifications of patients, thereby providing tools that others may use to make consistent, well-informed choices. What the discussion in this article adds to the insights of these experts is only a focus on the particular need to write guidelines for the specific purpose of facilitating the advance specification— in contracts or otherwise— of the precise level of care that consumers and public or private health plans wish to purchase.

VI. CONCLUSIONS

This Article recommends that the recently enacted federal program to develop practice guidelines for medical care not be perceived and implemented as a search for a unitary standard of medical care for the American health care system. The author’s fear, however, is not that physicians will find their style cramped by rigid rules or that all consumers will be forced to accept whatever government-convened experts determine to be good for them. Although these are the types of hazards that are usually associated with overregulation, the potential dangers in implementing the federal guidelines program in a quasi-regulatory manner are quite different.

Far from worrying that federally sponsored practice guidelines will be overly restrictive, this Article observes that guidelines developed with the understanding that they are to govern all U.S. medical care will inevitably be highly permissive. Whether developed exclusively by physician organizations or by more participatory political means, such guidelines would have to accommodate all defensible medical opinions and be suitable for use in all practice settings and in diverse economic

88. See, e.g., Brook, supra note 1 (stressing need for "explicit appropriateness ratings").
circumstances. They could therefore be precise and prescriptive only when the scientific evidence is conclusive and leaves no room for variation. Such permissive guidelines would be of only limited value in disciplining marginal physicians and allocating society's limited resources to their best uses. Indeed, they could seriously inhibit responsible efforts by consumers, employers, private payers, and government programs to resist paying for services that are classified as appropriate in the guidelines but are not valuable enough to justify their incremental cost. Permissive guidelines would thus be vulnerable to the objection, often directed at regulation of other kinds, that they protect the interests of the regulated more than they protect consumers.

This Article also offers an even more serious objection to administration of the federal guidelines program with a regulatory premise. Such an approach to guideline making would sacrifice a valuable — indeed, unparalleled — opportunity to overcome the severe market failures that currently impair the ability of the health care marketplace to allocate resources efficiently. It is quite feasible to view federal support for guideline development, not as a public standard-setting initiative, but as an effort to redress the inequalities in access to information that have long made consumers almost totally dependent on physicians and organized medicine to specify the services they must purchase. Moreover, the federal program's emphasis on the development of actual guidelines, in addition to the dissemination of the findings of effectiveness and outcomes research, may be interpreted as a public effort to go beyond the provision of information and to lower the very high costs of defining alternative standards and styles of medical care for the purpose of contracting for same. With better information on what particular services are worth and with the transaction costs of specifying precisely what they want to purchase substantially reduced, both public and private purchasers of medical care would be in a much better position to achieve an efficient match between the resources they have available and the medical services they obtain. The guidelines program should therefore be implemented with an express view to facilitating independent efforts, both public and private, to establish and enforce specific, customized standards to guide physician behavior in particular circumstances.

The strategy proposed in this Article for realizing the full potential of practice guidelines requires only that the administrators of the federal program appreciate the hazards of undue centralization of the standard-setting function and lean toward pluralism instead. Fortunately, there is nothing in the program's legislative mandate that compels its managers to do anything as radical as sponsor a search for a single set of rules — permissive or restrictive, as the case may be — to govern all medical care in America. A more conservative interpretation of their mission would put them in the more familiar business of supplying research findings, other information, and authoritative advice for
independent decision makers to use in making inevitably difficult choices about the health care they are purchasing. With such a mission, the program's object would be, not to obtain a consensus or an authoritative collective decision, but to elicit a variety of scientifically supported views with full explanations and documentation of the conclusions reached. Reflecting the differing needs of different users, guidelines might take different forms and reach different substantive conclusions on important matters. Guidelines that were developed for voluntary use in particular circumstances might be more prescriptive than guidelines intended for systemwide application. Such guidelines would be available for adoption by public or private health plans and for incorporation by reference in contracts governing particular provider/patient relationships.

The Article specifically proposes that the Forum for Quality and Effectiveness in Health Care, in addition to overseeing a typical government R&D program, establish its guidelines program in such a way that it serves, in effect, as a certifier of any practice guidelines that do not appear unsuitable for use by public or private decision makers. The Forum's responsibility would be to maintain oversight panels of experts and consumer representatives and to establish standards and criteria to guide their work. The panels would each have jurisdiction over guideline development in a discrete area of medical practice. They would proceed, as the statute contemplates, both by developing guidelines themselves and by adopting guidelines submitted by others, including not only the Forum's contractors but independent organizations as well. A panel's responsibility would be only to verify that guidelines proposed for adoption were responsibly developed and reflected reasonable interpretations of the scientific evidence and a reasonable balancing of relevant factors, possibly including cost considerations. There would be no occasion for the Forum or its panels to choose between competing or inconsistent guidelines or to decide finally how medicine should or should not be practiced.

There is no denying, given the many shortcomings of current medical practice, that the federal practice guidelines program can have some desirable effects even if it is implemented with the sole object of ruling definitively on what does and does not work in medicine. Guidelines with such a regulatory objective should raise the overall quality of care by improving clinical decision making. Whether their net effect would be to lower or raise the total cost of health care, guidelines should favorably affect efficiency, both by improving outcomes and by curbing some unproductive spending. Even if the guidelines program were only moderately successful in these respects, it could still contribute to the steady improvement of American medical care, and it would

89. See also supra text accompanying note 88.
almost certainly become a fixture on the health care scene. There is still an open question, however, whether the program will perpetuate the tradition of relying exclusively upon centrally determined standards to guide all medical care or will instead encourage promising pluralistic developments in the health care field. This Article argues that the practice guidelines movement will yield more benefits for the American people if it is administered in such a way as to enable them to make more explicit and informed decisions about the health care for which they are paying.