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PLAYING DOCTOR: CORPORATE MEDICAL PRACTICE AND MEDICAL MALPRACTICE

E. Haavi Morreim*

Although health plans once existed mainly to ensure that patients could pay for care, in recent years managed care organizations (MCOs) have attempted to limit expenditures by exercising significant influence over the kinds and levels of care provided. Some commentators argue that such influence constitutes the practice of medicine, and should subject MCOs to the same medical malpractice torts traditionally brought against physicians. Others hold that MCOs engage only in contract interpretation, and do not literally practice medicine.

This Article begins by arguing that traditional common law doctrines governing corporate practice of medicine do not precisely apply to the current situation because, whereas the traditional focus is on whether the corporation employs the physician, in the current setting corporations use many devices, not just employment, to influence medical care. Because an employment relationship is not the central question in determining whether an MCO is practicing medicine, a better definition is needed of what it is for a corporation (or a physician) to practice medicine. This definition will show that MCOs can and sometimes must practice medicine, thus opening the need to explore what sort of liability they should incur when they practice negligently.

Toward answering that question, the Article argues that the proper scope of medical malpractice and other tort liability for MCOs can only be discerned after it is determined what duty of care MCOs owe their subscribers. This question, in turn, should be guided by a focus on how to deliver good health care rather than by deciding, ex ante, whom we wish to hold liable when care has gone badly. In the quest to discern which tasks are best done by MCOs and which are best done by physicians, a reasonable division of labor between MCOs and physicians will be proposed. This division of labor acknowledges that MCOs must sometimes practice medicine, but will also show that MCOs currently practice medicine more than they should, primarily because contractual reliance on the concept of "medical necessity" requires them to practice medicine virtually every time they make a benefits determination. For a variety of reasons, the concept of "medical necessity" should be dropped entirely from health plan contracts. Finally, where MCOs do practice medicine, they should be subject to classic medical malpractice liability of the same sort to which physicians are subject. Applying these reforms in the context of corporate practice, however, requires some special analysis.

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Observers critical of “managed care”¹ contend that, whereas health plans formerly existed simply to ensure their members’ financial access to health care, many plans now exercise a heavy hand over—they “manage”—the medical content of that care. Through utilization management, practice guidelines, physician profiling, and other tools,² managed care organizations (MCOs) sometimes suggest approaches to patient care that differ substantially from the physician’s intended plan of care. Resentment on the part of many physicians and patients has prompted allegations that MCOs are now actively practicing medicine, and should be held liable in tort when their intrusions on clinical care amount to medical malpractice.

Other observers, concerned about uncontrolled escalation of health care costs, conversely argue that MCOs can and must limit their coverage. On this view, a contract interpretation or utilization review determining that a particular intervention is not covered is not a medical decision; it is simply a conclusion that the plan is not obligated to provide or pay for a particular intervention. Physicians and patients are still free to do as they choose because the plan has not dictated their decisions, only its own financial involvement.

1. In this Article, “managed care” will refer to any health plan that serves not only to finance patients’ access to health care, but also to “manage” the care by determining (at least in some instances) that certain types of care will be preferred over others, on medical or economic grounds or both. Managed care organizations (MCOs) thus range from the most traditional kinds of health maintenance organizations (HMOs) that have their own medical staffs, clinics, and hospital facilities, to managed indemnity insurers that scrutinize care prospectively and concurrently, even as they reimburse on a (usually discounted) fee-for-service basis. In this sense, the managed health plan is involved in providing as well as financing the care. It is in the context of providing, monitoring, and supervising care that allegations about corporate practice of medicine arise. See TEX. CIV. PRAC. & REM. § 89.001(8) (West, WESTLAW through 1997 Reg. Sess.); Marc A. Rodwin, *Managed Care and Consumer Protection: What Are the Issues?*, 26 SETON HALL L. REV. 1007, 1009 (1996).

2. These tools include three types of review for health care expenditures. In retrospective review a payor (or an independent reviewer with which it has contracted) decides, after care has been rendered, whether it will reimburse providers. In concurrent review, the health plan or review entity contacts physicians caring for its hospitalized members on a frequent basis, to ensure that the patient does not remain in the hospital longer than necessary and receives appropriate kinds and levels of care. In prospective review, physicians are expected to obtain the health plan’s pre-certification to ensure payment for contemplated hospitalizations, surgeries, or other costly interventions. See E. HAAVI MORREIM, *BALANCING ACT: THE NEW MEDICAL ETHICS OF MEDICINE’S NEW ECONOMICS* 34–35 (1995) [hereinafter MORREIM, *BALANCING ACT*].

In physician profiling, the health plan tracks which physicians utilize what levels of resources, sometimes disseminating the information to its medical staff in an attempt to encourage more cost-conscious care. In other cases, the profiles may be used to “deselect” (fire) a physician from the health plan’s physician staff. See Jerome P. Kassirer, *The Use and Abuse of Practice Profiles*, 330 NEW ENG. J. MED. 634, 634 (1994); Susanne Salem-Schatz et al., *The Case for Case-Mix Adjustment in Practice Profiling: When Good Apples Look Bad*, 272 JAMA 871, 871 (1994).

The issues are becoming contentious as patients increasingly allege that denials of resources cause adverse outcomes that could otherwise have been avoided. In *Corcoran v. United Healthcare, Inc.*,³ for instance, an MCO's denial of hospitalization, and substitution of limited home nursing services for a woman in a high-risk pregnancy, allegedly caused the death of her child. In *Wickline v. State*,⁴ physicians for a woman experiencing complications after vascular surgery requested eight extra days of hospitalization. When utilization reviewers determined that only four days were needed and her physicians then discharged her early, the patient suffered complications and eventual leg amputation. In other cases, health plans or their utilization reviewers determined that patients hospitalized for suicidal ideation did not require further inpatient care, whereupon the patients were discharged from the hospital and subsequently committed suicide.⁵

This Article focuses on two questions: whether MCOs⁶ as corporations literally practice medicine when they engage in activities such as close utilization management and, if they do practice medicine, whether they should be subject to classic medical malpractice liability of the same sort to which physicians are subject.

Briefly, this Article will show the following:

- traditional common law doctrines governing corporate practice do not precisely apply to the current situation because, whereas the traditional focus is on whether the corporation employs the physician, in the current setting

3. 965 F.2d 1321 (5th Cir. 1992) (holding that the patient's care was within the standard of care, and that the state's Medicaid utilization review program was not the proximate cause of the patient's post-surgical complications).

4. 239 Cal. Rptr. 810 (Ct. App. 1986) (holding that the patient's treatment was within the standard of care, and that the state's utilization review program was not the proximate cause of the patient's post-surgical complications).

5. See, e.g., *Tolton v. American Biodyne, Inc.*, 48 F.3d 937 (6th Cir. 1995); *Moscovitch v. Danbury Hosp.*, 25 F. Supp. 2d 74 (D. Conn. 1998); *Huss v. Green Spring Health Serv., Inc.*, 18 F. Supp. 2d 400 (D. Del. 1998); *Andrews-Clarke v. Travelers Ins. Co.*, 984 F. Supp. 49 (D. Mass. 1997); *Wilson v. Blue Cross*, 271 Cal. Rptr. 876 (Ct. App. 1990); *Muse v. Charter Hosp.*, 452 S.E.2d 589 (N.C. Ct. App.), *aff'd*, 464 S.E.2d 44 (N.C. 1995). Some cases concern the denial of mental health benefits, even though the patient did not commit suicide. See, e.g., *Doe v. Travelers Ins. Co.*, 167 F.3d 53 (1st Cir. 1999); *Brandon v. Aetna Serv., Inc.*, 46 F. Supp. 2d 110 (D. Conn. 1999); *Hughes v. Blue Cross*, 245 Cal. Rptr. 273 (Ct. App. 1988); see also Leigh Page, *Patient Death Prompts First Use of Texas' New HMO Law*, AMERICAN MED. NEWS, Nov. 9, 1998, at 38.

6. "MCO" in this context covers a range of health plan entities, from indemnity insurers that review and sometimes deny reimbursement for health services, to classic health maintenance organizations (HMOs) that more directly provide care through a panel of physicians, hospitals, home health agencies, and other providers.

corporations use many devices, not just employment, to influence medical care;

- because an employment relationship is no longer the central question in determining whether an MCO is practicing medicine, a new definition is needed of what it is for a corporation (or a physician) to practice medicine;
- this new definition will show that MCOs can and sometimes must practice medicine, thus opening the need to explore what sort of liability they should incur when they practice negligently;
- the proper scope of medical malpractice and other tort liability for MCOs can only be discerned after it is determined what duty of care MCOs owe their subscribers; this question, in turn, should be guided by a focus on how to deliver good health care rather than by deciding *ex ante* whom we wish to hold liable when care has been poor;
- in the quest to discern which tasks are best done by MCOs and which are best done by physicians toward the goal of good care, a reasonable division of labor between MCOs and physicians will be proposed;
- although the division of labor acknowledges that MCOs must sometimes practice medicine, it will also be shown that MCOs currently practice medicine more than they should, primarily because contractual reliance on the concept of “medical necessity” requires them to practice medicine virtually every time they make a benefits determination;
- for a variety of reasons, the concept of “medical necessity” should be dropped entirely from health plan contracts;
- where MCOs have practiced medicine, they should be subject to classic medical malpractice liability of the same sort to which physicians are subject; and
- assignment of medical malpractice liability to MCOs requires the usual tort elements regarding duty of care, injury, and causality, albeit with a few interesting twists.

Accordingly, Part I briefly reviews the history of the corporate practice doctrine—the 1930s common law tradition prohibiting

corporations from practicing medicine.⁷ The original doctrine proscribes corporations from hiring physicians as employees because such arrangements could divide physicians' loyalty and permit laymen to substitute their own judgment for physicians' professional expertise. Although the ban is anachronistic in many respects, the issues on which it was based are more lively today than ever. MCOs need not literally employ physicians in order to exercise considerable influence over medical care via a wide array of controls and incentives.

Part II inquires whether and in what sense MCOs ever literally practice medicine. Denial of payment or of care can significantly affect treatment decisions and thereby medical outcomes; but this does not, of itself, make the denial an instance of practicing medicine. Rather, an analysis of "practicing medicine" will point to two elements: making medical judgments, and using those judgments in ways that significantly influence patients' care and outcomes. Under these criteria MCOs do, and sometimes must, practice medicine.

Part III opens the question of legal accountability for such corporate medical practice. Corporations such as MCOs already face two basic kinds of tort liability for alleged deficiencies in quality of care: direct corporate liability for issues such as staff credentialing, and indirect liability for the actions of the MCO's employees or ostensible agents. Neither encompasses classic medical malpractice (practicing medicine below the standard of care) because neither envisions that MCOs are literally practicing medicine. Part III begins to explore the challenges of MCO liability in the context of this *nouveau-corporate* medical practice. Before a proper understanding of MCO liability can be developed, it is important to explore two proffered responses to the issue and the reasons why they do not work. The first would update the old corporate practice doctrine by forbidding MCOs from engaging in any medical practice, while the second would update old enterprise liability concepts by holding MCOs liable for everything. As the flaws in these approaches are explored, it will become evident that both assume the wrong starting point. Rather than beginning with the question, "whom do we wish to hold liable" when untoward outcomes result from cost constraints, the initial focus should instead be on promoting high-quality health care that is less likely to produce untoward outcomes in the first place. At that point, the proper first question is "who should control what" in the delivery of

7. More generally, the doctrine applies to all lay entities, not just to corporations, and the prohibition affects other professions, including law and dentistry.

health care. Only when it is clear who should do which jobs toward the goal of good care is it possible to assign liability for doing a poor job.

Accordingly, Part IV proposes a rough “division of labor” between physicians and MCOs. On the one hand, ample room for physicians’ clinical discretion is imperative for high-quality care. MCOs’ routine guidelines are not always medically well-founded, and even the best guides do not fit every patient. Reciprocally, unfettered physician practices do not always serve patients well, as numerous studies are beginning to show. This Part argues that MCOs have an important role to play in ensuring quality of care, particularly by identifying, promoting, and monitoring for patterns of care.

Part V begins to address the second central issue of this Article: whether health plans should be held liable for medical malpractice. The answer is yes, but those occasions should be relatively uncommon because, although Part IV concludes that sometimes it is both appropriate and inevitable for MCOs to practice medicine, Part V argues that such practice should be far less common than is presently the case. Because the concept of “medical necessity” serves as the cornerstone of most health care contracts, MCOs must routinely make medical judgments in order to make their benefits determinations. As a result, they routinely practice medicine. For a variety of reasons reviewed in Part V, the notion of “medical necessity” should be discarded in favor of a much more explicit specification of the type of care that the enrollee will receive for particular indications in a given plan—guidelines-based contracting. MCOs would still unavoidably practice medicine in certain instances, but only where guidelines are insufficiently specific or are medically inappropriate for a particular patient. Thus, as they reduce the extent to which they practice medicine, MCOs’ exposure to malpractice liability would diminish markedly.

Finally, Part VI looks at several issues that must be considered if malpractice liability is to be directly ascribed to MCOs.

I. CORPORATE PRACTICE OF MEDICINE: HISTORICAL OVERVIEW

Although the doctrine banning corporate practice of medicine is largely a common law phenomenon arising during the 1930s, its

roots go back earlier.⁸ Around the turn of the century, when allopathic physicians were competing with myriad other healers, newly enacted licensing laws required physicians to complete prescribed learning, pass examinations, and demonstrate the good character expected of a professional. Thereafter, quality of care rose and competition diminished. During the early part of the century, however, two new kinds of practice arrangements, contract practice and corporate practice, won the condemnation of the American Medical Association because they seemed to bode a diminution of physicians' growing stature and a retreat to the previous chaos.

In *contract practice*, corporations such as lumber and mining companies hired physicians to care for their employees, particularly in places like the Pacific Northwest, where physicians were not abundant. Although it ensured better access to care, it also limited patients' choice of physicians and meant that the corporation, rather than the physician, might decide how many patients would be seen.

In *corporate practice*, corporations marketed professional services (ranging from medicine and law to optometry and dentistry) to the public under their own brand name. Corporate practice was deemed particularly offensive, with images (and sometimes the reality) of crass commercialism. Courts ruling on these arrangements during the 1930s identified several potential hazards as they pointed to licensure laws and held that only licensed individuals, not corporations, can practice medicine, optometry, dentistry, law, or other professions.⁹ For present purposes, two of those hazards seem most pertinent.

8. For more detailed discussions of the history of the corporate practice doctrine, see PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* (1982); Jeffrey F. Chase-Lubitz, *The Corporate Practice of Medicine Doctrine: An Anachronism in the Modern Health Care Industry*, 40 VAND. L. REV. 445 (1987); Jerry P. Clousson & Joseph T. Butz, *A New Look for the Corporate Practice of Medicine Doctrine: Berlin v. Sarah Bush Lincoln Health Center*, 29 J. HEALTH & HOSP. L. 174 (1996); Michael A. Dowell, *The Corporate Practice of Medicine Prohibition: A Dinosaur Awaiting Extinction*, 27 J. HEALTH & HOSP. L. 369 (1994); Mark A. Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PA. L. REV. 431, 509-18 (1988); Lisa Rediger Hayward, *Revising Washington's Corporate Practice of Medicine Doctrine*, 71 WASH. L. REV. 403 (1996); Edward B. Hirshfeld & Gail H. Thomason, *Medical Necessity Determinations: The Need for a New Legal Structure*, 6 HEALTH MATRIX 3, 11-12 (1996); Sara Mars, *The Corporate Practice of Medicine: A Call for Action*, 7 HEALTH MATRIX 241 (1997); Judith Parker, *Corporate Practice of Medicine: Last Stand or Final Downfall?*, 29 J. HEALTH & HOSP. L. 160 (1996); Arnold J. Rosoff, *The Business of Medicine: Problems with the Corporate Practice Doctrine*, 17 CUMB. L. REV. 485 (1987).

9. Concerns are listed by various commentators:

First, physician employment by corporations controlled by lay persons arguably may reduce physician autonomy over medical judgments. Second, employed physicians may experience a sense of divided loyalty between their profit-seeking employer and

First, where physicians are employees, courts feared that laymen with no particular knowledge of medicine could dictate how many patients the physician would see, which treatments he could use, and other matters that courts believed should be left to a physician's professional discretion.¹⁰ After all, the defining criterion of

their treatment-seeking patients. Finally, public policy arguments have been raised to attack the commercialization of the medical profession. Critics of commercialization within the health care arena are concerned that investors in for-profit medical entities that employ physicians will exert too much pressure on their physician-employees to promote the sale of professional services in order to obtain large profits. This may create pressure on employed physicians to place a greater emphasis on profitability over quality of patient care.

Mars, *supra* note 8, at 249 (footnotes omitted). These concerns reflect the difficulty of establishing a relationship of personal confidence and trust between a patient and a corporation, and a diminution of trust between physicians and patients; an undue focus on profit by the corporation; a diminution of the medical profession's status, income, and control; crass commercialization of professional services; and potential emergence of fee-splitting. See Dowell, *supra* note 8, at 369; Hayward, *supra* note 8, at 406-07; Parker, *supra* note 8, at 161.

Leading cases include *Semler v. Dental Examiner*, 294 U.S. 608 (1935) (deciding that states may use police power to forbid certain types of dental advertising to protect the community from deception even if practices advertised are legitimate); *Bartron v. Codrington County*, 2 N.W.2d 337 (S.D. 1942) (finding legislature may exercise its police power to prohibit corporations from supplying licensed physician services for profit); *People v. Pacific Health Corp.*, 82 P.2d 429, 430 (Cal. 1938) (citing "evils of divided loyalty and impaired confidence"); *Parker v. Board of Dental Examiners*, 14 P.2d 67 (Cal. 1932); *People v. Merchants' Protective Corp.*, 209 P. 363 (Cal. 1922); *People v. United Medical Service*, 200 N.E. 157 (Ill. 1936); *Dr. Allison, Dentist v. Allison*, 196 N.E. 799 (Ill. 1935); *Bennett v. Indiana State Board*, 7 N.E.2d 977 (Ind. 1937); *State v. Bailey Dental Co.*, 234 N.W. 260 (Iowa 1931), and *Teseschi v. Mathis*, 183 A.2d 146 (N.J. 1936).

10. In *Bennett v. Indiana State Board*, the Indiana Supreme Court noted that

[t]he relationship between the licensed optometrist and his unlicensed employer is that of master and servant. The master is in a position where he may dictate to his servant the manner of conducting his business, the kind and nature of the goods to be sold and furnished to the patient, in order to procure the most favorable financial gain to the employer. And this may be done without regard to the public health, since the employer is a non-resident and beyond the jurisdiction of the courts of this state, and not licensed.

7 N.E.2d at 981. Similarly, the South Dakota Supreme Court argued that, where a stockholder company hires physicians:

[t]he object of such a company would be to produce an earning on its fixed capital. Its trade commodity would be the professional services of its employees. Constant pressure would be exerted by the investor to promote such a volume of sales of that commodity as would produce an ever increasing return on his investment. To promote such sales it is to be presumed that the layman would apply the methods and practices in which he had been schooled in the market place. The end result seems inevitable to us, viz., undue emphasis on mere money making, and commercial exploitation of professional services. . . . Such an ethical, trustworthy and unselfish professionalism as the community needs and wants cannot survive in a purely commercial atmosphere.

an employment relationship, as distinct from an independent contractor relationship, is the level of control that the employer can exert over the employee. One court explained:

[t]he test of the relationship is the right to control. It is not the fact of actual interference with the control, but the right to interfere that makes the difference between an independent contractor and a servant or agent. . . . An independent contractor has been said to be "one who, exercising an independent employment, contracts to do a piece of work according to his own methods and without being subject to the control of his employer, except as to the result of his work."¹¹

Second, the employment relationship was seen to divide the physician's loyalties. Instead of owing fealty exclusively to his patients' best interests, the employee-physician would also have duties to promote the best interests of his corporate master.¹²

Codington County, 2 N.W.2d at 346; *see also* *Holden v. Rockford Mem'l Hosp.*, 678 N.E.2d 342, 347 (Ill. App. Ct. 1997); *Dowell*, *supra* note 8, at 369 (explaining rationale for the corporate practice prohibition); *Hall*, *supra* note 8, at 514 (presenting similar policy arguments); *Mars*, *supra* note 8, at 249 (noting various public policy concerns regarding the corporate practice of medicine); *Parker*, *supra* note 8, at 161 (listing public policy arguments expanding the prohibition against corporate practice of medicine).

11. *Daw's Critical Care v. Department of Labor*, 622 A.2d 622, 631 (Conn. Super. Ct. 1992) (citations omitted) (deciding that provider of temporary nurses to medical facilities was not required to pay unemployment compensation tax). Furthermore, the Georgia Court of Appeals has stated that the nature of the employment relationship turns on control:

"The true test of whether the relationship is one of employer-employee or employer-independent contractor is whether the employer, under the contract either oral or written, assumes the right to control the time, manner, and method of executing the work, as distinguished from the right merely to require certain definite results in conformity to the contract." . . . Where a "hospital reserve(s) no right to control specific medical techniques employed by the . . . doctors, but merely exercise(s) a limited surveillance in order to monitor the quality of medical care provided,' these controls are not inconsistent with an employer-independent contractor relationship."

Charter Peachford Behavioral Health Sys. v. Kohout, 504 S.E.2d 514, 525 (Ga. Ct. App. 1998) (citations omitted).

Control is "the cornerstone of the master-servant relationship." William A. Chittenden III, *Malpractice Liability and Managed Health Care: History and Prognosis*, 26 *TORT & INS. L.J.* 451, 454 (1991).

12. *See Holden*, 678 N.E.2d at 347; *Dr. Allison*, 196 N.E. at 799 (employees of a corporation owe their first allegiance to the corporation, and second to the patient).

In a case involving corporate practice of law, the New York Court of Appeals held that

[t]he relation of attorney and client . . . involves the highest trust and confidence. It cannot . . . exist between an attorney employed by a corporation to practice law for it, and a client of the corporation, for he would be subject to the directions of the

Since the 1930s, explicit exceptions to the ban on corporate practice have been numerous.¹³ In many states, whatever is left of the doctrine is simply ignored,¹⁴ although a few states still enforce their corporate practice bans.¹⁵ In the current market, however,

corporation, and not to the directions of the client. There would be neither contract nor privity between him and the client, and he would not owe even the duty of counsel to the actual litigant. The corporation would control the litigation, the money earned would belong to the corporation, and the attorney would be responsible to the corporation only. His master would not be the client but the corporation, conducted it may be wholly by laymen, organized simply to make money and not to aid in the administration of justice which is the highest function of an attorney and counselor at law. The corporation might not have a lawyer among its stockholders, directors, or officers. Its members might be without character, learning or standing. There would be no remedy by attachment or disbarment to protect the public from imposition or fraud, no stimulus to good conduct from the traditions of an ancient and honorable profession, and no guide except the sordid purpose to earn money for stockholders.

In re Co-operative Law Co., 92 N.E. 15, 16 (N.Y. 1910); see also Mars, *supra* note 8, at 249.

13. Many states permit employment of physicians by HMOs, hospitals, teaching institutions, industrial organizations, professional corporations run by physicians, and selected other entities. See *Los Angeles County v. Ford*, 263 P.2d 638 (Cal. Ct. App. 1953) (finding that contracts between county board of supervisors and medical schools, where medical schools provided services in county hospitals, did not constitute unlawful corporate practice of medicine); Hayward, *supra* note 8, at 410; Mars, *supra* note 8, at 252; Parker, *supra* note 8, at 161; Rossoff, *supra* note 8, at 497.

14. See Hayward, *supra* note 8, at 413; Rossoff, *supra* note 8, at 497.

15. Some courts have recently struck down arrangements featuring physicians as employees. In *Conrad v. Medical Board*, the California Court of Appeals struck down a hospital district's effort to hire physicians, citing the corporate practice ban. "The doctrine is intended to ameliorate 'the evils of divided loyalty and impaired confidence' which are thought to be created when a corporation solicits medical business from the general public and turns it over to a special group of doctors, who are thus under lay control." 55 Cal. Rptr. 2d 901, 903 (Ct. App. 1996). In this case, employment agreements would have required the physician-employees

to meet targets of 4,600 patient encounters per year. If the physician does not meet the target, and if 45 percent of the fees generated by the physician are less than his or her base salary, then the employment contract will not be extended. The employment contract also provides for an incentive fund which represents additional compensation which the physician may receive from the surplus funds remaining after the employee-physicians' base salaries are deducted from a certain percentage of the collections made by the hospital's adult medicine division, the physicians' employer.

Id. at 905. In *Morelli v. Ehsan*, 756 P.2d 129 (Wash. 1988) (en banc), a Washington state court found a partnership featuring a physician, nurse, and business manager to have been an illegal, unenforceable arrangement. Similarly, a Texas appeals court invalidated a partnership between a physician and two non-physicians for operating a hospital emergency department. See *Flynn Bros., Inc. v. First Med. Assocs.*, 715 S.W.2d 782 (Tx. App. 1986); see also *Garcia v. Texas State Bd.*, 384 F. Supp. 434 (W.D. Tex. 1974).

Other cases invoke the ban in ways not anticipated in the 1930s. For instance, in two Illinois cases where employee-physicians left employment with a clinic or hospital and established a nearby independent practice site, lower courts refused to penalize their viola-

two things seem obvious. First, early courts' concerns about lay interference in clinical practice, and about division of physicians' loyalties, are as vital today as ever. Medical ethics literature is filled with commentators' worries about both.¹⁶ Second, earlier courts' specific focus on employment as the keystone of concern is now an anachronism. MCOs do not need to employ a physician in order to

tion of noncompete clauses in the original employment contract. Citing the corporate practice ban, these courts held that the employment contracts were void and unenforceable in the first place, thus excusing physicians from violating the noncompete clauses. See *Berlin v. Sarah Bush Lincoln Health Ctr.*, 664 N.E.2d 337, 340 (Ill. App. Ct. 1996), *rev'd*, 688 N.E.2d 106 (Ill. 1997). In *Holden v. Rockford Memorial Hospital*, an Illinois appellate court similarly upheld the traditional ban on corporate practice on grounds of stare decisis, while disagreeing with its content:

Indeed, the health maintenance organization (HMO) structure embodies many of the characteristics the corporate-practice-of-medicine doctrine was contrived to eradicate. For example, HMO management encourages physicians not to order expensive tests for patients that management deems to be of marginal diagnostic value. Indeed, the idea of an HMO is to contain medical costs while providing basic medical care to as many people as possible. Further, HMOs may solicit patients, thereby undermining the commercialism justification of the corporate-practice rule. Finally, inherent in the HMO design is the risk that a physician's loyalty will be divided between the employer and patient, which is the same risk that the corporate-practice-of-medicine doctrine seeks to protect against. Therefore, because the policy reasons that initiated the implementation of the corporate-practice-of-medicine doctrine have already been managed through the implementation of HMO organizations, these public policy concerns . . . appear to be not reason enough to continue to prohibit hospitals from employing physicians.

678 N.E.2d 342, 347 (Ill. App. Ct. 1997); see also *Early Detection Ctr., Inc. v. Wilson*, 811 P.2d 860 (Kan. 1991); Clousson & Butz, *supra* note 8, at 174; Hayward, *supra* note 8, at 414–16.

Subsequently, the Illinois Supreme Court reversed the *Berlin* decision, holding that hospitals, whether for-profit or not-for-profit, must be exempt from corporate practice prohibitions, because they too are licensed and their physician staffs are largely in control of quality of care. See *Berlin v. Sarah Bush Lincoln Health Ctr.*, 688 N.E.2d 106, 113–14 (Ill. 1997); see also *Holden v. Rockford Mem'l Hosp.*, 692 N.E.2d 374, 375 (Ill. App. Ct. 1998) (revising earlier *Holden* decision in light of the Supreme Court's holding in *Berlin*); *St. Francis Reg'l Med. Ctr. v. Weiss*, 869 P.2d 606, 618 (Kan. 1994) (concluding that no prohibition exists preventing a licensed hospital from contracting for the services of a physician).

16. See Council on Ethical and Judicial Affairs, *Ethical Issues in Managed Care*, 273 JAMA 330, 330–35 (1995); Ezekiel J. Emanuel & Nancy Dubler, *Preserving the Physician-Patient Relationship in the Era of Managed Care*, 273 JAMA 323, 323–30 (1995); Jerome P. Kassirer, *Is Managed Care Here to Stay?*, 336 NEW ENG. J. MED. 1013, 1013–14 (1997); Jerome P. Kassirer, *Managed Care and the Morality of the Marketplace*, 333 NEW ENG. J. MED. 50 (1995); Steven D. Pearson et al., *Ethical Guidelines for Physician Compensation Based on Capitation*, 339 NEW ENG. J. MED. 689, 689–93 (1998); Edmund D. Pellegrino, *Rationing Health Care: The Ethics of Medical Gatekeeping*, 2 J. CONTEMP. HEALTH L. & POL'Y 23, 23–45 (1986); Arnold S. Relman, *Medical Insurance and Health: What About Managed Care?*, 331 NEW ENG. J. MED. 471, 471–72 (1994); Arnold S. Relman, *Medical Practice Under the Clinton Reforms—Avoiding Domination by Business*, 329 NEW ENG. J. MED. 1574, 1574–76 (1993); Arnold S. Relman, *Shattuck Lecture—The Health Care Industry: Where Is It Taking Us?*, 325 NEW ENG. J. MED. 854, 854–59 (1991); Steffie Woolhandler & David U. Himmelstein, *Extreme Risk—The New Corporate Proposition for Physicians*, 333 NEW ENG. J. MED. 1706, 1706–07 (1995).

control him. They can exercise enormous influence—some would say control¹⁷—over medical judgments simply by deciding what they will and will not provide or pay for, particularly when they inform providers and patients in advance about their plans to deny coverage. Care has grown so costly that without assurance of funding, many providers will refuse to offer treatments and many patients will decline to seek them.

Accordingly, the questions concerning corporate practice of medicine have evolved. Instead of asking whether corporations should be permitted to employ physicians, we must now examine the “nouveau-corporate practice,” and inquire whether health plans’ broader panoply of economic controls, shy of actual employment, constitutes the practice of medicine; to what extent any such practice of medicine is (un)desirable; and whether MCOs should be, literally, directly liable for classic medical malpractice when they practice medicine.

II. DEFINING THE PRACTICE OF MEDICINE

A. *Defining the Argument*

Two opposing camps define the argument. On the one hand, physicians and other commentators have pointed out that MCOs’ economic judgments have an enormous impact on the care that patients receive. When an MCO undertakes close utilization management (UM), it tells the physician, or even the patient, precisely which interventions it will and will not cover—right down to particular tests and treatments such as drug choices. The reasons underlying coverage decisions are intense, often intrusive, matters of medical diagnosis and treatment. On this view, such detailed second-guessing of clinical decisions is clearly a form of medical practice and, where MCOs thereby change or significantly influence the patient’s course of care, these commentators conclude that the health plan is practicing medicine.

17. See Peter D. Jacobson & Scott D. Pomfret, *Form, Function, and Managed Care Torts: Achieving Fairness and Equity in ERISA Jurisprudence*, 35 Hous. L. Rev. 985, 1062 (1998) (“As an empirical matter, MCOs exert control over physicians. Indeed, control is their *raison d’être*. This control is used to influence physicians’ decision making away from the over-utilization of services that fee-for-service medicine encouraged. Most of the techniques employed to control costs are aimed at changing, with greater or lesser empirical success, physician behavior.”).

For example, in *Murphy v. Board of Medical Examiners*,¹⁸ a physician engaging in utilization review¹⁹ on behalf of an MCO denied authorization for gallbladder surgery by pointing to the patient's prior history of irritable bowel syndrome, her normal laboratory blood values, and the absence of evidence of stones on ultrasound examination. In this case the patient did not actually suffer an injury, because she received the surgery and eventually also the reimbursement when the surgery revealed she did have gallstones. The initial denial of payment was, however, sufficient to carry the suit forward.

The state's Board of Medical Examiners (BOMEX) noted that in cases like this, UR physicians' "decisions could adversely affect the health of a patient"²⁰ and concluded that because this UR physician had indeed practiced medicine, the Board had jurisdiction over the quality of his practice. The Arizona appellate court agreed:

Although Dr. Murphy is not engaged in the traditional practice of medicine, to the extent that he renders medical decisions his conduct is reviewable by BOMEX. Here, Dr. Murphy evaluated information provided by both the patient's primary physician and her surgeon. He disagreed with their decision that gallbladder surgery would alleviate her ongoing symptoms. [The patient's] doctors diagnosed a medical condition and proposed a non-experimental course of treatment. Dr. Murphy substituted his medical judgment for theirs and determined that the surgery was "not medically necessary." There is no other way to characterize Dr. Murphy's decision: it was a "medical" decision.²¹

18. 949 P.2d 530 (Ariz. Ct. App. 1997).

19. "Utilization review" (UR) and "utilization management" (UM) are nearly, though not exactly, interchangeable terms. UR is the narrower concept, usually applied to a health plan's decisions about which interventions it will cover for which patients. Such review can be retrospective, prospective, or concurrent. See *supra* note 2; see also J. Scott Andresen, *Is Utilization Review the Practice of Medicine? Implications for Managed Care Administrators*, 19 J. LEGAL MED. 431, 433-35 (1998). UM is a broader concept, encompassing UR and additionally some other tactics by which an MCO might try to limit or guide utilization. Disease management programs, for instance, typically focus on chronic ailments such as asthma, diabetes, or congestive heart failure, and attempt to help patients to maximize their control over their disease through careful adherence to medication and lifestyle regimens. See Thomas Bodenheimer, *Disease Management—Promises and Pitfalls*, 340 NEW ENG. J. MED. 1202, 1202 (1999); Robert S. Epstein & Louis M. Sherwood, *From Outcomes Research to Disease Management: A Guide for the Perplexed*, 124 ANNALS INTERNAL MED. 832, 835-36 (1996); John M. Harris, Jr., *Disease Management: New Wine in New Bottles?*, 124 ANNALS INTERNAL MED. 838, 840 (1996).

20. *Murphy*, 949 P.2d at 535.

21. *Id.* at 536. The court continued:

Similarly, in *Morris v. District of Columbia Board of Medicine*,²² the District of Columbia Board of Medicine concluded that a physician employed as medical director for a Blue Cross plan practiced medicine in his utilization review capacities. His actions could reasonably be expected:

“to influence the course of treatment of individual patients and, hence, to ‘treat’ them within the meaning of the Act.” . . . Although he “may not have treated or diagnosed patients directly, he had a considerable influence”—a “substantial impact”—“on the treatment of patients insured by Blue Cross,” since “if health insurance is not available, a procedure very well might not be performed.”²³

In this case, however, the appellate court disagreed with the Board on the ground that the defendant merely organized the physicians who performed the UR, did not have a vote, and did not on any occasion ask the committee to reconsider a decision.²⁴

In *Hand v. Tavera*,²⁵ the plaintiff had gone to the emergency room (ER) with a three-day headache and a history of significant hypertension. The ER physician observed him for three hours and, noting that Hand’s symptoms rose and fell with his blood pressure,

Dr. Murphy is not a provider of insurance. Instead, Dr. Murphy is an employee who makes medical decisions for his employer on whether surgeries or other non-experimental procedures are medically necessary. Such decisions are not insurance decisions but rather medical decisions because they require Dr. Murphy to determine whether the procedure is “appropriate for the symptoms and diagnosis of the [c]ondition,” whether it is to be “provided for the diagnosis,” care or treatment, and whether it is “in accordance with standards of good medical practice in Arizona.”

Id. A somewhat related case, *Long v. Great West Life & Annuity Insurance Co.*, 957 P.2d 823 (Wyo. 1998), features a patient with chronic back problems who had been scheduled for surgery. The procedure, however, was cancelled when his health plan’s utilization reviewer denied financial pre-authorization, suggesting steroid injections as a more appropriate approach. When the anesthesiologist whom the patient then asked to provide the steroid therapy refused on the ground that it would present risks with little prospect of benefit, UR suggested physical therapy. When magnetic resonance imaging showed a large herniated disk, a consulting neurosurgeon favored surgery over physical therapy. Although this litigation did not directly allege that the health plan had committed malpractice, the Wyoming Supreme Court noted that “[a]s described above, other courts have recognized that utilization review is medical decision-making, and a plan administrator that involves itself in a medical decision that amounts to a denial of treatment is making a medical decision.” *Id.* at 828.

22. 701 A.2d 364 (D.C. 1997).

23. *Id.* at 367.

24. *See id.* at 367–68.

25. 864 S.W.2d 678 (Tex. App. 1993).

concluded that he needed to be admitted to the hospital. Despite the ER physician's judgment, Dr. Tavera, the physician responsible for authorizing admissions for Hand's HMO, determined that the patient could be treated on an outpatient basis. Hand went home and suffered a fatal stroke several hours later. Initially the defendant prevailed on the ground that no physician-patient relationship existed, hence no duty of care. The decision was reversed on appeal. "We hold that when the health-care plan's insured shows up at a participating hospital emergency room, and the plan's doctor on call is consulted about treatment or admission, there is a physician-patient relationship between the doctor and the insured."²⁶ Without saying it in so many words, the court clearly felt that Dr. Tavera was practicing medicine, not making merely contractual coverage decisions.

On the other hand, MCOs generally insist that they do not practice medicine. Even when they engage in very detailed UM, they generally argue that they are simply interpreting contracts and making coverage decisions.²⁷ Physicians and other providers remain free to treat patients as they wish, even when the plan declines to finance their care.²⁸

A California appellate court echoed the theme: "the physician who complies without protest with the limitations imposed by a third party payor, when his medical judgment dictates otherwise,

26. *Id.* at 679. The court also noted that:

the contracts . . . show that the Humana plan brought Hand and Tavera together just as surely as though they had met directly and entered the physician-patient relationship. . . . In effect, Hand had paid in advance for the services of the Humana plan doctor on duty that night, who happened to be Tavera, and the physician-patient relationship existed.

Id.

27. See Ken Ortolon, *Coming in First*, TEX. MED., July 1997, at 26, 27.

28. As noted by the Ohio attorney general:

It is sometimes stated that, if a health insuring corporation refuses to certify a health care service, the patient will be unable to obtain the service in question, even though his personal physician recommends it. It should be noted, however, that an adverse determination by a health insuring corporation means that the health insuring corporation will not pay for, reimburse, provide, deliver, arrange for, or otherwise make available the service in question. . . . It does not mean that the physician is precluded from providing the service or that the patient is precluded from obtaining the service from another source or through other means. . . . A physician or other provider retains authority to provide whatever services are deemed appropriate for the patient, even if the services are not included under the plan of the health insuring corporation.

cannot avoid his ultimate responsibility for his patient's care."²⁹ The plaintiff's physician was "not paralyzed . . . nor rendered powerless to act appropriately if other action was required under the circumstances."³⁰

States' licensing and practice acts seem to support this general approach. Typically, to practice medicine is to "'diagnose, treat, operate or prescribe for any human disease, pain, injury, deformity or physical condition.'"³¹ Clearly, an MCO cannot physically exam-

29. Wickline v. State, 239 Cal. Rptr. 810, 819 (Ct. App. 1986).

30. *Id.* at 819. In *Adnan Varol, M.D. v. Blue Cross & Blue Shield*, 708 F. Supp. 826 (E.D. Mich. 1989), a group of psychiatrists sued a health plan on grounds that its utilization review decisions interfered with their medical practices and constituted the unauthorized practice of medicine. The court rejected the argument, pointing out that the plan's decisions about medical necessity are no more the practice of medicine when undertaken prospectively than when undertaken in the traditional retrospective mode. *See id.* at 833.

In *Association of American Physicians & Surgeons v. Weinberger*, 395 F. Supp. 125 (N.D. Ill. 1975), a physician organization alleged that federal regulations mandating utilization review had a chilling effect on medical practice. The district court disagreed, holding that there is no interference so long as the criteria acknowledge that a range of treatments and methods can be consistent with professionally accepted patterns of care. *See id.* at 135.

Other commentators note:

Coverage disputes are most appropriately viewed as an insurance-purchasing decision by a pool of subscribers, not a medical-treatment decision by an individual patient. The denial of coverage does not prevent the doctor from rendering care; it merely determines that, in the insurer's judgment, the subscriber pool has chosen not to pay for the particular treatment. Thus, where the parties leave the scope of coverage undefined, a particular case is rationally decided by asking only what range of treatment options the purchasers would have chosen to insure at the time they signed up, not what treatment they want to receive now that the insurance has been paid and their illness is manifest.

Mark A. Hall & Gerard F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637, 1676-77 (1992).

31. *St. Francis Reg'l Med. Ctr. v. Weiss*, 869 P.2d 606, 616 (Kan. 1994). Similarly, one of the early corporate practice cases notes that practice is

the diagnosis and treatment of ailments of human beings; the prescription of a form of treatment for the palliation of physical ailments of persons with the intention of receiving compensation therefor; and the maintenance of an office for the examination and treatment of persons afflicted or supposed to be afflicted by any ailment.

People v. United Med. Serv., 200 N.E. 157, 163 (Ill. 1936); *see also Bartron v. Codrington County*, 2 N.W.2d 337, 341 (S.D. 1942) (quoting a 1919 statute defining the practice of medicine as to "'recommend, prescribe or direct for the use of any person any drug, medicine, apparatus or other agency for the cure, relief or palliation of any ailment or disease of the mind or body, or for the cure or relief of any wound, fracture or bodily injury or deformity, after having received or with the intent of receiving therefor, either directly or indirectly, any . . . compensation'").

In the state of Washington, practicing medicine includes activities such as diagnosing, advising, prescribing, curing, or administering drugs. *See WASH. REV. CODE* § 18.71.011 (1999). In *Morris v. District of Columbia Board of Medicine*, 701 A.2d 364, 367 (D.C. 1997), the court noted that the District of Columbia Health Occupations Revision Act of 1986 defines the

ine, treat, prescribe for, or operate on a patient in the literal sense portrayed in these statutes.³² Only individual persons are capable of these acts, as the old corporate practice cases observe.³³ Additionally,

practice of medicine as “the application of scientific principles to prevent, diagnose, and treat physical and mental diseases, disorders, and conditions and to safeguard the life and health of any woman and infant through pregnancy and parturition.”

The Texas Medical Practice Act defines practicing medicine, in part, as publicly professing to be a physician or surgeon and professing to “diagnose, treat, or offer to treat any disease or disorder, mental or physical, or any physical deformity or injury by any system or method or to effect cures thereof,” or actually engaging in these activities. *Williams v. Good Health Plus, Inc.*, 743 S.W.2d 373, 375 (Tex. App. 1988); *see also* Hall, *supra* note 8, at 453 (referring to “physician licensing laws’ all-encompassing definition of medical practice as diagnosing, treating, or prescribing for any physical or mental condition”).

Some definitions partly define medical practice in terms of an “intention of receiving compensation therefor.” *United Med. Serv.*, 200 N.E. at 163; *see also* OHIO REV. CODE ANN. § 4731.34 (Anderson 1997) (defining a person who practices medicine as an individual who “examines or diagnoses for compensation of any kind, or prescribes, advises, recommends, administers, or dispenses for compensation of any kind, direct or indirect”); *Bartron*, 2 N.W.2d at 341. This feature, present in earlier definitions, has largely been dropped from current statutes. Indeed, had it been retained, it would imply that physicians rendering charity care are not practicing medicine at all. Admittedly, many states have had good Samaritan statutes to protect physicians who render care at the scene of an accident, and charitable immunity statutes protecting hospitals that provide care for the poor. However, these statutes accomplish their public policy aims of encouraging care for the poor and desperate, not by denying that it is medical care in the first place, but by explicitly stating that those who render care in these circumstances will be immune from liability.

32. States’ licensing statutes can be very unclear. Most states define practice of medicine in terms of diagnosis, treatment, prescription, or prevention of human disease, ailment, injury, or other condition. Given such vagueness, it is not surprising to find states’ interpretations can vary widely. In New Jersey, a “store owner was convicted of practicing medicine without a license when he advised customers on what foods they should eat after they had described their ailments.” *Anderson, supra* note 19, at 439 (citing *Pinkus v. MacMahon*, 29 A.2d 885 (N.J. 1943)). Indiana deems tattooing to constitute the practice of medicine, while Texas is willing to consider publishing a book to be medical practice, and Ohio requires a medical license to perform acupuncture. *See id.* at 440.

33. *See, e.g.*, *Semler v. Oregon State Bd.*, 294 U.S. 608 (1935); *People v. Pacific Health Corp.*, 82 P.2d 429, 430 (Cal. 1938); *Parker v. Board of Dental Exam’rs*, 14 P.2d 67, 71 (Cal. 1932); *People v. Merchants’ Protective Corp.*, 209 P. 363, 364 (Cal. 1922); *United Med. Serv.*, 200 N.E. at 162; *Dr. Allison, Dentist v. Allison*, 196 N.E. 799, 800 (Ill. 1935); *Bennett v. Indiana State Bd.*, 7 N.E.2d 977, 982 (Ind. 1937); *State v. Bailey Dental Co.*, 234 N.W. 260, 262 (Iowa 1931); *Teschchi v. Mathis*, 183 A. 146, 146 (N.J. 1936); *Bartron*, 2 N.W.2d at 343–46. Indeed, some courts have found that because corporate practice is illegal, corporations cannot employ physicians—and because the hallmark of employment is control over the employee’s conduct, then a corporation cannot possibly be guilty of practicing medicine, as it could not have exercised the requisite degree of control over the physician. *See Good Health Plus*, 743 S.W.2d at 378. In *Pickett v. CIGNA Healthplan*, No. 01-92-00803-CV, 1993 WL 209858 (Tex. App. June 17, 1993), the plaintiff sued her physicians and her HMO for medical malpractice. The trial court granted summary judgment for the HMO and the appellate court affirmed, because CIGNA did not actually provide care or employ the patient’s physicians. *See id.* at *3. Rather, it contracted with an independent practice association whose physicians provided the care. *See id.* at *2.

The court looked to the Texas Medical Liability and Insurance Act, which defined a health care liability claim as “a cause of action against a health care provider or physician

a number of states have declared by statute, or via attorneys general opinions, that UM does not constitute the practice of medicine.³⁴ On this view someone who only evaluates information for financial purposes and does not actively provide medical care for patients is not practicing medicine.³⁵

for treatment, lack of treatment, or other claimed departure from accepted standards of medical care.” The court then looked at the definition of “health care provider,” and found that CIGNA did not fall within it, noting further that HMOs in Texas do not comply with professional licensing requirements and thus, may not engage in the practice of medicine. The court concluded that CIGNA could not as a matter of law be liable for medical malpractice. Other courts have similarly held that an entity not licensed under the jurisdiction of the agency responsible for health care professionals is not a health care provider for purposes of medical malpractice claims.

Gretchen Garrison, *House Bill 335—Managed Care in Missouri*, 66 UMKC L. Rev. 775, 804 (1998) (citations omitted); see also *Freedman v. Kaiser Found. Health Plan*, 849 P.2d 811, 817 (Colo. Ct. App. 1992); *Bruttomesso v. Northeastern Conn. Sexual Assault Crisis Serv., Inc.*, 698 A.2d 795, 796 (Conn. 1997); *Sova Drugs, Inc. v. Barnes*, 661 So. 2d 393, 395 (Fla. Dist. Ct. App. 1995); *Sloan v. Metropolitan Health Council*, 516 N.E.2d 1104, 1107 (Ind. Ct. App. 1987) (citing *Iterman v. Baker*, 15 N.E.2d 365 (Ind. 1938)); *Propst v. Health Maintenance Plan, Inc.*, 582 N.E.2d 1142, 1143 (Ohio Ct. App. 1990); *Schwartz v. Brownlee*, 482 S.E.2d 827, 830 (Va. 1997); Chittenden, *supra* note 11, at 467–68. This view has been criticized:

One of the arguments HMOs most frequently raised was they simply were not making treatment decisions because that constitutes the practice of medicine. Managed care entities cannot practice medicine because the state bans the corporate practice of medicine, they argued. “That is analogous to a speeder telling a cop he couldn’t have been going 90 miles an hour because the speed limit is only 70,” Ms. Barron [Texas Medical Association lobbyist] said.

Ortolon, *supra* note 27, at 27.

34. In Ohio, for instance, “R.C. 1751.08(D) states plainly that a health insuring corporation holding a certificate of authority under R.C. Chapter 1751 ‘shall not be considered to be practicing medicine.’ . . . Pursuant to this provision, . . . the health insuring corporation is not considered to be practicing medicine in the conduct of its utilization review program under R.C. 1751.77-86” Ohio Op. Att’y Gen. No. 99-044 (Aug. 31, 1999) (citing *Propst v. Health Maintenance Plan*, 582 N.E.2d 1145 (1990)). Other attorneys general have opined similarly. See, e.g., Ark. Op. Att’y Gen. No. 90-104 (1990); 24 Kan. Op. Att’y Gen. 49, Op. No. 90-130 (1990); Miss. Op. Att’y Gen. No. 93-0088 (1993); 60 N.C. Op. Att’y Gen. 100 (1992). For further discussion, see *Andreson, supra* note 19, at 444–46. *But see* *Murphy v. Board of Med. Exam’rs*, 949 P.2d 530, 535 (Ariz. Ct. App. 1997); La. Op. Att’y Gen. No. 98-491 (1999).

35. This was the plaintiff’s argument in *Murphy*, 949 P.2d at 535. Because the physician who performs UR for a third-party payor does not practice medicine, the argument concluded, he should not be subject to review by the Board of Medical Examiners. The Arizona appellate court disagreed. See *id.* As noted by the North Carolina Attorney General in 1992, a denial of coverage

does not prohibit the patient from seeking other funding sources or from seeking treatment without third-party benefits, and it does not prohibit the attending physician from providing the treatment. . . . Thus, the person performing the utilization review is not diagnosing, operating on, prescribing for, administering to or treating

Partly in response to widespread opposition to intensive UM, many MCOs now use other forms of cost containment. Health plans have two basic ways to control costs: rules (by which the MCO determines precisely what it will cover) and incentives (wherein financial risk is shifted back to physicians and other providers).³⁶ For MCOs, a significant advantage of risk-sharing is that as they transfer substantial amounts of financial risk back to providers, they also transfer back clinical decision authority, and with it the responsibility. For example, some capitation arrangements pay a physician a flat fee in exchange for providing a specific list of patients with a designated set of services.³⁷ In one such arrangement, primary care physicians received twenty-eight dollars per patient per month, from which they covered the first \$5000 of each patient's care.³⁸ The MCO completely controlled its costs for those services because, at least within the \$5000 threshold, its costs were determined at the outset. At the same time, risk-sharing permits the physician wide clinical discretion. After all, if the physician is overly generous with services the costs come out of his own pocket, not the MCO's. If the physician has made the clinical decisions about what to do and whom to do it to with no specific input from the MCO, then he and not the MCO has been practicing medicine.

Still, financial risk-shifting only partly permits health plans to control costs without micro-managing utilization. Capitation arrangements generally cover only a limited range of services, such as outpatient physician care and associated laboratory and radiologic studies. The greater costs are for inpatient care. Health plans usually retain financial responsibility, and thereby the majority of control, over big-ticket services such as hospitalizations and surgeries, as well as high-cost drugs and diagnostics. Moreover, not all risk-sharing is capitation. Lesser financial incentives include bonuses, penalties, and withholding arrangements in which physicians receive only part of their payment, with the rest payable later (or not) depending on how costly patients' care has been.

any ailment, injury or deformity, but is merely deciding whether or not third-party payment is available.

60 N.C. Op. Att'y Gen. 100, 100 (1992).

36. See MORREIM, BALANCING ACT, *supra* note 2, at 32; Alan L. Hillman, *Managing the Physician: Rules Versus Incentives*, HEALTH AFF., Winter 1991, at 138; E. Haavi Morreim, *Revenue Streams and Clinical Discretion*, 46 J. AM. GERIATRICS SOC'Y 331 (1998).

37. See generally Donald M. Berwick, *Payment by Capitation and the Quality of Care* (pt. 5), 335 NEW ENG. J. MED. 1227 (1996) (discussing capitation's effect on health care quality).

38. See David Azevedo, *Did an HMO Doctor's Greed Kill Joyce Ching?*, MED. ECON., Feb. 16, 1996, at 43, 47; Erik Larson, *The Soul of an HMO*, TIME, Jan. 22, 1996, at 44.

Such arrangements reward physicians for being cost-conscious, but still leave a significant level of financial risk with the health plan.

Throughout, MCOs must exert considerable control over the ways in which their funds are used and thereby inevitably exert considerable influence over what type of care is provided to which patients. When they do this, the MCOs are accused of practicing medicine. Thus accused, they respond that their decisions determine money, not care.

The debate is captured particularly well in *Corcoran v. United Healthcare, Inc.*³⁹ A physician recommended inpatient care for a woman in a high-risk pregnancy, but her MCO determined that ten hours of home nursing care each day would be sufficient. When the fetus went into distress and died after the nurse had left for the day, the family sued for wrongful death and other torts. En route to its finding that all claims were preempted by ERISA, the Fifth Circuit discussed whether the plan's utilization review and denial of requested hospitalization constituted a medical decision or a benefits decision.⁴⁰

The MCO argued that the denial "was a decision made in its capacity as a plan fiduciary about what benefits were authorized under the Plan. All it did, it argues, was to determine whether Mrs. Corcoran qualified for the benefits provided by the plan by applying previously established eligibility criteria."⁴¹ The benefits decisions are based on medical information, but the basic activity was an administrative claims-handling.⁴²

The plaintiffs, in contrast, argued that the MCO was clearly making medical decisions when it decided that the patient did not medically need continuous hospitalization but could do as well with limited home nursing.⁴³ The utilization review process is rife

39. 965 F.2d 1321 (5th Cir.), *cert. denied*, 506 U.S. 1033 (1992).

40. If the decision were strictly a medical decision, the suit might not have been preempted by ERISA, because preemption applies only to suits "to recover benefits due . . . under the terms of [the] plan, to enforce . . . rights under the terms of the plan, or to clarify . . . rights to future benefits under the terms of the plan." Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1132(a)(1)(B) (1994). However, because the court found that the denial of inpatient hospitalization was a benefits determination rather than a medical decision, ERISA's preemption of state-based causes of action did apply. For further discussion of ERISA, see E. Haavi Morreim, *Benefits Decisions in ERISA Plans: Diminishing Deference to Fiduciaries, and an Emerging Problem for Provider-Sponsored Organizations*, 65 TENN. L. REV. 511 (1998); E. Haavi Morreim, *Medicine Meets Resource Limits: Restructuring the Legal Standard of Care*, 59 U. PITT. L. REV. 1, 76-94 (1997) [hereinafter Morreim, *Resource Limits*]; E. Haavi Morreim, *Moral Justice and Legal Justice in Managed Care: The Ascent of Contributive Justice*, 23 J.L. MED. & ETHICS 247 (1995) [hereinafter Morreim, *Contributive Justice*].

41. *Corcoran*, 965 F.2d at 1329.

42. *See id.* at 1330.

43. *See id.*

with medical decisions, they argued, as the plan determines whether a surgery is (un)necessary, how long a patient should be hospitalized, and which prescriptions and treatments are most appropriate.⁴⁴

The Fifth Circuit could not “fully agree with either United or the Corcorans.”⁴⁵ Despite the fact that medical decisions were ultimately left up to the beneficiary and her physician, that the MCO-beneficiary relationship was not precisely a physician-patient relationship, and that the MCO had contractually reserved the right to make benefits decisions on the basis of medical information, the court pointed out that prospective UR decisions have a powerful influence on treatment decisions, because the beneficiaries may be far less inclined to pursue treatments that they know in advance will not be reimbursed. The very purpose of prospective UR is to influence treatment decisions in just this way.⁴⁶ The court nevertheless concluded in favor of the MCO:

Ultimately, we conclude that United makes medical decisions—indeed, United gives medical advice—but it does so in the context of making a determination about the availability of benefits under the plan. Accordingly, we hold that the Louisiana tort action asserted by the Corcorans for the wrongful death of their child allegedly resulting from United’s erroneous medical decision is pre-empted by ERISA.⁴⁷

B. Three Inadequate Answers

Determining whether MCOs actually practice medicine requires a dismissal of three inadequate arguments. First, some commentators argue that an MCO’s denial of resources may have immediate and serious medical consequences, and that this impact on patients’ treatment and outcomes means that the MCO has practiced medicine. In rebuttal, however, the bare fact that an MCO’s denial of resources has a significant impact does not mean that the denial was a medical decision, or further that it constituted the practice of medicine. Suppose, for instance, that the MCO’s contract explicitly

44. See *id.* at 1331.

45. *Id.*

46. See *id.*

47. *Id.*

covers only thirty days of inpatient psychiatric care.⁴⁸ A patient who has reached this limit, and whose MCO has said “no further funding,” might be promptly discharged by the hospital as a direct consequence. Any ensuing problems, however, cannot be attributed to the MCO.⁴⁹ Because the limits of coverage in such a case are so clear, the health plan is simply applying the contract to the facts. The decision not to provide extra-contractual benefits can affect subsequent treatment decisions and thereby the patient’s medical outcome. However, the denial is fundamentally no different than a similar refusal by the patient’s next-door-neighbor, who also does not owe him any such funds and who also declines to provide them for free. Other examples include exclusions for particular services such as podiatry,⁵⁰ or more broadly for preexisting conditions.⁵¹ Accordingly, plaintiffs cannot claim that MCOs practice medicine simply because their decisions affect patients’ medical care and outcomes.⁵²

This conclusion is echoed in *Morris v. District of Columbia Board of Medicine*,⁵³ discussed just above, in which the D.C. Medical Board found that a health plan’s medical director had practiced medicine without a license. The finding was based on the physician’s ability to influence clinical decisions.⁵⁴ The appellate court overturned:

This definition of “treatment” is so open-ended that it cannot reasonably be squared with the statutory term. In normal medical usage, “treat” means “to care for . . . medically or surgically: deal with by medical or surgical means” Conduct that merely “[a]ffects,” “influences,” or “substantially impact[s]” on the course of such care by others cannot itself be treatment without converting a major part of the business of health insurers such as Blue Cross into the “practice of medicine.” Equating “treat[ment]” with any conduct that “practically [a]ffect[s]” it, in ways potentially involving no ex-

48. See, e.g., *Wilson v. Blue Cross*, 271 Cal. Rptr. 876, 880 (Ct. App. 1990) (noting that beneficiary’s policy covered up to 30 days of inpatient psychiatric care per 12-month period).

49. In *Wilson*, the patient had not exhausted all 30 days of his inpatient coverage; an outside UR entity suspended coverage on the ground that further inpatient care was not medically necessary. See *Wilson*, 271 Cal. Rptr. at 882–83.

50. See *Axelroth v. Health Partners*, 720 So. 2d 880 (Ala. 1998).

51. See *England v. John Alden Life Ins. Co.*, 846 F. Supp. 798 (W.D. Mo. 1994).

52. As another example, an employee who has been discharged from his job may also lose health insurance. Such a loss will probably affect that person’s health care and perhaps thereby his health, but we could not thereby conclude that the employer had been practicing medicine. (I owe this example to David Hyman).

53. 701 A.2d 364 (D.C. 1997).

54. See *id.* at 367.

ercise of medical judgment, is contrary to any sensible interpretation of the statute.⁵⁵

The second inadequate argument comes from health plans when they hold that, so long as their activities involve interpreting the contract, they cannot also be practicing medicine. In contrast to the above example of straightforward contractual caps on dollars or days, most health plan benefits decisions are based on antecedent medical conclusions. In *Corcoran v. United States* the court observed that the plan makes a medical decision in order to make its benefits decision. Moreover, such medically-based decisions permeate plans' benefits decisions, because the concept of "medical necessity" serves as the contractual cornerstone defining benefits in most health plans. "Under the test of 'medical necessity,' which serves almost universally as the contractual touchstone of plan coverage, the criteria used to check the spending discretion of providers are almost exclusively medical, not economic."⁵⁶ Thus, the fact that the MCO points to a contract does not, by itself, preclude the possibility that it practices medicine in the context of making benefits decisions.

55. *Id.* at 367 (citations omitted). Likewise, in his dissent in *Long v. Great West Life & Annuity Insurance*, 957 P.2d 823 (Wyo. 1998), Justice Richard V. Thomas argued:

It is clear . . . from the philosophical discussion that the premise for the assumed harm is that the insured will forego appropriate care because of the advanced advice that the carrier will not pay in full. The logical fallacy presented is that the carrier could be guilty of malpractice in a situation in which a physician could not. It would be fruitless to search for authority that a medical practitioner is guilty of malpractice because his patient decided not to pursue treatment because of the potential expense.

Id. at 833 (Thomas, J., dissenting).

In a similar vein, the California Supreme Court has held that insurers must have the power to determine which services they cover under the language of their contract, even if on occasion the insurer disagrees with the patient's own physician. See *Sarchett v. Blue Shield*, 729 P.2d 267, 273 (Cal. 1987); see also *Blue Cross & Blue Shield v. Smither*, 573 S.W.2d 363, 365 (Ky. Ct. App. 1978) ("Since a large part of today's rising medical costs are borne by organizations which offer medical benefits plans, such as Blue Cross and Blue Shield, we believe these organizations should be entitled to some measure of protection and should be allowed to challenge decisions made by doctors.").

56. CLARK C. HAVIGHURST, HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM 15 (1995); see also Mark A. Hall et al., *Judicial Protection of Managed Care Consumers: An Empirical Study of Insurance Coverage Disputes*, 26 SETON HALL L. REV. 1055, 1055-56 (1996) (arguing that covered benefits in both public and private insurance contracts are defined in terms of "medical necessity" which means "medically appropriate" and "excludes experimental care, nonstandard treatments, treatments without any known benefit, and treatment such as cosmetic surgery not intended to correct or relieve a medical condition").

In the third inadequate argument, health plans suggest that they cannot practice medicine because they cannot, for example, physically examine patients or perform surgical or diagnostic procedures. This assertion misunderstands, however, the essence of medical practice. Arguably, the most central element in clinical medicine is not the hands-on skills of examining patients and performing procedures. In many cases, lesser-trained personnel can master such techniques with considerable facility. Rather, the heart and soul of medicine as a learned profession is judgment. Thus, the surgeon's most crucial contribution is a series of judgments: whether this patient presents a surgical or nonsurgical problem and, if surgical, which particular procedure, using what particular implants or devices, would be most suitable. Intraoperatively there are judgments about what to do if the patient has idiosyncratic anatomy or, even more importantly, what to do if things go wrong. The skills of incising and suturing are obviously important and require significant training, but these activities are not the hallmark of being a physician. Similarly, the internist or pediatrician must gather history, symptoms, and signs, and make judgments about which diagnoses are most likely, which further tests are likely to yield useful information, at what risk, and how to weigh those risks against the hoped-for information. For therapy, further judgments weigh the likelihood of success for various treatments against their possible harms. The act of writing the orders, or even performing a diagnostic or therapeutic intervention, is usually considerably less demanding of their expertise. Throughout, uncertainties pepper the process. The judgments require empirical estimations of likelihood and normative evaluations about merits, and they are based on scientific literature, collective consensus, and the practitioner's own clinical experience.⁵⁷ Importantly, courts are embracing the notion that judgment is the central element of practicing medicine, even in settings such as telemedicine in which there is no physical contact whatever between physician and patient.⁵⁸

57. In its recent opinion on corporate practice of medicine, the Louisiana Board of Medical Examiners offered a definition of medical practice that places a primacy on judgment: "As contemplated by the Medical Practice Act . . . the essence of the practice of medicine is the *exercise of independent medical judgment* in the diagnosing, treating, curing or relieving of any bodily or mental disease, condition, infirmity, deformity, defect, ailment, or injury in any human being . . ." Board of Medical Examiners, Statement of Position: Corporate Practice of Medicine; Applicability of Louisiana Medical Practice Act to Employment of Physician by Corporation Other than a Professional Medical Corporation, Sept. 24, 1992, at 2 (emphasis added).

58. In the type of telemedicine most relevant to this discussion, a consulting physician at a geographic distance electronically gathers information about a patient, then offers opinions and recommendations. Such electronic consultation can be particularly valuable for

C. Resolving the Argument

Having refuted these three misconceptions, it is possible to develop a clearer view of what it is to practice medicine, whether as a physician or as a corporation. There are two elements, each of which is necessary, yet neither of which are alone sufficient. The first is the exercise of medical judgment—the formulation of opinions based on the esoteric, highly technical knowledge base that is distinctive to medicine as a profession. Cases like *Morris* and *Murphy*⁵⁹ illustrate that utilization management often involves medical judgments that can potentially disagree with treating physicians' opinions. As further discussed in Part V, health plans must often make medical judgments in order to make their coverage decisions, because most contracts base benefits decisions on the notion of "medical necessity"—a concept clearly requiring medical judgments.⁶⁰

Nevertheless, making a medical judgment does not, by itself, constitute the practice of medicine. A person sitting at a distance, merely contemplating someone's medical condition as an intellectual exercise, may be making medical judgments but obviously is not practicing medicine. To constitute practice, a medical judgment must in some sense be carried out. It must be used to determine, or at least significantly influence, what type of care will be provided to a particular patient. This is the second element of practicing medicine.

The notion of "significant influence" must be included alongside "determining" the patient's care, because even physicians do not always determine their patients' care. The patient, after all, has some say in the matter. He can decline what is offered, request an alternative approach, or ostensibly agree with what is proposed and then fail to adhere. From a legal standpoint, the inquiry into

bringing sophisticated expertise to patients in isolated areas, or for bringing sophisticated expertise to patients with unusual conditions. Clearly, in this setting the physician does no "hands-on" work whatever—until, perhaps, refined technologies become available for such interventions as remote, robotic surgery. In the meantime, telemedicine represents a situation in which the physician's sole contribution is to provide his medical judgment. For a very useful discussion of potential liabilities surrounding telemedicine, see Patricia C. Kuszler, *Telemedicine and Integrated Health Care Delivery: Compounding Malpractice Liability*, 25 AM. J.L. & MED. 297 (1999) (considering the application of medical negligence liability theories to telemedicine and integrated delivery health plans); see also Nicolas P. Terry, *Cyber-Malpractice: Legal Exposure for Cybermedicine*, 25 AM. J.L. & MED. 327 (1999) (examining the "content-related liability exposure of health care providers operating in cyberspace").

59. See *supra* text accompanying notes 18, 22.

60. See *infra* Part V.A.

whether the MCO exerted the requisite level of influence would most plausibly be understood in classic causality terms as whether the MCO's coverage decision was a "substantial factor" in bringing about the treatment decision and in turn the patient's outcome.⁶¹

"Substantial factor" can be elusive to define. In this Article it will be understood in terms of two dimensions. First, it must be the case that the MCO actually owes (coverage for) the medical service in question. As noted previously, when the MCO does not owe, for example, more than thirty days of inpatient care, or care for pre-existing conditions, then its refusal to provide coverage beyond that cannot be "the cause" of the patient's hospital discharge, any more than a similar refusal by some neighbor down the street.⁶² In such cases, the patient's lack of money is clearly an important factor in his decision to forego care; but because the health plan clearly did not owe the coverage, the lack of money is an unfortunate fact of life, not the fault of this MCO. Of course, there will be cases where it is unclear initially whether the health plan owes coverage. Courts will have to answer that question as part of their broader inquiry into whether the MCO practiced medicine, and whether it may be held liable for malpractice.⁶³

The other dimension in determining whether an MCO's denial of coverage is a "substantial factor" in a decision about treatment (and in any adverse outcomes resulting from that decision) is the question whether the denial was "material" to the decision. Materiality, a notion adapted here from the law of informed consent,⁶⁴ refers to information or decisional factors that are important enough (at least potentially) to sway a decision one way or another. As patients decide what sort of treatment to undergo, or as physicians decide what to offer, they will consider numerous factors. In some cases a health plan's decision may not be crucial: the patient

61. See *Wilson v. Blue Cross*, 271 Cal. Rptr. 876, 883 (Ct. App. 1990) ("The actors' negligent conduct is a legal cause of harm to another if (a) his [or her] conduct is a substantial factor in bringing about the harm, and (b) there is no rule of law relieving the actor from liability . . .") (quoting RESTATEMENT (SECOND) OF TORTS § 431 (1977)).

62. In other words, in certain situations an agent bears causal responsibility, or not, because she antecedently bore a duty of care. For example, the parent is the cause of a child's starvation, not because the parent was the only one who failed to feed the child—where a child has starved, many people have failed to feed it—but because the parent is the one who antecedently had a duty to see to it that the child was fed. Thus the parent, and not some stranger down the street, is the cause because of a prior duty. For further exploration of the relationship between causality and the duty of care, see E. Haavi Morreim, *Whodunit? Causal Responsibility of Utilization Review for Physicians' Decisions, Patients' Outcomes*, 20 L. MED. & HEALTH CARE 40 (1992).

63. See *infra* notes 254–82 and accompanying text.

64. See *Canterbury v. Spence*, 464 F.2d 772 (D.C. 1972) (providing the standards of informed consent).

may have to pay only slightly more out of pocket, or providers may be willing to waive their charges, or other sources of funding may be available. However, because medicine can be very expensive and alternate sources of care are increasingly difficult to obtain, it will often be the case that a third party payor's adverse coverage decision will weigh heavily if not decisively: either providers will refuse to offer it, or the patient will decline the intervention because he cannot afford it.⁶⁵ The question of

65. Several courts have acknowledged the close connection between funding and the availability of care. One court took judicial notice of the fact that many patients rely on health insurance to cover all or part of the high costs of major medical care. The court noted that "absent pre-claim verification of insurance coverage, patients may be forced to leave a hospital without receiving medical treatment—even though they are insured for the medical services they seek to obtain—because they lack other sufficient financial resources to pay the costs of treatment." *Mimbs v. Commercial Life Ins. Co.*, 832 F. Supp. 354, 358 (S.D. Ga. 1993) (discussing that health plan had incorrectly stated, in prospective UR, that the proposed care would not be covered).

The Fifth Circuit discussed funding and availability of care at some length in *Corcoran*:

A prospective decision is . . . different in its impact on the beneficiary than a retrospective decision. In both systems, the beneficiary theoretically knows in advance what treatments the plan will pay for because coverage is spelled out in the plan documents. But in the retrospective system, a beneficiary who embarks on the course of treatment recommended by his or her physician has only a potential risk of disallowance of all or a part of the cost of that treatment, and then only after treatment has been rendered. In contrast, in a prospective system a beneficiary may be squarely presented in advance of treatment with a statement that the insurer will not pay A beneficiary in the latter system would likely be far less inclined to undertake the course of treatment that the insurer has at least preliminarily rejected.

By its very nature, a system of prospective decisionmaking influences the beneficiary's choice among treatment options to a far greater degree than does the theoretical risk of disallowance of claim facing a beneficiary in a retrospective system. Indeed, the perception among insurers that prospective determinations result in lower health care costs is premised on the likelihood that a beneficiary, faced with the knowledge of specifically what the plan will and will not pay for, will choose the treatment option recommended by the plan in order to avoid risking total or partial disallowance of benefits.

Corcoran v. United HealthCare, Inc., 965 F.2d 1321, 1331–32 (5th Cir.), cert. denied, 506 U.S. 1033 (1992).

In *Long v. Great West Life & Annuity Insurance Co.*, 957 P.2d 823, 827 (Wyo. 1998), the Wyoming Supreme Court noted that

[a]lthough the attending physician is the ultimate decisionmaker regarding a patient's treatment, it is, as commentators note, naive to assume that a provider's determination that recommended care is not medically necessary, and therefore not covered by insurance or the health plan, will not affect the treatment ultimately received by the patient.

Other courts have likewise "recognized the 'commercial realities' facing third-party providers of health care services, noting that . . . one of the first steps in accepting a patient for treatment is to determine a financial source for the cost of care to be provided." *Cypress*

materiality is thus quite fact-specific, and can only be answered by examining the details of each case.⁶⁶

In sum, MCOs can and do practice medicine.⁶⁷ Not all of their benefits determinations, however, constitute medical practice. Where the contract is clear and requires no medical judgment (as with a cap on days or dollars), a denial of benefits is not the practice of medicine, even if it has an enormous impact on the patient's care. Barring ambiguities, it is the straightforward application of the language to the facts. In contrast, where the contract requires the plan to make its own medical judgment in order to make its benefits decision, as when benefits hinge on "medical necessity," and where such judgments determine or strongly influence the patient's actual course of care, then the plan has practiced medicine.

III. LIABILITY FOR MCOs: TWO APPROACHES AND THEIR PROBLEMS

What sort of liability should MCOs bear when their medical practice constitutes malpractice? MCOs as business enterprises are already subject to various sorts of liability, such as fraud for false advertising, or breach of contract where they fail to deliver promised services.⁶⁸ This Article, however, particularly inquires whether

Fairbanks Med. Ctr. Inc. v. Pan-American Life Ins. Co., 110 F.3d 280, 283 (5th Cir. 1997) (citing Memorial Hosp. Sys. v. Northbrook Life Ins. Co., 904 F.2d 236, 246 (5th Cir. 1990)).

66. See PAUL T. MENZEL, STRONG MEDICINE 145 (1990). For a case illustration regarding potentially material information about financial (non)coverage for care, see Mark G. Kuczewski & Michael DeVita, *Managed Care and End-of-Life Decisions*, 158 ARCHIVES INTERNAL MED. 2424 (1998).

67. A similar concept of medical practice appeared in 1890, as the Kansas Supreme Court noted:

The practice of medicine may be said to consist in three things: *First*, in judging the nature, character, and symptoms of the disease; *second*, in determining the proper remedy for the disease; *third*, in giving or prescribing the application of the remedy to the disease. If the person who makes a diagnosis of a case also gives the medicine to the patient, he is, in our judgment, practicing medicine.

Underwood v. Scott, 23 P. 942, 943 (Kan. 1890); see also State Electro-Med. Inst. v. Platner, 103 N.W. 1079, 1081 (Neb. 1905) (defining the medical practitioner as one "who undertakes to judge the nature of disease or to determine the proper remedy therefor, or to apply the remedy"). Unfortunately, this view did not prevail, as a wide range of subsequent courts opined that the mere hiring of a physician constituted the practice of medicine.

68. Chittenden offers an extensive discussion of current and prospective avenues of liability against managed care organizations, including: (1) vicarious liability (including respondeat superior and ostensible agency); (2) direct liability (for selection and control of

MCOs can be subject to classic medical malpractice claims of the same sort to which physicians are subject. At present, they have not been. Rather, problems in quality of care have raised direct and indirect tort liability for MCOs, neither of which is equivalent to medical malpractice.

Under direct liability, specifically corporate negligence, a health plan owes certain duties directly to enrollees, such as to exercise due care in selecting, monitoring, and retaining its physician staff.⁶⁹

providers); (3) direct liability (for breach of contract, consumer fraud, breach of fiduciary duties); (4) direct negligence in design or implementation of quality assurance or utilization review programs); (5) direct liability (RICO). See generally Chittenden, *supra* note 11 *passim*. Chittenden's discussion includes brief reference to health plans' duties to disclose their cost-containment and incentive systems. See *id.* at 483. Since that article was written, other cases have supported this potential cause of action, at least in ERISA cases. See *Shea v. Esensten*, 107 F.3d 625 (8th Cir. 1997); *Drolet v. HealthSource, Inc.*, 968 F. Supp. 757 (D.N.H. 1997); *McConocha v. Blue Cross & Blue Shield*, 898 F. Supp. 545, 551 (N.D. Ohio 1995).

Breach of contract cases include *Charles v. Kender*, 646 N.E.2d 411 (Mass. App. Ct. 1995); *Dunn v. Praiss*, 656 A.2d 413 (N.J. 1995); *Williams v. HealthAmerica*, 535 N.E.2d 717 (Ohio Ct. App. 1987) (permitting breach of contract claim against physician); *McClellan v. Health Maintenance Organization*, 604 A.2d 1053 (Pa. Super. Ct. 1992); and *Kaiser Foundation Health Plan v. Bridewell*, 946 S.W.2d 642 (Tex. App. 1997).

In a number of cases, state law claims for breach of contract were held to be preempted by ERISA. See, e.g., *Cannon v. Group Health Serv.*, 77 F.3d 1270 (10th Cir. 1996); *Kuhl v. Lincoln Nat'l Health Plan*, 999 F.2d 298 (8th Cir. 1993); *Corcoran*, 965 F.2d at 1321; *Ramirez v. Inter-Continental Hotels*, 890 F.2d 760 (5th Cir. 1989); *Andrews-Clarke v. Travelers Ins. Co.*, 984 F. Supp. 49 (D. Mass. 1997); *Hemphill v. Unisys Corp.*, 855 F. Supp. 1225 (D. Utah 1994); *Metroplex Infusion Care v. Lone Star Container Corp.*, 855 F. Supp. 897 (N.D. Tex. 1994); *Elsesser v. Hospital of Philadelphia College of Osteopathic Med.*, 802 F. Supp. 1286 (E.D. Pa. 1992); *Rollo v. Maxicare, Inc.*, 695 F. Supp. 245 (E.D. La. 1988).

Similarly, William Sage summarizes three established categories of corporate liability for health plans: (1) vicarious liability (as employers are liable for employees—e.g. the Veterans Administration, academic medical centers, etc.); (2) direct liability (via cases against hospitals, e.g., for inadequately reviewing credentials and monitoring performance); (3) private contracting (e.g., as a health plan voluntarily pays liability insurance for its physicians). See William M. Sage, *Enterprise Liability and the Emerging Managed Health Care System*, L. & CONTEMP. PROBS., Spring 1997, at 159, 173–75.

William Helvestine discusses various possibilities for liability pursuant to UR, as undertaken by various entities, including: negligence, breach of contract, insurance bad faith, infliction of emotional distress, warranty theories, products liability, defamation and interference with contractual advantage, antitrust, liability of consultants and employees, state regulation, direct liability, vicarious liability, and others. See William A. Helvestine, *Legal Implications of Utilization Review*, in *CONTROLLING COSTS AND CHANGING PATIENT CARE?* 169, 175–90 (Bradford H. Gray & Marilyn J. Field eds., 1989).

Mark Hall likewise discusses theories of liability, including tortious interference with advantageous relationships and fee-splitting. See Hall, *supra* note 8, at 460–504; see also Allen D. Allred & Terry O. Tottenham, *Liability and Indemnity Issues for Integrated Delivery Systems*, 40 ST. LOUIS U. L.J. 457, 457–83 (1996); Linda V. Tiano, *The Legal Implications of HMO Cost Containment Measures*, 14 SETON HALL LEGIS. J. 79, 84–100 (1990).

69. Corporate negligence as applied to health plans is based on similar duties placed on hospitals, and includes duties to select, monitor, and retain only qualified physician staff. In the case of health plans, courts have also identified duties to avoid defective design and implementation of utilization management programs, among other duties; in other cases, plaintiffs allege misrepresentation or fraud where health plans do not deliver what they

Indirect, or vicarious, liability takes two forms. In the more traditional form a health plan may be held liable for the misdeeds of its employees, including physician-employees.⁷⁰ More recently some health plans have also been held liable for the actions of physicians who, although independent contractors, are believed by the MCO's subscribers to be "ostensible agents" of the MCO.⁷¹

Despite these avenues of direct and indirect liability, MCO corporations do not bear liability for medical malpractice at this time. They can vicariously assume or at least share in the blame for the actions of the physicians they employ or contract with; or they can be liable for their own inadequacies in selecting or monitoring those physicians. Both stop shy of holding the MCO directly at

purported they would. See *Wilson v. Blue Cross*, 271 Cal. Rptr. 876, 878-80 (Ct. App. 1990); *Wickline v. State*, 228 Cal. Rptr. 661, 670-71 (Ct. App. 1986); *Welsh v. Bulger*, 698 A.2d 581, 585-86 (Pa. 1997); *Thompson v. Nason Hosp.*, 591 A.2d 703, 706-09 (Pa. 1991); *Shannon v. McNulty*, 718 A.2d 828, 831, 835-36 (Pa. Super. Ct. 1998); *McClellan v. HMO*, 604 A.2d 1053, 1058-60 (Pa. Super. Ct. 1992); *Chittenden*, *supra* note 11, at 468-73; *Hall*, *supra* note 8, at 458-59 (discussing *Darling v. Charleston Community Mem'l Hosp.*, 211 N.E.2d 253 (Ill. 1965)); *Clark C. Havighurst, Making Health Plans Accountable for the Quality of Care*, 31 GA. L. Rev. 587, 601-03 (1997).

In some of these cases, a claim for direct negligence that might otherwise go forward is preempted by federal law (through ERISA). See *Travelers Ins.*, 984 F. Supp. at 54-56, 62-64; *Dearmass v. Av-Med, Inc.*, 865 F. Supp. 816, 817-18 (S.D. Fla. 1994); *Kearney v. U.S. Healthcare, Inc.*, 859 F. Supp. 182, 185-87 (E.D. Pa. 1994); *Elsesser*, 802 F. Supp. at 1290-91 (holding that claims are preempted for misrepresentation, though not for ostensible agency); *Altieri v. Cigna Dental Health, Inc.*, 753 F. Supp. 61, 64 (D. Conn. 1990); see also *Sage*, *supra* note 68, at 186-87.

70. Hospitals often employ physicians in specialties such as radiology, anesthesiology, and pathology. Some HMOs, in particular the "staff-model" HMOs, employ virtually all their physicians. See *Schleier v. Kaiser Found. Health Plan*, 876 F.2d 174, 177-78 (D.C. Cir. 1989); *Sloan v. Metropolitan Health Council*, 516 N.E.2d 1104, 1105-06 (Ind. Ct. App. 1987). *But see Chase v. Independent Practice Ass'n, Inc.*, 583 N.E.2d 251, 253-55 (Mass. App. Ct. 1991).

71. Ostensible agency originally emerged as a way of describing hospitals' relationships with physicians. Ordinarily a hospital cannot be held liable for the actions of independent contractors such as physicians, because they do not employ these individuals or control their actions. However, when the plaintiff has been induced to think that the physician actually is an employee of the hospital, and relies on that belief, the hospital may be liable as though it were an employer. See, e.g., *Insinga v. LaBella*, 543 So. 2d 209 (Fla. 1989); *Clark v. Southview Hosp. & Family Health Ctr.*, 628 N.E.2d 46 (Ohio 1994).

More recently the doctrine has been extended to MCOs. As with hospitals, an MCO cannot ordinarily be held liable for the actions of physicians who are independent contractors. Such arrangements are found, for instance, in the independent practice association (IPA) form of HMOs. (In an IPA, the HMO contracts for services from a variety of physicians in private practice. These physicians typically practice in their own offices and may have contracts with a variety of insurers and MCOs.) When an HMO holds itself out as the actual provider of services, however, or represents that the physicians are its employees so that the patient looks to the HMO more than to the physician for care (and perhaps also relies on such representations), then the physician may be the "ostensible agent" of the HMO, and the HMO may thereby be vicariously liable for damages the physician causes. See, e.g., *Kearney*, 859 F. Supp. at 188; *Elsesser*, 802 F. Supp. at 1290; *Boyd v. Albert Einstein Med. Ctr.*, 547 A.2d 1229 (Pa. Super. Ct. 1988).

fault for committing medical malpractice, because practicing medicine is an activity heretofore deemed to lie exclusively within the control of physicians.⁷²

There are various possible responses to this gap between the fact that corporations do practice medicine, and the fact that they have not actually been subject to liability for medical malpractice. This Part examines two proposals. The first would fix the gap by precluding MCOs from practicing medicine at all, while the second would place on the MCOs all liability for quality of care. Both proposals and their problems will be discussed here, thereby opening the door to a superior approach in the Parts that follow.

A. Permitting Employment, Proscribing Interference

The first proposal is to fix the flaws in the old corporate practice ban. The original doctrine, prohibiting employment of physicians, has become largely anachronistic as HMOs, hospitals, and a variety of other entities routinely hire physicians rather than relating to them as independent contractors. It is just one part of a massive reorganization of the economic structures by which health care is now delivered.⁷³ At the same time it has been recognized that,

72. It may be noted, however, that plaintiffs are increasingly willing to accuse health plans of classic medical malpractice as distinct from simply (and sloppily) using the term in connection with corporate negligence or vicarious liability. In *Brandon v. Aetna Services, Inc.*, 46 F. Supp. 2d 110 (D. Conn. 1999), the plaintiff alleged

that Defendants committed malpractice by engaging in the practice of medicine or psychiatry "by undertaking to make decisions about what psychiatric and psychological treatment was and was not appropriate for Mr. Brandon," and then failing to exercise the degree and skill ordinarily exercised by psychiatrists and psychologists in Connecticut or Vermont by failing or refusing to "approve and pay for at least six months of treatment."

Id. at 112. The district court held that ERISA preempted this claim.

Other exceptions in which the plaintiff tries to claim that the plan literally practiced medicine include *Kuhl v. Lincoln Nat'l Health Plan*, 999 F.2d 298, 300 (8th Cir. 1993), *cert. denied*, 510 U.S. 1045 (1994); *Corcoran v. United HealthCare, Inc.*, 965 F.2d 1321, 1378 (5th Cir.), *cert. denied*, 506 U.S. 1033 (1992); *Garrison v. Northeast Georgia Med. Ctr., Inc.*, 66 F. Supp. 2d 1336, 1341 (N.D. Ga. 1999); *Roessert v. Health Net*, 929 F. Supp. 343, 346 (N.D. Cal. 1996); *Williams v. California Physicians' Serv.*, 85 Cal. Rptr. 2d 497, 511 (Ct. App. 1999); *Williams v. Good Health Plus, Inc.*, 743 S.W.2d 373, 378 (Tex. App. 1988).

73. For further discussion of that reorganization see John K. Iglehart, *Medicaid and Managed Care*, 332 NEW ENG. J. MED. 1727 (1995); Philip R. Kletke et al., *Current Trends in Physicians' Practice Arrangements*, 276 JAMA 555 (1996); Bruce E. Landon et al., *A Conceptual Model of the Effects of Health Care Organizations on the Quality of Medical Care*, 279 JAMA 1377 (1998); Morreim, *Resource Limits*, *supra* note 40.

although employment relationships are defined by the extent to which a master controls the nature and manner of a servant's work,⁷⁴ an employment relationship is hardly the only means by which MCOs exert control over physicians. Health care is often so costly that patients can ill afford to pay out of pocket, and providers straining under reduced fees, financial risk-sharing, and increasingly frequent reimbursement denials and delays are less able than ever before to provide care for free. Hence, an MCO's denial of coverage, or even a UR process that is a bit too sluggish, can exert a powerful influence over which services are actually available.⁷⁵

Notwithstanding such broadened opportunities for corporate control of medicine, it can also be argued that the flourishing diversity of economic arrangements for health care delivery has helped to spawn useful innovations and to contain the costs that had previously been spiraling out of control. The Federal Trade Commission (FTC) has long been opposed to the traditional corporate practice ban for just such reasons. In the 1940s, the Supreme Court held that the American Medical Association (AMA) had illegally restrained trade when it tried to discourage its physician members from practicing in an HMO setting.⁷⁶ Beginning in 1975, the FTC ordered the AMA to remove its ethics-code restrictions on contract and corporate practice because these provisions stifled innovation and illegally restrained trade.⁷⁷

74. See *Daw's Critical Care v. Dept. of Labor*, 622 A.2d 622, 631 (Conn. Super. Ct. 1992). The court noted:

The test of the relationship is the right to control. It is not the fact of actual interference with the control, but the right to interfere, that makes the difference between an independent contractor and a servant or agent. . . . An independent contractor has been said to be "one who, exercising an independent employment, contracts to do a piece of work according to his own methods and without being subject to the control of his employer, except as to the result of his work."

Id.; see also *Charter Peachford Behavioral Health Sys., Inc. v. Kohout*, 504 S.E.2d 514, 525 (Ga. Ct. App. 1998); *Jacobson & Pomfret*, *supra* note 17, at 1062.

75. See *supra* note 65.

76. See *American Med. Ass'n v. United States*, 317 U.S. 519, 531-32 (1943).

77. See *Chase-Lubitz*, *supra* note 8, at 475. The FTC found several anticompetitive effects of the corporate ban:

First, the provisions sought to limit price competition among doctors by fixing the adequacy of compensation and by prohibiting competitive bidding. Second, the provisions inhibited competition by limiting hospitals, prepaid health plans, and lay entities to the traditional fee-for-service method of compensation and by proscribing their use of salaries and other more cost-efficient payment methods. Last, the provisions restricted arrangements between physicians and nonphysicians and, therefore, prevented the creation of more economical business structures.

One approach, now advanced by a number of commentators, retains but significantly modifies the corporate practice doctrine. Corporations should be permitted to employ physicians, but with one major caveat: they must not interfere with physicians' clinical decisions. Thus, Mars argues that "[u]nless a corporation is truly interfering with its employed physicians' medical judgments, there seems to be no sound basis for the continued blanket and unconditional prohibition on contractual employment arrangements."⁷⁸ Mars suggests that "[t]he line of demarcation that courts have drawn, based on structure, should be reanalyzed in terms of whether the form of arrangement is truly interfering with a physician's freedom of action"⁷⁹

In fact, several states have moved in this direction. In 1996, Tennessee enacted legislation freeing hospitals from the corporate practice ban while mandating that they not interfere with physicians' medical judgment.⁸⁰ Similarly, a South Dakota statute, while continuing to ban corporate practice per se, stipulates that employing physicians does not constitute practicing medicine so long as the relationship does not "'[i]n any manner, directly or indirectly, supplant, diminish or regulate the physician's independent judgment concerning the practice of medicine or the diagnosis and treatment of any patient.'"⁸¹

Superficially, the proposal seems attractive because the real concern about corporate practice of medicine is not the employment status, but the control that MCOs can exert over physicians. Instead of proscribing particular kinds of structural arrangements such as employment, the remedy is to require MCOs to stop practicing medicine—to cease making their own medical judgments and intruding them into clinical patient care decisions.

Such intuitive appeal fades quickly, however, as the proposal's implications are traced out. "Interfering" in clinical decisions

Id. at 476-77; see also *American Med. Ass'n v. FTC*, 638 F.2d 443 (2d Cir. 1980), *aff'd per curiam*, 455 U.S. 676 (1982); Dowell, *supra* note 8, at 370; Mars, *supra* note 8, at 268; Parker, *supra* note 8, at 167; Rosoff, *supra* note 8, at 493.

78. Mars, *supra* note 8, at 251-52.

79. *Id.* at 265-66; see also Dowell, *supra* note 8, at 372 (in the corporate employment context, the "management agreement should clearly acknowledge the physician will have complete control over matters of diagnosis, treatment, and medical judgment"); Hayward, *supra* note 8, at 428.

80. See TENN. CODE ANN. §§ 63-6-204, 63-6-225, 63-11-205 (1997); see also Mars, *supra* note 8, at 276-77.

81. Hayward, *supra* note 8, at 428 (citing S.D. CODIFIED LAWS § 36-4-8.1 (Michie Supp. 1995)). In like manner, the Texas HMO Act stipulates that the Act does not "authorize any person to regulate, interfere, or intervene in any manner in the practice of medicine or any healing art." TEX. INS. CODE ANN. § 20A.29(b) (West 1981).

seems to be defined as any action that might prompt a physician to refrain from undertaking a particular intervention or to change his proposed course of care. This definition seems implicit, for instance, in *Muse v. Charter Hospital of Winston-Salem, Inc.*⁸² A sixteen-year-old boy, admitted to a psychiatric hospital for suicidal ideation, was discharged by the hospital when his insurance funding ceased. The North Carolina appellate court held that, by discharging the boy solely because funding had expired, the hospital had “interfered” with the physician’s medical judgment. A “hospital has a duty to the patient to obey the instructions of a doctor, absent the instructions being obviously negligent or dangerous. . . . In light of these holdings, it seems axiomatic that the hospital has the duty not to institute policies or practices which interfere with the doctor’s medical judgment.”⁸³

Thus, *Muse* instructs that a hospital must permit physicians to provide care in whatever way they see fit.⁸⁴ The problem with this prescription is that every medical decision is also a spending decision. If physicians have unfettered medical freedom they also have unfettered economic freedom to spend others’ money and use others’ resources. The implication is that hospitals (or MCOs) should have essentially no power to control costs. In an era when the cost of care has risen to nearly unbearable levels, it is difficult

82. 452 S.E.2d 589, 594 (N.C. Ct. App. 1995).

83. *Id.* at 594. Interestingly, other potentially relevant causal factors were dismissed by the court. The patient could have been transferred to a state facility, but was not. Instead, he was doing reasonably well at discharge and went on a week-long vacation with family, after which he began outpatient treatment. Questions were raised about the quality of physicians’ care, both in the inpatient and subsequent outpatient settings. Nevertheless, the court held that the hospital was the cause of the boy’s subsequent suicide because it had interfered with medical judgment.

84. A similar view is expressed in dicta by the Seventh Circuit:

We must remember that doctors, not insurance executives, are qualified experts in determining what is the best course of treatment and therapy for their patients. Trained physicians, and them [sic] alone, should be allowed to make care-related decisions (with, of course, input from the patient). Medical care should not be subject to the whim of the new layer of insurance bureaucracy now dictating the most basic, as well as the important, medical policies and procedures from the boardroom.

Herdrich v. Pegram, 154 F.3d 362, 377 (7th Cir. 1998); *see also Wickline v. State*, 192 Cal. App. 3d 1630, 1645 (1987) (“[T]he physician who complies without protest with the limitations imposed by a third party payor, when his medical judgment dictates otherwise, . . . cannot point to the health care payor as the liability scapegoat when the consequences of his own *determinative* medical decisions go sour.”) (emphasis added); *Mt. Sinai Hosp. v. Zorek*, 271 N.Y.S.2d 1012, 1016 (Civ. Ct. 1966) (stating that only the treating physician can determine appropriate treatment for a given condition); *Pappas v. Asbel*, 675 A.2d 711, 716 (Pa. Super. Ct. 1996) (stating that medical judgments ought to prevail over health plans’ cost concerns).

to defend giving any one party so much control over shared financial resources.

Once we agree that MCOs may—indeed must—“interfere” at least sometimes with physicians’ spending decisions in order to conserve resources,⁸⁵ we are left with powerful questions about who should control what in the delivery of health care. Part IV addresses the issue, after we see this very same question arise via another route.

B. Enterprise Liability

While the above approach has MCOs abjure all medical practice (by never “interfering” with physicians’ judgment), an alternative has MCOs assume all legal liability, regardless of who engaged in the medical practice at issue. Whereas the approach discussed above would have plans avoid medical malpractice liability by avoiding medical practice, under enterprise liability plans bear all liability, including malpractice, because they are viewed as the best locus of responsibility.

Enterprise liability was proposed originally as a way to address broader flaws in the tort system.⁸⁶ Its earliest version advocated consolidating tort liability at the locus where most malpractice incidents happened, identified at that time as the hospital. By focusing all litigation against a single party, it was hoped that faster, less costly resolution of tort claims might be achieved. Further, hospitals might use their influence to enhance the quality of care delivered within their walls while, reciprocally, physicians no longer under the pressure of malpractice suits could avoid the heavy costs of malpractice insurance and feel less impelled to resort to costly defensive medicine.

85. A number of courts have found that it is sometimes legitimate for health plans to deny coverage for resources that a physician might otherwise like to use. See *Free v. Travelers Ins. Co.*, 551 F. Supp. 554, 560 (D. Md. 1982); *Sarchett v. Blue Shield*, 729 P.2d 267, 272–73 (Cal. 1987); *Blue Cross & Blue Shield v. Smither*, 573 S.W.2d 363, 365 (Ky. Ct. App. 1978); *Lockshin v. Blue Cross*, 434 N.E.2d 754, 756–57 (Ohio Ct. App. 1980). But see *Van Vector v. Blue Cross Ass’n*, 365 N.E.2d 638, 643 (Ill. App. Ct. 1977).

86. See Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Choice of the Responsible Enterprise*, 20 AM. J.L. & MED. 29 (1994) [hereinafter Abraham & Weiler, *Responsible Enterprise*]; Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381 (1994) [hereinafter Abraham & Weiler, *Evolution*]; William M. Sage et al., *Enterprise Liability for Medical Malpractice and Health Care Quality Improvement*, 20 AM. J.L. & MED. 1 (1994). For an excellent discussion of historical and current concepts of enterprise liability, see Sage, *supra* note 68, at 173–79.

Enterprise liability as a hospital-oriented concept gained little foothold, partly because changing economic conditions soon meant that health plans, rather than hospitals, became the important locus of control over the financing, delivery, and accountability of care.⁸⁷ Several commentators, however, now support translating the essential concepts underlying enterprise liability into the world of MCOs. As Clark C. Havighurst, one of its leading advocates, recently proposed, "MCOs, as distinguished from indemnity-type health insurers, should bear exclusive legal responsibility for the negligence of physicians treating their subscribers or enrollees."⁸⁸ Accordingly, on this view health plans should bear all liability "for personal injuries and other losses arising from care rendered by health care providers to enrollees under the contract between the health plan and the purchaser of coverage."⁸⁹

Several rationales support enterprise liability. For one thing, as health plans are the main agents of cost containment, they may need the specter of legal liability to keep their cost-cutting from paring down quality.⁹⁰ At the same time, health plans are better positioned than individual physicians to serve as the centers for information technology, disease management, and other population-oriented health care improvements.⁹¹ Moreover, "physicians—relieved of many concerns over individual liability—might participate more readily in cooperative decision making and might be less resistant to clinical practice guidelines and

87. See Havighurst, *supra* note 69, at 603–06, 622; Sage, *supra* note 68, at 159–64, 169–70, 191.

88. Havighurst, *supra* note 69, at 587.

89. *Id.* at 626. Enterprise liability, in other words, would be a form of automatic vicarious liability. See *id.* at 617. It might also be described in terms of nondelegable duties. See *id.* at 614. Other sources discuss the notion of nondelegable duties. See *Thompson v. Nason Hosp.*, 591 A.2d 703 (Pa. 1991); *Walls v. Hazleton State Gen. Hosp.*, 629 A.2d 232 (Pa. Commw. Ct. 1993); *Simmons v. Tuomey Reg'l Med. Ctr.*, 498 S.E.2d 408 (S.C. Ct. App. 1998); *Sampson v. Baptist Mem'l Hosp. Sys.*, 940 S.W.2d 128 (Tex. App. 1996); William S. Brewbaker III, *Medical Malpractice and Managed Care Organizations: The Implied Warranty of Quality*, L. & CONTEMP. PROBS., Spring 1997, at 117, 147–48; Chittenden, *supra* note 11, at 464–65.

Brewbaker discusses a related notion, suggesting that health plans should be held to an implied warranty on the quality of their care. Brewbaker distinguishes implied warranties from enterprise liability mainly insofar as the latter restricts liability exclusively to the health plan or some other single entity. Under Brewbaker's approach, physicians could still be liable in addition to the health plan. See Brewbaker, *supra*, at 134–41. Sage also discusses the merits of the idea, though he does not so heartily endorse it. See Sage, *supra* note 68, at 166–69.

90. See Havighurst, *supra* note 69, at 589; Sage, *supra* note 68, at 164, 166.

91. See Havighurst, *supra* note 69, at 600; Sage, *supra* note 68, at 167, 196.

other efforts by health plans to induce cost-effective practice on a system-wide basis."⁹²

Finally, and of particular concern to Havighurst, "[t]he market-oriented health policy of the 1980s and 1990s could easily give way to heavy-handed government regulation of MCOs unless private-law remedies for torts and breach of contract are perceived to provide adequate deterrence of quality lapses."⁹³ Such regulatory intrusions could squelch a wide array of potentially useful cost-saving and quality-enhancing innovations in health care delivery. Accordingly, Havighurst concludes that "[e]nterprise liability is the logical legal culmination of the shift to de facto corporate responsibility that is revolutionizing American health care."⁹⁴

In sum, conferring legal accountability on MCOs may be the only way to deflect undesirable regulation, legitimize managed care in the eyes of the public and its political representatives, ensure a reasonable level of quality, and secure a viable level of market freedom to assure innovation and improved delivery of care into the future.⁹⁵

Despite its apparent advantages, the idea of requiring MCOs to bear liability for physicians' errors as well as for their own lapses has major drawbacks. An underlying rationale is to encourage MCOs to be more involved not only in selecting and monitoring their physicians, but also in influencing day-to-day clinical practice.⁹⁶ Yet it is not clear that increasing health plans' clinical influence, via increasing their legal risks, is necessarily desirable. An instructive parallel comes from health plans' growing economic risks, which have prompted them to exercise greater clinical controls as a way of controlling their costs. Some tactics have been obviously quite crude.⁹⁷ Others have been more subtle. Intensive

92. Sage, *supra* note 68, at 166.

93. Havighurst, *supra* note 69, at 590-91. As troubling questions about MCOs' quality of care are pressed, "a strong backlash against HMOs and other managed care plans is threatening to move many decisions out of the hands of competing health plans and into the hands of Congress or state legislatures." *Id.* at 591.

94. Havighurst, *supra* note 69, at 588.

95. *See id.* at 594-95.

96. *See id.* at 616.

97. Some MCO rules have caused fairly obvious inefficiencies. In some MCOs, a physician must seek approval for every intervention over \$200, for instance, perhaps waiting long periods, only to speak with a utilization clerk lacking the education or medical sophistication to understand the question; an MCO may "deselect" a physician for ordering an ambulance to transport an unconscious patient; specialist referrals might be limited to just one visit; or the MCO may contract with hospitals and other facilities far from members' homes, potentially exacerbating an illness or injury while a patient is en route to the distant site. *See* Marsha R. Gold et al., *A National Survey of the Arrangements Managed-Care Plans Make with Physicians*, 333 *NEW ENG. J. MED.* 1678 (1995); Joan B. Trauner & Julie S. Chesnutt, *Medical*

UR and gatekeeping arrangements, for instance, are costly and may be only marginally effective.⁹⁸ Tightly constrained pharmaceutical formularies may save short-term drug costs, but can raise rates of hospitalization and emergency room use, as some patients experience greater side-effects and adherence problems with older, cheaper, or generic drugs that are not quite equivalent to their newer counterparts.⁹⁹ Failure to make timely specialist referrals can generate multiple visits, extensive testing, and treatment failures.¹⁰⁰

If MCOs' increased economic risk has precipitated clinically counterproductive intrusions, it might be expected that increasing their legal risk would have a similar effect because whoever bears risk, whether economic or legal, has an incentive to take whatever available measures might limit that risk. Those measures, particularly if undertaken by people with legal or business expertise but no clinical medical expertise, may interfere with good patient care.¹⁰¹

Groups in California: Managing Care Under Capitation, HEALTH AFF., Spring 1996, at 159; Edward Felsenthal, *When HMOs Say No to Health Coverage, More Patients Are Taking Them to Court*, WALL ST. J., May 17, 1996, at B1; Richard K. McDonald, *My Practice Almost Destroyed Me*, MED. ECON., Mar. 11, 1996, at 181.

98. See Robert L. Bree et al., *Effect of Mandatory Radiology Consultation on Inpatient Imaging Use*, 276 JAMA 1595, 1597 (1996); Stanley Goldfarb, *Physicians in Control of the Capitated Dollar: Do Unto Others . . .*, 123 ANNALS INTERNAL MED. 546, 546 (1995); Stephen N. Rosenberg et al., *Effect of Utilization Review in a Fee-for-Service Health Insurance Plan*, 333 NEW ENG. J. MED. 1326, 1328-29 (1995); Martin F. Shapiro & Neil S. Wenger, *Rethinking Utilization Review*, 333 NEW ENG. J. MED. 1353, 1353 (1995).

99. See Susan D. Horn et al., *Formulary Limitations and the Elderly: Results from the Managed Care Outcomes Project*, 4 AM. J. MANAGED CARE 1105, 1105 (1998); Steven A. Schroeder & Joel C. Cantor, *On Squeezing Balloons—Cost Control Fails Again*, 325 NEW ENG. J. MED. 1099, 1099 (1991); Stephen B. Soumerai et al., *A Critical Analysis of Studies of State Drug Reimbursement Policies: Research in Need of Discipline*, 71 MILBANK Q. 217, 217 (1993) [hereinafter Soumerai, *Critical Analysis*]; Stephen B. Soumerai et al., *Effects of Limiting Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services by Patients with Schizophrenia*, 331 NEW ENG. J. MED. 650, 654 (1994); Stephen B. Soumerai et al., *Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes*, 325 NEW ENG. J. MED. 1072, 1074-76 (1991); Dan A. Streja et al., *Selective Contracting and Patient Outcomes: A Case Study of Formulary Restrictions for Selective Serotonin Reuptake Inhibitor Antidepressants*, 5 AM. J. MANAGED CARE 1133, 1133-34 (1999).

100. See Barbara Gerbert et al., *Primary Care Physicians as Gatekeepers in Managed Care: Primary Care Physicians' and Dermatologists' Skills at Secondary Prevention of Skin Cancer*, 132 ARCHIVES DERMATOLOGY 1030, 1035 (1996); Robert S. Kirsner & Daniel G. Federman, *Lack of Correlation Between Internists' Ability in Dermatology and Their Patterns of Treating Patients with Skin Disease*, 132 ARCHIVES DERMATOLOGY 1043, 1043 (1996).

101. Havighurst himself has noted the connection between risk and control in an earlier work, suggesting that hospitals might willingly accept increased liability in order to gain increased control. He notes hospitals' response to the case of *Darling v. Charleston Community Memorial Hospital*, 211 N.E.2d 253 (Ill. 1965), in which liability was imposed on a hospital for its physician staff's failures: "More surprising than the legal result in that case was the widespread reaction to it, which suggested that hospital managers had been waiting for some excuse to demand more cooperation and quality assurance from their medical staffs." Clark

These concerns, already raised by physician groups,¹⁰² are only part of the problem. An even deeper problem concerns the very standards by which to judge the quality of medical care. Under the common law, the standard of care that physicians owe their patients is determined almost exclusively by the profession itself. With some variations permitted for schools of thought, specialty fields, locality, and other factors,¹⁰³ physicians' prevailing practices almost universally determine the kind and quality of care to which a patient is entitled. If MCOs become solely responsible for adverse medical outcomes, it is reasonable to expect that they will require their physicians to adhere closely to MCO-chosen guidelines. The more rigid the adherence, the more those guidelines will actually become prevailing practice. Once that happens, then adherence will almost always be legally adequate to ward off adverse malpractice judgments, regardless of how poorly patients fare under them. The only alternative to this scenario, under enterprise liability, would be for courts to abandon their traditional reliance on prevailing physician practices and establish some sort of court-ordered standards that may be no better than MCO-ordered standards.¹⁰⁴

C. Havighurst, *Doctors and Hospitals: An Antitrust Perspective on Traditional Relationships*, 1984 DUKE L.J. 1071, 1079.

102. See Havighurst, *supra* note 69, at 628; Sage, *supra* note 68, at 170 n.46.

103. See E. Haavi Morreim, *Cost Containment and the Standard of Medical Care*, 75 CAL. L. REV. 1719, 1729-43 (1987).

104. One well-known example in which a court attempted to manufacture a standard of care to supplant the physician-based standard it considered inadequate is *Helling v. Carey*, 519 P.2d 981 (Wash. 1974). A young woman visited her ophthalmologist repeatedly for eye problems, but her underlying glaucoma was discovered too late to save her sight. Because glaucoma is almost completely confined to older patients, the standard of care had not included testing patients under age 40. The court saw fit to change the standard of care, contradicting prevailing practice:

The precaution of giving this test to detect the incidence of glaucoma to patients under 40 years of age is so imperative that irrespective of its disregard by the standards of the ophthalmology profession, it is the duty of the courts to say what is required to protect patients under 40 from the damaging results of glaucoma.

We therefore hold, as a matter of law, that the reasonable standard that should have been followed under the undisputed facts of this case was the timely giving of this simple, harmless pressure test . . . and that, in failing to do so, the defendants were negligent, which proximately resulted in the blindness sustained by the plaintiff for which the defendants are liable.

Id. at 983.

The court failed to consider some relevant data. Once one recognizes that the tonometry test used to detect glaucoma has very poor sensitivity and specificity (that is, it has high numbers of both false-positives and false-negatives), and once these are brought to the under-40 population that has a very low incidence of glaucoma, the actual value of the test is stunningly low, and cumulative costs are stunningly high. On one analysis, if the test were

Havighurst might not be unduly disturbed by such an outcome. His objective, as noted, is to foster greater MCO influence over day-to-day clinical practice.¹⁰⁵ Such amplified MCO control, however, may not be altogether benign. The guidelines by which MCOs currently determine which interventions they will cover are not always of the highest scientific caliber, and even well-founded guidelines do not apply to every patient.¹⁰⁶

Even more troubling, quality in a realm as complex as health care is unlikely to be achieved by a strictly one-way flow in which information, guidelines, and instructions go from the MCO to the physicians as the former "supervises" the latter to ensure that its standards are met. Optimal quality of care requires that physicians reciprocally "supervise" the MCO, to advise when a guideline is not effective, or when it would disserve a particular patient's needs.¹⁰⁷ Checks and balances are essential. If an MCO bears all legal responsibility for adverse outcomes, however, and if its very adoption of a particular guideline will tend to make that guideline the standard of care, then MCOs may not be warmly receptive to physicians' challenges.

At the same time, physicians in such a system may be extremely reluctant to challenge their MCOs. Under the current system, the prospect of a malpractice suit shadows physicians, but they know that the great majority of adverse outcomes do not lead to malpractice claims, even where the injury was the product of negligence.¹⁰⁸ With the further knowledge that problems in rapport and relationships are more likely to trigger suits than adverse outcomes,¹⁰⁹ physicians can take reasonable steps to avoid lawsuits. Where tort claims are nevertheless filed, the financial costs of liti-

routinely used for patients under age 40, for every one patient whose glaucoma was correctly diagnosed by the test, some 17,500 other young people would have test results that falsely indicated the presence of glaucoma. If the test were repeated on this group, the number of false-positives would be reduced to 12,250. In all, "twenty-eight rounds of tonometry tests, 83,348 separate tests, would be required to reduce the number of false positives to fewer than two. At a mean charge of \$25 per test, this series of tests would cost \$2,083,700." Eric E. Fortess & Marshall B. Kapp, *Medical Uncertainty, Diagnostic Testing, and Legal Liability*, 13 L. MED. & HEALTH CARE 213, 217 (1985).

105. See Havighurst, *supra* note 69, at 616-17.

106. See *infra* notes 118-39 and accompanying text.

107. For further discussion, see *infra* Part IV.

108. See Troyen A. Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients—Results of the Harvard Medical Practice Study I*, 373 NEW ENG. J. MED. 370, 373 (1991).

109. See generally Wendy Levinson, *Physician-Patient Communication: A Key to Malpractice Prevention*, 272 JAMA 1619 (1994); Wendy Levinson et al., *Physician-Patient Communication: The Relationship with Malpractice Claims Among Primary Care Physicians and Surgeons*, 277 JAMA 553 (1997); Berkeley Rice, *Where Doctors Get Sued the Most*, MED. ECON., Feb. 27, 1995, at 109; Paul A. Sommers, *Malpractice Risk and Patient Relations*, 20 J. FAM. PRAC. 299 (1985).

gation and adverse judgments will be covered by malpractice insurers. Nothing can remove completely the threat of malpractice suits, but in most situations the issue can remain reasonably well in the background of daily clinical practice.

The scene could be strikingly different under enterprise liability. Here the MCO, not the tort lawyer, poses the threat. That threat is constant, not intermittent. The prospect of being fired, or of having one's privileges or income reduced, may be far more likely and more immediate. A vigilant MCO that monitors its physicians' every move has a better chance of spotting a deviation from standards than does the average patient. Moreover, the financial damages of being disciplined by the MCO are borne, not by an insurer, but by the physician himself. Those costs can be enormous.

One answer is for the physician to ensure that his care is of high quality. More realistically, the physician may seek to ensure that his care is high-quality *as perceived by the MCO*. He will be rewarded for following the guidelines, not for challenging them. If the MCO's guidelines are inferior, then let the MCO bear the liability. Under such a scenario, where physicians may be penalized for challenging the MCO, but not penalized for failing to challenge, physicians may not be eager to help improve quality by pointing out MCOs' flaws. As a further disincentive to being the "squeaky wheel," MCOs typically evaluate physicians, not only on their medical quality, but also on their economic performance. Being a costly physician can just as easily trigger an unfavorable review as being a poor-quality physician. Thus, although enterprise liability theoretically gives health plans an incentive to strive for quality, it may actually give physicians perverse incentives to cooperate in only superficial ways. That sort of don't-rock-the-boat complicity could produce a mediocrity that no one would embrace.

Such heightened MCO control over clinical practices raises the very specters that prompted the original corporate practice bans so many years ago: supervision of intimate, medically sensitive decisions by non-medical personnel, and a dividing of physicians' allegiances between patients and corporations. As the Indiana Supreme Court noted:

The master is in a position where he may dictate to his servant the manner of conducting his business, the kind and nature of the goods to be sold and furnished to the patient, in order

to procure the most favorable financial gain to the employer.
And this may be done without regard to the public health
.....¹¹⁰

When corporations feel pressed to control every detail of the medical care for which they bear legal risk, even beyond the economic risks they now bear, the potential implications are troubling.

C. The Real Dispute: Who Should Control What

After first concluding that MCOs can and do practice medicine, Part II turned to the question of what sort of liability MCOs ought to bear when they practice medicine. An important lesson has emerged from examining two attempts to resolve that challenge. Statutes forbidding health plans from “interfering” with physicians’ clinical judgment avoid the problems of *nouveau-corporate* practice of medicine, but at the cost of handing virtually all clinical and thereby all economic control to physicians. Such a scheme grants doctors virtually unlimited freedom to spend other people’s money. Reciprocally, however, enterprise liability gives all legal responsibility, and thereby virtually all clinical control, to the health plans. Their opportunities to practice medicine would burgeon unacceptably. Between these unsavory alternatives—ceding all economic control to physicians, versus ceding all clinical control to health plans—there must surely be a better answer.¹¹¹

The better answer begins with the suggestion that the foregoing analyses start with the wrong questions. The first approach began with the implicit question of how to preserve clinical control in physicians’ hands, a view presupposing that all control should indeed be in physicians’ hands. In a comparable vein, proponents of

110. *Bennett v. Indiana State Bd.*, 7 N.E.2d 977, 981 (Ind. 1937). Similarly, the South Dakota Supreme Court feared an “undue emphasis on mere money making, and commercial exploitation of professional services. . . . Such an ethical, trustworthy and unselfish professionalism as the community needs and wants cannot survive in a purely commercial atmosphere.” *Bartron v. Codington County*, 2 N.W.2d 337, 346 (S.D. 1942).

111. Physicians and plans, of course, are hardly the only players in the delivery of health care. Employers, other kinds of providers and, above all, patients have a key role. However, physicians have the legally crucial power of prescription, and with it a virtual monopoly over access to many diagnostic and therapeutic interventions. Health plans, including employers where plans are self-funded, have a similar near-monopoly over access to the funding that is prerequisite to most health care. Because these two entities play such a crucial role, attention in this Article focuses on them exclusively.

enterprise liability¹¹² began with the question “whom do we want to bear liability in health care,” a view presupposing that the most important question is who should bear the costs of adverse outcomes. But as argued above, we should not assign liability to an MCO for anything we do not want the MCO to control in the first place.

Accordingly, instead of asking “how do we preserve physician control” or “who should bear liability,” the first question should be “whom do we want to control which aspects of health care.” If we want high-quality health care and efficient, effective health care systems, we must ask which party is able to perform best for a given aspect of health care. On the other side of the same coin, if we do not want a particular party to exercise control over some aspect of health care, then we should not assign liability to that party. Rather, liability should be ascribed, post hoc, to those who, by antecedent analysis, could and should have exercised control. However, the answer to the question who should control what aspects of health care is neither simple nor self-evident.

IV. CLINICAL CONTROL: PHYSICIANS VERSUS HEALTH PLANS

This Part suggests that high-quality health care should best be achieved by a sharing of control and responsibility, appropriately distributed between physicians and health plans.

A. Limits on Health Plans' Control

Physicians must be able to exercise a considerable degree of independent clinical discretion in the care of individual patients.¹¹³ The reasons are classic and familiar.

First, it has already been noted¹¹⁴ that the most central characteristic of medicine as a learned profession is the requirement of

112. See Abraham & Weiler, *Evolution*, *supra* note 86, at 399–414; Abraham & Weiler, *Responsible Enterprise*, *supra* note 86, at 29–36; Sage, *supra* note 68, at 162; Sage et al., *supra* note 86, at 7.

113. See generally E. Haavi Morreim, *Saving Lives, Spending Money: Shepherding the Role of Technology*, in *ETHICS AND VALUES IN HEALTH CARE AND MEDICINE ON THE FRONTIERS OF THE TWENTY-FIRST CENTURY* 63 (James Bono & Stephen Wear eds., forthcoming 2000) [hereinafter Morreim, *Saving Lives*].

114. See *supra* note 57 and accompanying text.

judgment. The physician must bring scientific generalities and finely honed skills to the care of patients whose personal and biological idiosyncrasies may defy any standard routines of care. The hallmark of a profession is the need to make judgments that combine an esoteric, expansive knowledge with a host of uncertainties and peculiarities inherent in individual situations, toward the objective of meeting deeply important human needs.¹¹⁵ At some point, only a physician who has personally examined a patient can discern the specific character of that person's symptoms, evaluate which are most important, and bring these together into a coherent picture of what is happening and what could or should be done. Although more distant observers can comment intelligently about the best general approach to the assessment and management of a problem, a professional directly involved with the patient is almost always in the best position to determine whether those suggestions actually fit the realities of the case.

Second, in the era of high technology medicine it has become nearly impossible to provide even simple, mundane kinds of care without ready access to an array of resources. An orthopedist cannot diagnose a fracture without radiographs, and cannot surgically reduce that fracture without a well-equipped operating facility; the oncologist needs sophisticated pharmaceuticals, radiation, and chemotherapy; the infectious disease specialist needs quick access to laboratory tests and antibiotics to treat bacterial meningitis or pneumonia; the primary care physician must be free to provide a variety of common tests and treatments. Admittedly, not all medical routines are well-conceived, and vexing questions arise concerning new technologies. As argued below,¹¹⁶ health plans have a legitimate role in providing general guidance for both medical and economic efficiency in health care. But in daily clinical care, physicians should not be required to fight for every resource at every step for every patient. Endless delays to secure innumerable approvals can be medically hazardous, not to mention demoralizing to physicians and patients alike. In general, physicians require ample freedom to examine the patient, determine that certain ordinary steps are reasonable, and take them.

Third, good health care is often impossible to provide without a personal relationship between patient and provider. The patient who does not trust her physician may be unwilling to disclose

115. For a useful introduction, with references, concerning the defining characteristics of professions, see David T. Ozar, *Profession and Professional Ethics*, in 4 ENCYCLOPEDIA OF BIOETHICS 2103, 2103-12 (Warren T. Reich ed., 1995).

116. See *infra* Part IV.C.1.

medical history that is crucial to diagnostic accuracy, or may be unwilling to adhere to treatment if she does not believe that her provider is both knowledgeable and devoted to her best interests as an individual. Physicians can examine and prescribe endlessly, but if patients refuse to cooperate, it is to little avail. Reciprocally, the patient who asks for a particular intervention has deep suspicions if his physician, embedded in financial incentives or in an MCO-controls-all health plan, suggests that such an intervention is unnecessary. The result can be a gamesmanship that thwarts both clinical quality and economic controls.

Such physician-patient trust requires that physicians have sufficient flexibility to negotiate with patients to reach mutually acceptable courses of action. If the physician does not have the discretion to offer choices suitable to the patient's personal circumstances and values, then in an important sense, the physician and patient do not relate to each other. Rather, they relate to a third party who tells each of them what to do.¹¹⁷ The more severely MCOs limit physicians' capacity to fine-tune guidelines to patients' needs, the less opportunity arises to build trust, and the poorer those patients' care may be.

Finally, even though physicians admittedly can err, and even though their clinical routines are not always based on the best science and judgment, MCOs are not necessarily better-suited to do the job. In particular, the tools by which MCOs currently second-guess physicians' judgments are often deeply flawed. Although practice guidelines have proliferated in health care,¹¹⁸ many of those by which MCOs make benefits determinations and UM decisions, and which they expect physicians to follow, have little, no, or poor-quality scientific basis. The reasons are numerous.

Many important topics in medicine have not been studied scientifically.¹¹⁹ Coronary artery bypass surgery, for example, was first

117. See Morreim, *supra* note 36, at 333.

118. According to one estimate, some 75 national organizations have developed about 1800 sets of guidelines. See Jon Gabel, *Ten Ways HMOs Have Changed During the 1990s*, HEALTH AFF., May/June 1997, at 134, 142.

119. As noted by Feinstein, clinical research, as opposed to basic science and laboratory research, has long been looked down upon as being somehow inferior "applied" work. As a result, until recently funding has focused mainly on the latter. See Alvan R. Feinstein, *Clinical Judgment Revisited: The Distraction of Quantitative Models*, 1230 ANNALS INTERNAL MED. 799 (1994). Other commentators have noted that those who use guidelines

cannot help but notice that guideline developers must often reckon with research that is modest in rigor, discordant, or nonexistent. Although most guidelines are an amalgam of evidence and expert opinion, methods of integrating knowledge and experience into guidelines, particularly when data are sparse, are neither as mature nor as transparent as methods of incorporating research results.

performed in 1964, but its efficacy was not scientifically evaluated until 1977; similarly, angioplasty to open up clogged arteries in the heart was “performed in hundreds of thousands of patients prior to the first randomized clinical trial demonstrating efficacy in 1992.”¹²⁰ In another example, as of 1988, a national conference on antithrombotic therapy¹²¹ evaluated the scientific foundation for various existing recommendations on which physicians based treatment. The American College of Chest Physicians found that only twenty-four percent of such recommendations were based on scientific studies, while fifty-five percent were based on uncontrolled clinical observations. Ten years later, forty-four percent of the recommendations were science-based, though this was largely because of Food and Drug Administration requirements for the testing of new drugs.¹²² Where scientific studies are available, they are not always incorporated into guidelines because groups and organizations that construct guidelines may have agendas other than scientific purity, or they may simply fail to perform a sufficiently thorough search for available studies.¹²³

Moreover, the very best kind of science, the randomized, double-blind controlled trial, does not always apply well to ordinary patients. In order to test strictly for the effects of the specific drug or procedure under investigation, scientific study design must be restricted to patients fitting a narrow set of eligibility criteria. Typically the research subjects must suffer from only the particular disease whose treatment is being studied, with a minimum of other diseases and medications. After all, when subjects suffer simultaneously from multiple diseases and treatments, it is difficult for scientists to distinguish between the effects of the study-treatment and all the other potentially confounding factors.¹²⁴ Once the study

Deborah Cook & Mita Giacomini, *The Trials and Tribulations of Clinical Practice Guidelines*, 281 JAMA 1950, 1950 (1999).

120. James E. Dalen, “Conventional” and “Unconventional” Medicine, 158 ARCHIVES INTERNAL MED. 2179, 2180 (1998).

121. Antithrombotic therapies are blood-thinning, or anti-clotting, treatments used to prevent stroke, pulmonary embolism, and the like.

122. See Dalen, *supra* note 120, at 2179–80.

123. See Judith Wilson Ross, *Practice Guidelines: Texts in Search of Authority*, in GETTING DOCTORS TO LISTEN: ETHICS AND OUTCOMES DATA IN CONTEXT 41–70 (Philip J. Boyle ed., 1998).

124. In scientific research, evaluation of diseases and treatments

generally requires a priori hypotheses, randomization (to eliminate selection bias and confounding), homogeneous patients at high risk for the outcome, experienced investigators who follow a protocol, a comparative measure such as placebo (if ethical), and intensive follow-up to ensure compliance. Under these circumstances, if a treat-

is complete, however, its results are applied in clinical practice to all the more complex patients who could never have been eligible for the study.¹²⁵

Outcomes studies are an emerging kind of research intended to establish better correlations between what physicians do during clinical care and the results that patients actually experience, both long- and short-term. Outcomes studies in general suffer from a lack of standardized methodologies—what counts as an outcome, which costs should be tallied, and the like.¹²⁶ Among the legitimate

ment proves to be better than a placebo (or a comparative measure), one can be reassured that the treatment can work.

However, questions may remain about the ability of the treatment to work adequately in a broader range of patients and in usual practice settings in which both patients and providers face natural barriers to care.

Epstein & Sherwood, *supra* note 19, at 833; *see also* Alvan R. Feinstein & Ralph I. Horwitz, *Problems in the "Evidence" of "Evidence-Based Medicine,"* 103 AM. J. MED. 529 (1997); Kenneth B. Wells & Roland Sturm, *Care for Depression in a Changing Environment,* HEALTH AFF., Fall 1995, at 78, 80.

125. *See generally* Epstein & Sherwood, *supra* note 19. Regarding coronary bypass surgery, some experts observed that "only 4 to 13 percent of the patients who now undergo this operation would meet the eligibility criteria for the randomized controlled trials that established its efficacy." Annetine C. Gellins et al., *Capturing the Unexpected Benefits of Medical Research,* 339 NEW ENG. J. MED. 693, 694 (1998). Sometimes the result of the discrepancy between eligible research subjects and ordinary patients is that even well-researched new drugs and procedures must be quickly withdrawn from the market, as they suddenly produce undesirable results and side-effects that were not seen during the research period. *See, e.g.,* Michael A. Friedman et al., *The Safety of Newly Approved Medicines: Do Recent Market Removals Mean There Is a Problem?,* 281 JAMA 1728 (1999); Elyse Tanouye, *American Home Withdraws New Drug to Ease Pain, After Death of 4 Patients,* WALL ST. J., June 23, 1998, at A3.

126. *See, e.g.,* E. Andrew Balas et al., *Interpreting Cost Analyses of Clinical Interventions,* 279 JAMA 54, 56 (1998); Arnold Epstein, *Performance Reports on Quality—Prototypes, Problems, and Prospects,* 333 NEW ENG. J. MED. 57, 58–59 (1995); Robert G. Evans, *Manufacturing Consensus, Marketing Truth: Guidelines for Economic Evaluation,* 123 ANNALS INTERNAL MED. 59, 59 (1995); Feinstein, *supra* note 119, at 800; Jerome P. Kassirer & Marcia Angell, *The Journal's Policy on Cost-Effectiveness Analyses,* 331 NEW ENG. J. MED. 669, 669 (1994); Soumerai et al., *Critical Analysis,* *supra* note 99, at 249.

For a summary of economic analysis, see Task Force on Principles for Economic Analysis of Health Care Technology, *Economic Analysis of Health Care Technology: A Report on Principles,* 123 ANNALS INTERNAL MED. 61 (1995). Economic outcomes research offers

unique methodologic choices, such as which types of costs to include (direct, indirect, intangible, induced), which perspective to apply (that of society, payer, provider, patient), which design to adopt (cost-identification, cost-benefit, cost-effectiveness, cost-utility), from where to obtain costs (indemnity database, managed care or capitated database, hospital cost systems, Medicare, Medicaid), and whether to collect resource consumption data prospectively or retrospectively through various modeling techniques.

methodologies, each has significant advantages and disadvantages. For instance, administrative databases (hospital billing records) permit great breadth, quantity, and easy availability of data, but are often littered with gaps and inaccuracies.¹²⁷ Furthermore, because many organizations undertake their outcomes studies independently, it is difficult for any single project to be large enough to achieve statistical significance.¹²⁸

In designating endpoints of study, one study might take survival alone as the mark of success, while another might focus on survival without major neurological deficits. Compare Hilary E. Whyte et al., *Extreme Immaturity: Outcome of 568 Pregnancies of 23–26 Weeks' Gestation*, 82 OBSTETRICS & GYNECOLOGY 1 (1993), with Marilee C. Allen et al., *The Limit of Viability—Neonatal Outcome of Infants Born at 22 to 25 Weeks' Gestation*, 329 NEW ENG. J. MED. 1597 (1993).

Regarding guidelines activities more generally, Power has noted:

These guidelines activities are uncoordinated . . . and different agencies sometimes issue different guidelines on the same topic. Occasionally, their recommendations conflict.

At least some of these differences are probably attributable to the vastly different methods used to create the guidelines. Methodological differences include the types of people selected to be in the expert group, methods used to collect and synthesize evidence, methods used to structure the group discussion and arrive at consensus, and degree to which recommendations are linked directly with the evidence behind them.

Elaine J. Power, *Identifying Health Technologies That Work*, 274 JAMA 205, 205 (1995); see also Mark Holoweiko, *When an Insurer Calls Your Treatment Experimental*, MED. ECON., Sept. 11, 1995, at 172; Laurie Jones, *Does Prevention Save Money?*, AMER. MED. NEWS, Jan. 9, 1995, at 17, 22.

127. See generally John Hornberger & Elizabeth Wrone, *When to Base Clinical Policies on Observational Versus Randomized Trial Data*, 127 ANNALS INTERNAL MED. 679 (1997); Lisa I. Iezzoni, *Assessing Quality Using Administrative Data*, 127 ANNALS INTERNAL MED. 666 (1997); Wayne A. Ray, *Policy and Program Analysis Using Administrative Data Banks*, 127 ANNALS INTERNAL MED. 712 (1997).

128. Epstein and Sherwood note:

Even when measures are aggregated, statistical power may be insufficient to detect a significant improvement in outcomes. For example, in a modestly sized health plan with 25,000 members, one might estimate that 150 persons have diabetes and use insulin. Even if all 150 participated in a program that reduced the number of diabetes-related complications by 50% through improved diet, exercise, and appropriate use of insulin, the statistical power would be too low to document the program value compared with complication rates with a previous program.

Epstein & Sherwood, *supra* note 19, at 833; see also Mary L. Durham, *Partnerships for Research Among Managed Care Organizations*, HEALTH AFF., Jan./Feb. 1998, at 111, 114. For further discussion of the scientific problems behind health plans' practice guidelines, see BERUCH A. BRODY, *ETHICAL ISSUES IN DRUG TESTING, APPROVAL, AND PRICING* (1995); American College of Physicians, *The Oversight of Medical Care: A Proposal for Reform*, 120 ANNALS INTERNAL MED. 423 (1994); David M. Eddy, *Three Battles to Watch in the 1990s*, 270 JAMA 520 (1993); Robert G. Evans, *Manufacturing Consensus, Marketing Truth: Guidelines for Economic Evaluation*, 123 ANNALS INTERNAL MED. 59, 59 (1995); Alan M. Garber, *Can Technology As-*

In other cases, outcomes studies look scientific, yet lack any acceptable methodology at all,¹²⁹ while still others may be corrupted by researchers' personal conflicts of interest.¹³⁰ In some cases, studies are undertaken by drug and device manufacturers, insurers, managed care organizations, or employers, all of whom may have substantial conflicts of interest.¹³¹ Such conflicts do not inherently mean that the resulting research will be biased or inaccurate, but the hazards cannot be dismissed. At the other end, studies undertaken by government or academic groups may completely ignore considerations of economics and cost-effectiveness.¹³²

Rather like outcomes studies, post-marketing research on FDA-approved products is typically undertaken to demonstrate which pharmaceuticals or other products are most cost-effective. Yet such research has no official requirements for scientific rigor, and

assessment Control Health Spending?, HEALTH AFF., Summer 1994, at 115, 124; Alan L. Hillman et al., *Avoiding Bias in the Conduct and Reporting of Cost-Effectiveness Research Sponsored by Pharmaceutical Companies*, 324 NEW ENG. J. MED. 1362 (1991); Kassirer & Angell, *supra* note 126, at 669; David A. Kessler et al., *Therapeutic-Class Wars—Drug Promotion in a Competitive Marketplace*, 331 NEW ENG. J. MED. 1350 (1994); Steven D. Pearson et al., *Critical Pathways as a Strategy for Improving Care: Problems and Potential*, 123 ANNALS INTERNAL MED. 941, 943–44 (1995); Drummond Rennie, *Thyroid Storm*, 277 JAMA 1238 (1997); Henry Thomas Stelfox et al., *Conflict of Interest in the Debate Over Calcium-Channel Antagonists*, 338 NEW ENG. J. MED. 101 (1998); Task Force on Principles for Economic Analysis of Health Care Technology, *supra* note 125, at 61; Steven H. Woolf & Robert S. Lawrence, *Preserving Scientific Debate and Patient Choice: Lessons from the Consensus Panel on Mammography Screening*, 278 JAMA 2105 (1997); George Anders, *Limits on Second-Eye Cataract Surgery Are Lifted by Major Actuarial Firm*, WALL ST. J., Dec. 15, 1994, at B6; Ralph T. King, Jr., *In Marketing of Drugs, Genentech Tests Limits of What Is Acceptable*, WALL ST. J., Jan. 10, 1995, at A1.

129. One pharmaceutical company, for instance, compiled an extensive registry listing patients who had a particular illness (e.g., heart attack) and what treatments they received with what outcome. The registry paid physicians to provide considerable information about the use of drugs manufactured by the company, but not about patients who received alternate treatments. As a result, the data is not only *not* the product of any controlled trials, it does not even include comparative information. Although it has the look of science and is often cited by physicians, it is thus not seriously scientific. See King, *supra* note 128.

Similarly, a study of clot lysis in patients who have suffered heart attack might, if funded by the manufacturer of one particularly expensive drug, incorporate methodological or analytic techniques that might tend to favor that drug. See BRODY, *supra* note 128, at 144–52.

130. See BRODY, *supra* note 128; Stelfox, *supra* note 128.

131. See Andrew F. Nelson et al., *The State of Research Within Managed Care Plans: 1997 Survey*, HEALTH AFF., Jan./Feb. 1998, at 128.

132. One study found that the majority of guidelines in peer-reviewed medical literature in fact do not mention costs at all, and only 14% provided any estimates about costs of various options for care. See Terrence M. Shaneyfelt et al., *Are Guidelines Following Guidelines? The Methodological Quality of Clinical Practice Guidelines in the Peer-Reviewed Medical Literature*, 281 JAMA 1900, 1904 (1999); see also Larry Culpepper & Jane Sisk, *The Development of Practice Guidelines: A Case Study in Otitis Media with Effusion*, in GETTING DOCTORS TO LISTEN: ETHICS AND OUTCOMES DATA IN CONTEXT 71, 80 (Philip J. Boyle ed., 1998).

studies are sometimes more of a marketing device than a bona fide research effort.¹³³

Where a dearth of credible studies requires the use of expert consensus panels to fill in the blanks, further opportunities for bias arise if those who choose the experts have a financial interest in the conclusions those panels reach. Absent good science, or science supporting their objectives, guidelines-creators may simply rely on the *Merck Manual*, Medicare guidelines, "an administrator who 'asked friends who are doctors,' or an insurance company's employee-physician (usually not a specialist in the field in question) who reads textbooks and discusses the issue with other insurance company physicians."¹³⁴ As several commentators recently observed, "materials such as the practice guidelines prepared by Milliman and Robertson, a well-known actuarial firm, often rely on insurers' own decisions rather than on well-designed scientific research."¹³⁵ Even where guideline developers attempt to remain as free of bias and conflict of interest as possible, their personal values can powerfully influence their final recommendations, as for example when they evaluate the desirability of various outcomes.¹³⁶

Equally important, guidelines often do not leave room for issues that are personally important to patients. Many studies only collect data on a limited array of outcomes, such as mortality or tumor shrinkage, and do not include factors such as a treatment's effects

133. The only requirement is that the results of such studies not be used in official marketing. See Hillman et al., *supra* note 128. In the worst examples, some of these studies are simply marketing devices, without any scientific merit. One such "study," for instance, was ostensibly intended to

assess the efficacy and tolerability of [the company's drug] in controlling mild-to-moderate hypertension. The sponsor used its sales force to recruit 2500 office-based "investigators" who were frequent prescribers of drugs in the therapeutic class in question. Each investigator was to enroll 12 patients (for a total enrollment of 30,000) and was offered reimbursement of \$85 per patient enrolled, or \$1050 per physician.

The "study" was not capable of achieving even the modest objectives stated. There was no control group, and the study was not blinded. There was thus no possibility that it would generate useful data on efficacy and little likelihood that it would produce data on safety other than the potential for detecting a rare adverse event.

Kessler et al., *supra* note 128, at 1351.

134. Angela R. Holder, *Medical Insurance Payments and Patients Involved in Research*, 16 IRB 19, 19 (1994).

135. Sara Rosenbaum et al., *Who Should Determine When Health Care Is Medically Necessary?*, 340 NEW ENG. J. MED. 229, 231 (1999).

136. See Shaneyfelt et al., *supra* note 132, at 1904.

on quality of life.¹³⁷ Neither do they always have room for patients' personal preferences,¹³⁸ which can be crucial for long-term adherence to therapy, a factor especially important in chronic illness. In sum, MCOs cannot at present claim to provide any divine revelation of how health care should be delivered, either in broad terms or for their own particular enrollees. To the extent that guidelines are plainly inapplicable in individual cases, physicians must have discretion if they are to meet patient needs.¹³⁹

B. Limits on Physicians' Control

From these limits on health plans' capacities, however, it would be a mistake to infer that unlimited clinical discretion for physicians would be the best way to optimize health care. Contrary to common assumptions, physicians—even those within a subspecialty area—do not necessarily share a basic set of knowledge and skills. Clinical practices vary widely, often with no underlying basis in patients' illnesses.¹⁴⁰ “[S]everal studies estimate that only 15 to 20

137. See Fred Gifford, *Outcomes Research and Practice Guidelines: Upstream Issues for Downstream Users*, HASTINGS CTR. REP., Mar.–Apr. 1996, at 38, 42; Ian F. Tannock, *Treating the Patient, Not Just the Cancer*, 317 NEW ENG. J. MED. 1534 (1987).

138. See Feinstein & Horwitz, *supra* note 124, at 532–33; Robert S. Hayward et al., *Users' Guides to the Medical Literature* (pt. VIII.A), 274 JAMA 570 (1995); Spencer B. King et al., *A Randomized Trial Comparing Coronary Angioplasty with Coronary Bypass Surgery*, 331 NEW ENG. J. MED. 1044 (1994).

139. See Lucian L. Leape, *Translating Medical Science into Medical Practice: Do We Need a National Medical Standards Board?*, 273 JAMA 1534 (1995); Elaine J. Power, *Identifying Health Technologies That Work*, 274 JAMA 205 (1995); Steven H. Woolf, *Practice Guidelines: A New Reality in Medicine* (pt. III), 153 ARCHIVES INTERNAL MED. 2646, 2646 (1993).

140. See generally Elliott S. Fisher et al., *Hospital Readmission Rates for Cohorts of Medicare Beneficiaries in Boston and New Haven*, 331 NEW ENG. J. MED. 989 *passim* (1994); Elliott S. Fisher et al., *Prioritizing Oregon's Hospital Resources: An Example Based on Variations in Discretionary Medical Utilization*, 267 JAMA 1925 *passim* (1992); Edward Guadagnoli et al., *Variation in the Use of Cardiac Procedures After Acute Myocardial Infarction*, 333 NEW ENG. J. MED. 573 *passim* (1995); Lucian L. Leape et al., *Does Inappropriate Use Explain Small-Area Variations in the Use of Health Care Services?*, 263 JAMA 669 (1990); Lucian L. Leape et al., *Relation Between Surgeons' Practice Volumes and Geographic Variation in the Rate of Carotid Endarterectomy*, 321 NEW ENG. J. MED. 653 *passim* (1989) [hereinafter Leape et al., *Practice Volumes and Geographic Variation*]; Louise Pilote et al., *Regional Variation Across the United States in the Management of Acute Myocardial Infarction*, 333 NEW ENG. J. MED. 565 *passim* (1995); Frans Van de Werf et al., *Variations in Patient Management and Outcomes for Acute Myocardial Infarction in the United States and Other Countries*, 273 JAMA 1586 *passim* (1995); Jonathan P. Weiner et al., *Variation in Office-Based Quality: A Claims-Based Profile of Care Provided to Medicare Patients with Diabetes*, 273 JAMA 1503 *passim* (1995); H. Gilbert Welch et al., *An Analysis of Inpatient Practice Patterns in Florida and Oregon*, 330 NEW ENG. J. MED. 607 *passim* (1994); W. Pete Welch et al., *Geographic Variation in Expenditures for Physicians' Services in the United States*, 328 NEW ENG. J. MED. 621 *passim* (1993); David E. Wennberg, *Variation in the Delivery of Health Care: The Stakes Are High*,

percent of medical practices can be justified on the basis of rigorous scientific data establishing their effectiveness."¹⁴¹

Part of this variation arises from the uncertainties that permeate medicine. As noted above, many features of human function and physiology are not yet scientifically understood; the complete range of effects and side-effects of many drugs and treatments has yet to be fully detailed. Moreover, no individual physician knows everything that his profession as a whole knows, nor will any one physician master every skill with the utmost proficiency; patients sometimes present biological idiosyncrasies that defy the textbooks. Consequently, most clinical scenarios permit multiple acceptable approaches. Choosing one approach over another is less a matter of science and medicine than a matter of values and the management of uncertainty.¹⁴² It becomes difficult for physicians to insist that they alone should be entitled to make all judgment calls.¹⁴³

128 ANNALS INTERNAL MED. 866 *passim* (1998); David E. Wennberg et al., *The Association Between Local Diagnostic Testing Intensity and Invasive Cardiac Procedures*, 275 JAMA 1161 *passim* (1996) [hereinafter Wennberg et al., *Invasive Cardiac Procedures*]; John E. Wennberg, *Outcomes Research, Cost Containment, and the Fear of Health Care Rationing*, 323 NEW ENG. J. MED. 1202 *passim* (1990); John E. Wennberg, *Unwanted Variations in the Rules of Practice*, 265 JAMA 1306 *passim* (1991); John E. Wennberg, *Which Rate Is Right?*, 314 NEW ENG. J. MED. 310 *passim* (1986); John E. Wennberg et al., *Are Hospital Services Rationed in New Haven or Over-Utilised in Boston?*, LANCET, May 23, 1987 at 1185 [hereinafter Wennberg, et al., *Rationed*]; John E. Wennberg et al., *Hospital Use and Mortality Among Medicare Beneficiaries in Boston and New Haven*, 321 NEW ENG. J. MED. 1168 *passim* (1989) [hereinafter Wennberg et al., *Hospital Use*]; John E. Wennberg et al., *The Paradox of Appropriate Care*, 258 JAMA 2568 *passim* (1987) [hereinafter Wennberg et al., *Paradox*].

141. Paul G. Shekelle et al., *The Reproducibility of a Method to Identify the Overuse and Underuse of Medical Procedures*, 338 NEW ENG. J. MED. 1888, 1888 (1998).

142. Mark Hall addresses the confusion inherent in practicing medicine: "Medicine abounds with situations in which alternative clinical strategies are available with no scientific evidence indicating which is preferable." Hall, *supra* note 8, at 481; see also JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 165-206 (1984); Renee C. Fox, *Training for Uncertainty*, in *THE STUDENT-PHYSICIAN: INTRODUCTORY STUDIES IN THE SOCIOLOGY OF MEDICAL EDUCATION* 207, 212 (Robert G. Merton et al. eds., 1957).

143. See Katz, *supra* note 142, at 205-06; E. Haavi Morreim, *The Law of Nature and the Law of the Land: Of Horses, Zebras, and Unicorns*, 53 PHAROS 2 (1990).

Mark Hall views the situation in strong terms:

To a large extent, this preservation of professional autonomy is unjustified. Unquestionably, sound medical practice requires a degree of restriction on interference with the details of medical treatment, whether from a lay or professional source. The scientific foundations of medicine justify some group autonomy and its judgmental nature justifies some individual autonomy. It is wrong, however, to insist on absolute freedom from control. When the unknown value of medical procedures leaves a broad range of acceptable methods of patient management and medical practice—the current situation with the great bulk of medicine—it is difficult to maintain that influencing physicians to exercise their judgment conservatively is inappropriate. To the extent that restrictions on institutional influence lack a strong quality-of-care justification, they serve primarily to protect the vested interests of physicians.

Perhaps more importantly, physicians do not always adhere even to those practices that are known and widely agreed to be good and appropriate. Overuse, underuse, and misuse of medical interventions are common, presenting significant problems in the quality of health care provided throughout the U.S.¹⁴⁴ One recent analysis suggested:

The dominant finding of our review is that there are large gaps between the care people should receive and the care they do receive. This is true for all three types of care—preventive, acute, and chronic. . . . A simple average of the findings of the preventive care studies shows that about 50 percent of people received recommended care. . . . An average of 70 percent of patients received recommended acute care, and 30 percent received contraindicated acute care. For chronic conditions, 60 percent received recommended care and 20 percent received contraindicated care.¹⁴⁵

Examples of overuse are not hard to find. Antibiotics have often been used with unnecessary frequency at unnecessary levels of potency, with the result that resistant organisms are increasingly a problem.¹⁴⁶ Similar concerns arise regarding the use of growth

Hall, *supra* note 8, at 535.

144. See Mark R. Chassin & Robert W. Galvin, *The Urgent Need to Improve Health Care Quality*, 280 JAMA 1000 (1998). Chassin and Galvin describe the problems of underuse, overuse, and misuse:

Underuse is the failure to provide a health care service when it would have produced a favorable outcome for a patient. . . . Overuse occurs when a health care service is provided under circumstances in which its potential for harm exceeds the possible benefit. . . . Misuse occurs when an appropriate service has been selected but a preventable complication occurs and the patient does not receive the full potential benefit of the service.

Id. at 1002; see also Thomas Bodenheimer, *The American Health Care System: The Movement for Improved Quality in Health Care*, 340 NEW ENG. J. MED. 488 (1999); Mark A. Schuster et al., *How Good Is the Quality of Health Care in the United States?*, 76 MILBANK Q. 517 (1998).

145. Schuster et al., *supra* note 144, at 520–21. Schuster's analysis reviews a large number of studies that report on quality of health care in the United States.

146. See Chassin & Galvin, *supra* note 144; Culpepper & Sisk, *supra* note 132, at 77; Scott F. Dowell et al., *Principles of Judicious Use of Antimicrobial Agents for Pediatric Upper Respiratory Tract Infections*, 101 PEDIATRICS 163, 165–71 (1998); Gilles L. Fraser et al., *Antibiotic Optimization: An Evaluation of Patient Safety and Economic Outcomes*, 157 ARCHIVES INTERNAL MED. 1689 (1997); Ralph Gonzales et al., *Antibiotic Prescribing for Adults with Colds, Upper Respiratory Tract Infections, and Bronchitis by Ambulatory Care Physicians*, 278 JAMA 901 (1997); Ralph Gonzales et al., *Decreasing Antibiotic Use in Ambulatory Practice*, 281 JAMA 1512 (1999); William J. Hueston, *Antibiotics: Neither Cost Effective nor "Cough" Effective*, 44 J. FAM. PRAC. 261 (1997); Nirmal Joshi & David Milfred, *The Use and Misuse of New Antibiotics*, 155 ARCHIVES INTERNAL MED. 569 (1995); Donald N. MacKay, *Treatment of Acute Bronchitis in Adults Without Underlying*

hormone therapy in children who have no growth hormone deficiency.¹⁴⁷ Likewise, although ample evidence suggests that coronary angiography and revascularization (cardiac bypass surgery) should not be routinely used over more conservative medication-based approaches, United States physicians use the surgery vastly more often than their Canadian and European counterparts, with no apparent justification in terms of patients' degree of illness or infirmity.¹⁴⁸ Some studies suggest on a more general level that from eight to forty-six percent of surgeries (depending on the type of surgery) may be unnecessary.¹⁴⁹ In the same vein, intensive surveillance of women in preterm labor "had no effect on the primary

Lung Disease, 11 J. GEN. INTERNAL MED. 557 (1996); Ann-Christine Nyquist et al., *Antibiotic Prescribing for Children with Colds, Upper Respiratory Tract Infections, and Bronchitis*, 279 JAMA 875 (1998); Benjamin Schwartz et al., *Why Do Physicians Prescribe Antibiotics for Children with Upper Respiratory Tract Infections?*, 279 JAMA 875 (1998).

147. See Barry B. Bercu, *The Growing Conundrum: Growth Hormone Treatment of the Non-Growth Hormone Deficient Child*, 276 JAMA 567 (1996); Leona Cutler et al., *Short Stature and Growth Hormone Therapy*, 276 JAMA 531 (1996); Beth S. Finkelstein et al., *Insurance Coverage, Physician Recommendations, and Access to Emerging Treatments: Growth Hormone Therapy for Childhood Short Stature*, 279 JAMA 663 (1998).

148. See Richard A. Lange & L. David Hillis, *Use and Overuse of Angiography and Revascularization for Acute Coronary Syndromes*, 338 NEW ENG. J. MED. 1838 (1998). Lange and Hillis describe this phenomenon:

Although the patients enrolled in the United States were more likely than their Canadian counterparts to undergo coronary angiography (68 percent vs. 35 percent, respectively) and subsequent revascularization (31 percent vs. 12 percent), the incidence of reinfarction and death during more than three years of follow-up was similar. The chief predictors of the decision by U.S. physicians to use coronary angiography were a relatively young age of the patient and the availability of a catheterization facility. Furthermore, there was marked regional variation within the United States in the rates of use of angiography and revascularization, which was not explained by differences in the characteristics of the patients or the incidence of complications of myocardial infarction.

Id. at 1838. Excessive use is probably related to the more widespread availability of facilities and trained personnel in the U.S. See *id.* at 1839.

There is, however, a counterargument. At least one study has shown that, although the U.S. level of coronary bypass surgery may not always lead to improved survival, it has been associated with improved quality of life and reduction of symptoms of angina. See Christian W. Hamm et al., *A Randomized Study of Coronary Angioplasty Compared with Bypass Surgery in Patients with Symptomatic Multivessel Coronary Disease*, 331 NEW ENG. J. MED. 1037 (1994). In comparisons between the U.S. and Canada, higher rates of the surgery in the U.S. were associated with improved quality of life. See Jack V. Tu et al., *Coronary Artery Bypass Graft Surgery in Ontario and New York State: Which Rate Is Right?*, 126 ANNALS INTERNAL MED. 13 (1997). By the same token, Canadians also had to wait a significantly longer period of time to receive surgery, thus by implication living with angina symptoms for a longer period. See Daniel B. Mark et al., *Use of Medical Resources and Quality of Life After Acute Myocardial Infarction in Canada and the United States*, 331 NEW ENG. J. MED. 1130 (1994); Elizabeth A. McGlynn et al., *Comparison of the Appropriateness of Coronary Angiography and Coronary Artery Bypass Graft Surgery Between Canada and New York State*, 272 JAMA 934 (1994).

149. See Bodenheimer, *supra* note 144, at 488.

outcomes . . . , but did lead to significantly more unscheduled visits and greater use of prophylactic tocolytic drugs."¹⁵⁰ A two-year follow-up of some patients who had undergone angioplasty for coronary artery disease (including many with only mild disease) showed that the angioplasty "had reduced symptoms only in the group with severe angina, yet doubled the risk of nonfatal myocardial infarction (MI) or death overall."¹⁵¹

In other cases, underuse is the problem. Heart disease provides leading examples. During a myocardial infarction, thrombolytic (clot-busting) agents can dramatically improve survival rates. Yet these drugs are seriously underused.¹⁵² Similarly, for patients who have survived an MI, aspirin and beta-blocker (β -blocker) drugs can significantly reduce the likelihood of a second episode. Yet recent studies show that only an average of 37.3% of physicians prescribe these drugs for their post-MI patients.¹⁵³ In a study looking at the actual filling of prescriptions for cardiology patients, "less than 50% of cardiologists' patients were taking β -blockers."¹⁵⁴ It is likewise well-known that patients with congestive heart failure can benefit greatly from ACE inhibitor (angiotensin-converting enzyme inhibitor) drugs. Yet in one study, "on chart review of patients with congestive heart failure at one academic medical center, only three quarters of eligible patients were taking an [ACE] inhibitor, and only 60% of these were at doses known to be efficacious."¹⁵⁵

150. Elliot S. Fisher & H. Gilbert Welch, *Avoiding the Unintended Consequences of Growth in Medical Care: How Might More Be Worse?*, 281 JAMA 446, 447 (1999) (arguing that discrete clinical interventions do not necessarily increase safety and may result in more harm).

151. *Id.*

152. See Harlan M. Krumholz et al., *Thrombolytic Therapy for Eligible Elderly Patients with Acute Myocardial Infarction*, 277 JAMA 1683, 1683 (1997) (illustrating that physicians do not treat eligible patients with thrombolytic agents based on physicians' clinical judgments rather than omissions); Chris L. Pashos et al., *Trends in the Use of Drug Therapies in Patients with Acute Myocardial Infarction: 1988-1992*, 23 J. AM. C. CARDIOLOGY 1023, 1023 (1994).

153. See Thomas J. Wang & Randall S. Stafford, *National Patterns and Predictors of β -Blocker Use in Patients with Coronary Artery Disease*, 15 ARCHIVES INTERNAL MED. 1901, 1904 (1987); see also Thomas M. Burton, *An HMO Checks Up on its Doctors' Care and Is Disturbed Itself*, WALL ST. J., July 8, 1998, at A1 (discussing a survey by the nation's largest managed care company showing many of its physicians routinely don't prescribe essential drugs or perform diagnostic tests); Ron Winslow, *Studies Show Doctors Underprescribe Beta Blockers for Heart Attack Patients*, WALL ST. J., Aug. 19, 1998, at B5 (referring to two studies indicating physicians underprescribe beta blockers for elderly heart-attack patients).

154. Martin T. Donohoe, *Comparing Generalist and Specialty Care: Discrepancies, Deficiencies, and Excesses*, 158 ARCHIVES INTERNAL MED. 1596, 1598 (1998).

155. *Id.* at 1597. Another study investigated whether physicians prescribe treatments appropriately for patients with acute MI. This includes giving aspirin, appropriately withholding calcium channel blockers for those with impaired left ventricular function, prescribing ACE inhibitors at discharge, using thrombolytics or angioplasty for reperfusion, prescribing beta-blockers at discharge, and advising patients to quit smoking. The study

In like manner, it is well-known that many surgery patients are at significantly increased risk for thromboembolism. Although an array of safe and effective means can greatly reduce this risk, in fact they are often not used. In a study of Medicare patients from twenty community hospitals in Oklahoma, appropriate preventive “[p]rophylaxis measures were implemented for only 160 (38%) of 419 patients studied. . . . Only 97 (39%) of 250 patients . . . at very high risk received any form of prophylaxis and of these 97, only 64 patients (66%) received appropriate measures.”¹⁵⁶

In other instances, physicians widely fail to prescribe diuretics for hypertension, despite evidence that they are safe and effective. Instead, prescribing habits for hypertension and other common conditions lean toward high-cost, highly-advertised newer drugs such as calcium-channel antagonists that may, in fact, have greater risks and lower efficacy.¹⁵⁷ More broadly, evidence indicates that

found that aspirin was used 86% during hospitalization and 78% after, calcium channel blockers were appropriately withheld 82% of the time, use of ACE inhibitors at discharge was only 60%, reperfusion was 67%, beta-blocker prescription at discharge was 50%, and smoking cessation advice was 42%. Researchers concluded: “Substantial geographic variation exists in the treatment of patients with acute myocardial infarction [AMI], and these gaps between knowledge and practice have important consequences. Therapies with proven benefit for AMI are underused despite strong evidence that their use will result in better patient outcomes.” Gerald T. O’Connor et al., *Geographic Variation in the Treatment of Acute Myocardial Infarction*, 281 JAMA 627, 627 (1999).

156. Dale W. Bratzler et al., *Underuse of Venous Thromboembolism Prophylaxis for General Surgery Patients: Physician Practices in the Community Hospital Setting*, 158 ARCHIVES INTERNAL MED. 1909, 1909 (1998).

In a similar vein, although it has been known for many years that prenatal administration of corticosteroids for fetuses at risk of premature delivery can greatly reduce mortality and morbidity, physicians’ actual adherence to this recommendation was low until highly focused educational efforts were undertaken. See generally Laura C. Leviton et al., *Methods to Encourage the Use of Antenatal Corticosteroid Therapy for Fetal Maturation: A Randomized Controlled Trial*, 281 JAMA 46, 46 (1999) (noting the reduced risks of corticosteroid therapy and its low level of use before information dissemination).

157. See Marrin Moser, *Why Are Physicians Not Prescribing Diuretics More Frequently in the Management of Hypertension?*, 279 JAMA 1813 (1998). As Furberg and Psaty note regarding the question whether drugs called calcium agonists (CAs) should be used for hypertension:

The documentation on efficacy and safety is limited to small, short-term clinical trials, typically a few hundred patients treated for 2 to 3 months. Pharmaceutical companies have used skillful marketing based on concepts and mechanisms of action to promote these agents and have avoided for more than a decade calls for large-scale, randomized clinical trials to determine the effect of these drugs on major cardiovascular disease end points. Clinicians have chosen to prescribe CAs without proper evidence of health efficacy and long-term safety.

Curt D. Furberg & Bruce M. Psaty, *Should Dihydropyridines Be Used as First-Line Drugs in the Treatment of Hypertension? The Con Side*, 155 ARCHIVES INTERNAL MED. 2157, 2157 (1995); see also Frank A. Lederle et al., *Reserpine and the Medical Marketplace*, 153 ARCHIVES INTERNAL MED. 705, 705 (1993).

many physicians unwittingly base treatment and drug selection decisions more on drug advertisements than on medical literature.¹⁵⁸

Preventive medicine likewise can receive short shrift. Many physicians, particularly primary care providers, do not prescribe standard anti-asthma medications, such as inhaled corticosteroids.¹⁵⁹ Physicians also commonly fail to order standard diabetes care, such as frequent glucose monitoring, regular cholesterol checks, and annual retinal exams.¹⁶⁰ Other routine health maintenance interventions are often neglected for the population at large.¹⁶¹ In still other examples, physicians widely fail to use antibiotics for ulcers caused by *H pylori* bacteria; recognize and treat depression in the outpatient setting; use anticoagulents for patients in chronic atrial fibrillation; or use breast-conserving surgery for women with localized breast tumors.¹⁶²

Diagnostic accuracy is not always better than therapeutic choices. In a ten-year retrospective review of autopsies at a major New Orleans medical center, researchers found that of the 250 tumors found at autopsy, 111 were undiagnosed or misdiagnosed. Of particular concern, in fifty-seven percent of these patients, the underlying cause of death was directly related to the undiagnosed or misdiagnosed malignancy.¹⁶³ In other diagnostic areas, several

158. See generally Jerry Avorn et al., *Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians*, 73 AM. J. MED. 4 (1982); Ronald I. Shorr & William L. Greene, *A Food-Borne Outbreak of Expensive Antibiotic Use in a Community Teaching Hospital*, 273 JAMA 1908 (1995).

159. See Antonio P. Legorreta et al., *Compliance with National Asthma Management Guidelines and Specialty Care: A Health Maintenance Organization Experience*, 158 ARCHIVES INTERNAL MED. 457, 459 (1998); see also Donohoe, *supra* note 154, at 1599.

160. See Donohoe, *supra* note 154, at 1600; Leape, *supra* note 139, at 1535; Weiner et al., *supra* note 140, at 1506; Burton, *supra* note 154, at A1.

161. See Burton, *supra* note 152, at A1. One study focused on physicians in United HealthCare plans at three sites. The study examined the following issues: whether physicians measured potassium levels in patients on diuretics; whether more than one H₂ agonist was (inappropriately) prescribed for patients with peptic ulcer disease; whether insulin-dependent diabetics had their A1C levels measured; and whether insulin-dependent diabetics received an annual eye exam. Across the three plans, the figures were 41%, 50%, and 47% for measuring potassium levels; 21%, 18%, and 20% for inappropriate prescription of more than one H₂ agonist; 26%, 26%, and 23% for measuring A1C levels; and 46%, 43%, and 62% for annual eye exams. The chief medical officer of the plan concluded: "Mediocre" is the best word to describe the clinical performance revealed in these measures." Lee N. Newcomer, *Physician, Measure Thyself*, HEALTH AFF., July/Aug. 1998, at 32, 35.

162. See Donohoe, *supra* note 154, at 1600. Of note, the use of breast-conserving surgery is rising in some areas, though not always with the use of adjunctive radiation therapy. See Gerald F. Riley et al., *Stage at Diagnosis and Treatment Patterns Among Older Women with Breast Cancer: An HMO and Fee-for-Service Comparison*, 281 JAMA 720, 721 (1999); Xianglin Du, *Increase in the Use of Breast-Conserving Surgery*, 282 JAMA 326 (1999) (letter to the editor).

163. See Elizabeth C. Burton et al., *Autopsy Diagnoses of Malignant Neoplasms: How Often Are Clinical Diagnoses Incorrect?*, 280 JAMA 1245 (1998); see also George D. Lundberg, *Low-Tech Autopsies in the Era of High-Tech Medicine*, 280 JAMA 1273 (1998).

studies suggest that “[s]imple clinical prediction rules have proven superior to physician judgment in the [sic] diagnosis of acute abdominal pain, acute myocardial infarction, streptococcal tonsillitis, pneumonia, intracellular [versus] extracellular causes of jaundice, presence of ankle fracture, survival after diagnosis of Hodgkin’s disease or coronary artery disease.”¹⁶⁴

Even simpler techniques of physical examination may not always be mastered. A recent study evaluated the ability of residents in internal medicine and family practice to recognize important sounds when listening to patients’ hearts. Overall, the residents recognized only twenty percent of the sounds. The study found:

all residents we tested had great difficulty in identifying 12 commonly encountered and important events. Residents were incorrect 4 of 5 times, improved little with year of training, and were not more accurate than a group of medical students. Indeed, trainees in both residencies were less accurate than students [for certain kinds of heart sounds]. . . . [W]e found minimal gains, if any, as a result of residency training. Deficiencies of this type will probably persist even after residents enter practice. Indeed, increasing evidence in the literature seems to suggest that errors in physical diagnosis are commonly encountered among generalists. These errors may even lead to greater utilization of resources and a higher cost of care.¹⁶⁵

When significant clinical deficiencies such as those listed above are directly pointed out to physicians, they do not always move quickly to change their clinical practices. Studies suggest that concerted, systematic attempts to encourage physicians to adopt improved approaches often fail.¹⁶⁶ Some observers have perhaps

164. BASIC BENEFITS AND CLINICAL GUIDELINES 48–49 (David C. Hadorn ed., 1992) (citations omitted).

165. Salvatore Mangione & Linda Z. Nieman, *Cardiac Auscultatory Skills of Internal Medicine and Family Practice Trainees: A Comparison of Diagnostic Proficiency*, 278 JAMA 717, 721 (1997).

166. Commentators confirm that “[m]ost guidelines . . . have not been successful in changing physician behavior.” Landon et al., *supra* note 73, at 1379 (citing as evidence S.R. Weingarten et al., *Evaluation of a Pneumonia Practice Guideline in an Interventional Trial*, 153 AM. J. RESPIRATORY CRITICAL CARE MED. 1110 (1996)); see also Jeremy M. Grimshaw & Ian T. Russell, *Effect of Clinical Guidelines on Medical Practice: A Systematic Review of Rigorous Evaluations*, 342 LANCET 1317 (1993); Lawrence M. Lewis et al., *Failure of a Chest Pain Clinical Policy to Modify Physician Evaluation and Management*, 25 ANNALS EMERGENCY MED. 9 (1995). Physicians do not always stay up-to-date via the commonly presumed means of browsing medical journals, attending professional meetings, and conferring regularly with colleagues. See C.

cynically suggested that entrepreneurial concerns may not be irrelevant. For example, organized medicine's support for the early corporate bans allegedly was at least partly based on fears about lost revenues and increased competition.¹⁶⁷ A number of antitrust suits chastising organized medicine for its resistance to HMOs and to contract medicine point out that at least sometimes, when certain business practices have been condemned as unethical or as bad medicine, an underlying concern has been economic.¹⁶⁸

Errors in the broader health care context have also been studied in recent years. A widely cited study of adverse events in New York hospitals during 1984 concluded that the rate of adverse events was 3.7%. Although errors do not entail substandard care, the researchers further concluded that the rate of negligent adverse events was one percent.¹⁶⁹ In the realm of drugs alone, one recent

David Naylor, *Better Care and Better Outcomes: The Continuing Challenge*, 279 JAMA 1392, 1392 (1998).

167. See STARR, *supra* note 8, at 25–29 (1982).

168. In *American Medical Association v. United States*, 317 U.S. 519 (1943), the Supreme Court held that the American Medical Association (AMA) was guilty of antitrust violations as it opposed prepaid group practice and forbade its members to interact with physicians in such arrangements. The AMA “conspired to boycott Group Health in order to prevent it from marketing medical services in competition with petitioners’ doctor members.” *Id.* at 523.

In another antitrust case against the AMA, the Seventh Circuit held that the organization’s long-term opposition to chiropractic care was not just rooted in concerns for public health; it was also rooted in the desire to eliminate competition. See *Wilk v. American Med. Ass’n*, 895 F.2d 352 (7th Cir. 1990).

In *Virginia Pharmacy Board v. Virginia Consumer Council*, 425 U.S. 748 (1976), the Supreme Court struck down a rule of the state pharmacy board, which had declared it to be unethical to advertise drug prices. The Court noted wide variations in prices and suggested that secrecy about prices served more to keep prices high than to protect consumers. See *id.* at 754, 763.

In *Goldfarb v. Virginia State Bar*, 421 U.S. 773 (1975), the Court struck down the state of Virginia’s minimum fee schedule for attorneys as anticompetitive. In a footnote, the Court observed that one county had declared that reducing one’s fees below the prevailing minimum was an unethical form of solicitation. See *id.* at 777 n.4. In 1962, the Fairfax County Bar had declared that “although there is an ethical duty to charge a lower fee in a deserving case, if a lawyer “‘purely for his own advancement, intentionally and regularly bills less than the customary charges of the bar for similar services . . . [in order to] increase his business with resulting personal gain, it becomes solicitation . . . and also a violation of Canon 7, which forbids the efforts of one lawyer to encroach upon the employment of another.’” *Id.*

The Court acknowledged that the professions may have certain ethical tenets that differ from business, but did not deem such a possibility to be a justification of anticompetitive activity in the case under consideration. See *id.* at 786–87; see also *National Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 696 (1978).

169. See Brennan et al., *supra* note 108; Lucian L. Leape et al., *The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Malpractice Study*, 324 NEW ENG. J. MED. 377 (1991). Leape notes that a one percent rate of negligent errors may seem acceptable, but

study looked at all medication-prescribing errors in a teaching hospital, from January 1, 1987 through December 31, 1995. During that period, the rate of errors per written-order, per admission, and per patient-day all increased significantly.¹⁷⁰

Such rising rates of error, omission, and excess are not entirely surprising. During the past several decades, "an explosion has occurred in the proliferation and supply of drugs, the availability of technological tests and bedside procedures, and the array of high-tech diagnostic methods and invasive therapeutic maneuvers. Each of these changes creates new opportunities for error."¹⁷¹ As medical science and the health care systems within which it is provided become increasingly complex, it may simply be impossible to expect physicians to continue their traditionally unilateral responsibility for care and outcomes.

C. Who Should Control What: Finding a Reasonable Balance

At this point several observations sit somewhat uneasily together. On the one hand, forbidding health plans to "interfere" with physicians' judgment would effectively require them to give physicians unfettered clinical discretion. Such unfettered physician discretion can be financially costly and will not necessarily produce optimal care for individuals or for broader populations.

a 1% failure rate is substantially higher than is tolerated in industry, particularly in hazardous fields such as aviation and nuclear power. As W.E. Deming points out . . . even 99.9% may not be good enough: "If we had to live with 99.9%, we would have: 2 unsafe plane landings per day at O'Hare, 16,000 pieces of lost mail every hour, 32,000 bank checks deducted from the wrong bank account every hour."

Lucian L. Leape, *Error in Medicine*, 272 JAMA 1851 (1994).

170. See Timothy S. Lesar et al., *Medication-Prescribing Errors in a Teaching Hospital*, 157 ARCHIVES INTERNAL MED. 1569, 1570 (1997). Another study finds that fatal adverse drug reactions (whether or not the product of either error or negligent error) rank between the fourth and sixth leading cause of death in the U.S. See Jason Lazarou et al., *Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies*, 279 JAMA 1200, 1202 (1998).

171. Alvan R. Feinstein, *System, Supervision, Standards, and the "Epidemic" of Negligent Medical Errors*, 157 ARCHIVES INTERNAL MED. 1285, 1286 (1997). Feinstein further notes: "The combination of shortened durations of time for both the patient in hospital and the house officer on a service has reduced the house officer's sense of continuity of care within the hospital . . . and has increased the difficulties of maintaining rigorous patterns of supervision and discussion." *Id.* at 1287.

On the other hand, the guidelines by which health plans exert clinical control may be based on unsound research or on no science at all. Even scientifically well-founded guidelines cannot supplant the need for professional judgment that can fine-tune clinical care to meet individual patients' distinctive biological and personal needs.

If one conclusion seems evident, it is that neither physicians nor health plans should monopolize clinical control. A thoughtful division of labor, based mainly on who is better suited to do which tasks, appears to make more sense. What follows should not be deemed a definitive decree concerning the allocation of control. It is at most a suggestion of one reasonable approach to allocating responsibilities between health plans and physicians. It does not propose a rigid separation. As health care delivery evolves, considerable blurring of these boundaries is likely. Some tasks seem more suitable for the organization level, while others seem more suited to the personal, clinical level. Because this Article principally concerns corporate practice of medicine, attention will focus on health plans.

1. Health Plans—Clearly, there are some things that only physicians or related practitioners will do.¹⁷² Only an individual clinician can physically examine a patient, ask about medical and social history, and probe for further information. Only an individual patient can discuss matters of intimate privacy or personal importance crucial to diagnosis and treatment. Only an individual surgeon can decide, when something goes wrong in the midst of surgery, what should be done at that moment. Health plans cannot hope to review every physical exam and history; cannot scrutinize the differential diagnosis¹⁷³ for every patient with vague complaints; cannot second-guess every x-ray or ultrasound reading; cannot build a warm, deeply trusting relationship with each patient; and cannot determine, on their own, when their guidelines do not fit a particular patient. In short, health plans have no choice but to trust that, as a general rule, their physicians know how to practice medicine in the care of individual patients.¹⁷⁴

172. For some of these functions, other kinds of practitioners can serve equally well, including advanced practice nurses and physicians' assistants.

173. "Differential diagnosis" is a term commonly used in clinical medicine to indicate the various diagnoses that might be possible, given the patient's initial signs, symptoms, history, etc. Further diagnostic evaluation and work-up (further tests and examinations) then help the physician whittle down this list to one or a small number of working diagnoses, on the basis of which treatment options are considered.

174. In this assessment one might at least somewhat disagree with the Pennsylvania Supreme Court in *Thompson v. Nason Hospital*, 591 A.2d 703 (1991). A hospital was sued for its

Accordingly, rather than obsessively peering over shoulders and second-guessing every individual clinical encounter, health plans should fulfill four main functions. First, they must focus on the business aspects of running a health care system. Where plans undertake to provide care rather than merely reimburse it, or where they limit subscribers' choices among providers of care, they must next monitor what happens under their auspices. There are two aspects to this monitoring. On a positive note they should identify and encourage the delivery of patterns of good care—their second function. A more negative dimension involves health plans' third function, the identification and correction (when reasonable) of defective care. In both these realms, health plans must focus not so much on individual episodes as on overall patterns of care. The fourth function is the practice of medicine in certain circumstances. Each of these functions deserves discussion.

Health plans' first and most obvious domain is the business side. The chief function of a health plan is, of course, to ensure that the right care (or payment, in the case of an indemnity plan) flows to the right people, for the right purposes, in a timely fashion, and as

physicians' failure to recognize the dangers posed by some medications a patient had taken prior to being injured in a motor vehicle accident. *See id.* at 704–05. In an amicus brief the state's hospital association argued that it is neither realistic nor appropriate to expect the hospital to conduct daily review and supervision of the independent medical judgment of each member of the medical staff of which it may have actual or constructive knowledge. *See id.* at 708. The court disagreed, holding:

It is well established that a hospital staff member or employee has a duty to recognize and report abnormalities in the treatment and condition of its patients. If the attending physician fails to act after being informed of such abnormalities, it is then incumbent upon the hospital staff member or employee to so advise hospital authorities so that appropriate action might be taken. When there is a failure to report changes in a patient's condition and/or to question a physician's order which is not in accord with standard medical practice and the patient is injured as a result, the hospital will be liable for such negligence.

Id. at 709 (citations omitted).

To a certain extent, a hospital (or health plan) surely may be expected to "control" its employees by establishing policies, periodically checking on compliance with those policies, and having procedures in place to address failures to adhere to those policies. It is also reasonable to expect that the hospital will require nurses and other qualified personnel to report clearly aberrant instances of care, so far as they can discern within their training and scope of practice. It is neither feasible nor reasonable to expect, however, that an institution be aware of, anticipate, or avert each and every instance of inadequate conduct on the part of its employees and staff members. Such levels of scrutiny would require constant, one-on-one supervision of every physician at every moment. If courts nevertheless want to impose liability even where the institution has implemented proper policies and could not have avoided the adverse outcome, then it might be plausible to suppose that such a court is more interested in finding a party affluent enough to pay for injuries than in apportioning damages according to fault or blameworthiness.

promised in the contract. For an indemnity plan this will be financial payment, whether to indemnify patients for expenses incurred, or to pay providers directly for goods and services rendered. In an HMO-type plan this will mean arranging for the availability of enough of the right kinds of providers and facilities, in enough of the right locations, to ensure that the full spectrum of promised services will be readily available to enrollees. It also means forging appropriate contractual and financial relationships with such providers. Transferring high levels of financial risk to physician groups who are too inexperienced to manage resources under capitation, for instance, can be a poor business practice that, in turn, can have serious medical implications for subscribers.

Admittedly, such business matters cannot be distinguished crisply and cleanly from medical issues. As noted, every medical decision is also a spending decision, and any decision to cut business costs will almost certainly have medical implications, whether immediate or long-term. Still, some functions are obviously business-related and clearly are the health plan's responsibility—from arranging for facilities and housekeeping, to equipment purchases and maintenance, reimbursing covered medical interventions, and paying the electric bills.¹⁷⁵

Regarding the second function, identifying and encouraging patterns of good care, it should be noted that modern health plans virtually cannot operate without using some sort of clinical guidelines to decide which care is covered under the plan. It is a business necessity with obvious clinical implications.¹⁷⁶ Ideally used as a coherent set of protocols that suggest scientifically well-founded ways to handle routine problems, guidelines have become an important tool for promoting consistency of care, integrating new information into clinical practice, and shaving off common practices that are nevertheless pointless or injurious.

Good guidelines are especially needed regarding serious illnesses and injuries. Here, at the cutting edge of medicine where life and death are the most uncertain, where excesses and inadequacies of care can have the most dire consequences, where the newest technologies may or may not deliver wondrous results, and

175. Several courts have distinguished between purely business functions and clinically-oriented activities. See, e.g., *Women's Med. Ctr. v. Finley*, 469 A.2d 65, 73 (N.J. Super. Ct. App. Div. 1983). Other courts reject the distinction, including *Parker v. Board of Dental Examiners*, 14 P.2d 67, 73 (Cal. 1932).

176. Health plans are not necessarily restricted to a single set of guidelines. Different large purchasers (such as employers) may want different levels of coverage, and these in turn may require variations in the guidelines that the health plan applies to beneficiaries' care.

where the greatest amounts of money are spent,¹⁷⁷ it is particularly important for health plans to ensure that care is provided effectively and resources are used wisely.¹⁷⁸

Systematic technology assessment should be the cornerstone of health plans' coverage decisions in this difficult realm.¹⁷⁹ The resultant guidelines can help health plans not only to make more rational, evidence-based decisions, but to respond more fairly and consistently to treatment requests from members of a given plan. Such fairness is particularly important with respect to dire illness and cutting-edge care. If one person in Plan X receives a bone marrow transplant that is then denied to another person with the same disease in the same plan, the latter patient can easily complain of unjust treatment, perhaps even at the cost of her life.¹⁸⁰

Guidelines need not focus exclusively on what is and is not financially covered. HMOs especially are defined at least partly by the fact that they are not merely pass-through financial agents, but directly arrange for their enrollees' care. Therefore, they should actively seek to ensure that high-quality care is delivered under

177. For example, many companies have adopted innovative policies, such as medical savings account plans, to provide their employees the flexibility to control the costs of their own health care. See Editorial, *Consumer-First Health Care*, WALL ST. J., July 21, 1994, at A14.

178. See Morreim, *Saving Lives*, *supra* note 113.

179. See Linda A. Bergthold, *Medical Necessity: Do We Need It?*, HEALTH AFF., Winter 1995, at 180, 186–89 (analyzing the history and evolution of the term medical necessity from an insurance concept to a rationing tool); Norman Daniels & James E. Sabin, *Last Chance Therapies and Managed Care: Pluralism, Fair Procedures, and Legitimacy*, HASTINGS CTR. REPORT, Mar.–Apr. 1998, at 32 (providing different models of managing experimental and last chance therapies as examples of how decision making regarding coverage can include fairness and legitimacy); David A. Grimes, *Technology Follies: The Uncritical Acceptance of Medical Innovation*, 269 JAMA 3030, 3030 (1993) (suggesting critical evaluation of new technologies before they are widely adopted); Holoweiko, *supra* note 126, at 171; Stanley Joel Reiser, *Criteria for Standard Versus Experimental Therapy*, HEALTH AFF., Summer 1994, at 127, 130–31 (outlining criteria to illustrate distinctions between standard and experimental therapies and suggesting a new category, cross-over therapy); James E. Sabin & Norman Daniels, *Determining "Medical Necessity" in Mental Health Practice*, HASTINGS CTR. REP., Nov.–Dec. 1994, at 5 (proposing a rationale for determining medical necessity in the administration of health insurance benefits); Earl P. Steinberg et al., *Insurance Coverage for Experimental Technologies*, HEALTH AFF., Winter 1995, at 143 (proposing policy options for payment of new technologies that take into account the necessity of balancing various interests); see also *Bucci v. Blue Cross-Blue Shield*, 764 F. Supp. 728, 731 (D. Conn. 1991). In *Bucci*, the insurer applied a five-factor "Technical Evaluation Criteria" test to evaluate new technologies. "Summarized, the criteria are (1) government regulatory approval; (2) evidence which permits conclusions as to the effect on patient health; (3) demonstrated improvement of the patient's health; (4) demonstration of medical benefit at least equal to that offered by established alternative treatment; and (5) improvement other than in investigational settings." *Id.* at 731. The court, however, rejected the criteria as invalid on the ground that they were subjective in nature and imprecise. See *id.* at 732–33.

180. See Morreim, *Saving Lives*, *supra* note 113; William M. Sage, "Health Law 2000": *The Legal System and the Changing Health Care Market*, HEALTH AFF., Fall 1996, at 9, 13–14; Michael Meyer & Andrew Murr, *Not My Health Care*, NEWSWEEK, Jan. 10, 1994, at 36–38.

their auspices. In that effort, they should strive affirmatively to enhance quality of care. This will mean making sure not only that their physicians refrain from delivering treatments that an enrollee does not need or did not purchase, but also reciprocally that physicians provide the care that the plan has promised and that patients need. As noted above, physicians do not always provide even the care that is of obvious, agreed-upon benefit.¹⁸¹ Accordingly, standards for such things as preventive care and routine management of chronic illnesses such as diabetes, arthritis, and asthma will be two important areas in which health plans undertake affirmative leadership.

As a practical matter, health plans are ordinarily in a better position than the lone clinician to identify effective patterns of care. Few individual physicians have time for the kind of systematic literature search that can help them to distinguish between solid research that warrants changing their clinical routines and more transient findings that do not warrant change. In contrast, health plans can and should make it their business to evaluate ongoing research and scientific consensus, especially regarding those aspects of medicine that are most amenable to general guidelines. Because all health plans must choose and make explicit the levels of care they will cover, and because some additionally furnish that care, they should do so on the basis of the best available evidence.¹⁸² Fortunately, a number of efforts are under way to collect, evaluate, and promulgate evidence-based guidelines.¹⁸³

181. See *supra* notes 144–45 and accompanying text.

182. See Daniels & Sabin, *supra* note 179, at 38–40.

183. Weingarten describes some of these efforts:

The *Clinical Practice Guidelines Directory* (<http://www.ama-assn.org>) serves as a repository of guidelines on more than 2000 topics from more than 90 organizations. It is easy to use and can quickly point a reader toward the sources of guidelines on relevant topics. The *U.S. Preventive Services Task Force Guide to Clinical Preventive Services Second Edition* [(visited Nov. 16, 1999) <<http://odphp.050phs.dhhs.gov/pubs/guidecps/>>] is an evidence-based source of preventive care recommendations Another resource available on the Internet is the National Guideline Clearinghouse, which includes guidelines that meet specific criteria for being evidence-based. The Agency for Health Care Policy and Research, in partnership with the American Association of Health Plans and the American Medical Association, has invited developers of practice guidelines, including professional societies, to submit guidelines for possible inclusion in the National Guideline Clearinghouse. Guidelines must contain systematically developed statements that satisfy the Institute of Medicine's definition of a guideline . . . be developed under the auspices of a medical organization; be derived from a systematic review of the relevant literature and science; have been developed, reviewed, or revised in the past 5 years; and be available in English.

The mandate to choose, scrutinize, and improve guidelines need not mean that each health plan should work in isolation from other plans. Indeed, collective investigation, if undertaken by consortia of health plans and other research entities, is more likely to produce credible results than if each plan, struggling in isolation, reinvents its own peculiar wheel.¹⁸⁴ Neither does it mean lock-step, one-size-fits-all mandates. Because not even the best guidelines will fit every patient, and because various purchasers have different levels of resources to spend on health care, discretion, flexibility, and ranges of options are important. Nevertheless, guidelines for routine care do help remind physicians that, in the absence of contraindications or exceptional circumstances, certain things should generally be provided for patients with particular conditions.

As health plans do the homework for continually improving routines of care, they can institute mechanisms for helping physicians to learn and implement these routines in daily practice. The ordinary physician, busy each day with large numbers of patients, may know very well the need for inhaled steroids for asthma and ACE inhibitors for congestive heart failure. But a hectic pace may make it difficult simply to remember everything that must be done dur-

Scott Weingarten, *Using Practice Guideline Compendiums to Provide Better Preventive Care*, 130 ANNALS INTERNAL MED. 454, 455 (1999). The website for the National Guideline Clearinghouse is <<http://www.guideline.gov>>.

184. Collective efforts using combined resources may produce better results than the less well-funded and potentially biased investigations of any one health plan. Fortunately, some collaborative research and guidelines construction is already underway. A large number of major corporations have pooled funds to create the Foundation for Accountability (FACCT), an organization that is conducting outcomes studies on a variety of conditions. The research looks not only at standard morbidity and mortality, as many such studies do, but also investigates quality of life, return to normal functions of living, and other matters important to a broader view of medical outcomes. See Ken Terry, *Can Functional-Status Surveys Improve Your Care?*, MED. ECON., Aug. 12, 1996, at 126.

In an analogous effort, the Managed Care Outcomes Study, funded by six MCOs and the National Pharmaceutical Council, recently led to publication of a study indicating that excessively stringent formulary limits tend perversely to increase patient visits to outpatient offices, emergency rooms, and hospitals, and to raise overall costs of care. See Horn et al., *supra* note 99, at 1105. In the same vein, the HMO Research Network coordinates 12 research organizations located within integrated health care organizations. See Durham, *supra* note 128, at 111.

The Ambulatory Sentinel Practice Network (ASPN) looks at common clinical dilemmas, and has created guidelines, for example, for CT scanning in new-onset headache, whether and when to do dilation and curettage after uncomplicated miscarriage, whether there should be hospitalization of every woman with pelvic inflammatory disease, and whether to prescribe 10-day antibiotic course for every child with otitis media. See Paul A. Nutting et al., *Practice-Based Research Networks Answer Primary Care Questions*, 281 JAMA 686 (1999). For further discussion see Morreim, *Saving Lives*, *supra* note 113; Morreim, *Resource Limits*, *supra* note 40, at 49–52.

ing that ever-briefer office or bedside visit.¹⁸⁵ MCOs can help by creating computer-based systems to remind physicians to implement recognized improvements to care.¹⁸⁶ By the same techniques they can also play a major role in helping, for instance, to reduce error rates with medications.¹⁸⁷ Aside from computer aids, an MCO can initiate ongoing education, working with medical leaders in the community.¹⁸⁸ MCOs can also undertake their own health-promotion initiatives, such as support groups and education and exercise classes for groups such as diabetics, asthmatics, and the elderly.¹⁸⁹

185. A physician in the office may only have 10 to 15 minutes with a patient.

Yet, in that time, the physician may also need to call the MCO to authorize a specialty referral, consult a directory to determine which specialist is on the MCO panel, refer to a managed care formulary to choose a drug, and even take a call from a hospital nurse urging the physician to discharge another patient before the end of the day. Under these circumstances, it is difficult to keep the physician focused on the many initiatives each MCO employs to achieve . . . improved quality and reduced costs.

Harry L. Leider, *Influencing Physicians: The Three Critical Elements of a Successful Strategy*, AM. J. MANAGED CARE, Apr., 1998, at 583.

186. See *supra* notes 140–71 and accompanying text; see also Jerry Avorn et al., *Reduction of Incorrect Antibiotic Dosing Through a Structured Educational Order Form*, 148 ARCHIVES INTERNAL MED. 1720 (1988); David W. Bates et al., *Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors*, 280 JAMA 1311 (1998); Robert B. Elson & Donald P. Connelly, *Computerized Patient Records in Primary Care: Their Role in Mediating Guideline-Driven Physician Behavior Change*, 4 ARCHIVES FAM. MED. 698 (1995); R. Scott Evans et al., *A Computer-Assisted Management Program for Antibiotics and Other Antiinfective Agents*, 338 NEW ENG. J. MED. 232 (1998); Giles K. Fraser et al., *Antibiotic Optimization: An Evaluation of Patient Safety and Economic Outcomes*, 157 ARCHIVES INTERNAL MED. 1689 (1997); Richard Garibaldi, *Computers and the Quality of Care—A Clinician's Perspective*, 338 NEW ENG. J. MED. 259 (1998); Atel Gawande, *When Machines Become Doctors, Will Doctors Become Machines?*, MED. ECON., Oct. 5, 1998, at 144; Dereck L. Hunt et al., *Effects of Computer-Based Clinical Decision Support Systems on Physician Performance and Patient Outcomes*, 280 JAMA 1339 (1998); Mark Morhane et al., *Improving Prescribing Patterns for the Elderly Through an Online Drug Utilization Review Intervention*, 280 JAMA 1249 (1998); J. Marc Overhage et al., *Computer Reminders to Implement Preventive Care Guidelines for Hospitalized Patients*, 156 ARCHIVES INTERNAL MED. 1551 (1996); Robert A. Raschke et al., *A Computer Alert System to Prevent Injury from Adverse Drug Events*, 280 JAMA 1317 (1998).

187. Sage and Jorling note:

[T]he most common cause of serious medication errors with respect to antibiotics is a failure to note a patient's known allergy, a mistake that can be addressed at the institutional level by devoting greater resources to eliciting information, developing more effective charting and communication among providers, and maintaining a work environment that promotes attentiveness.

William M. Sage & James M. Jorling, *A World That Won't Stand Still: Enterprise Liability by Private Contract*, 43 DEPAUL L. REV. 1007, 1021 (1994) (footnote omitted).

188. See Leider, *supra* note 185.

189. See Deborah A. Grandinetti, *What It Takes for Big Groups to Succeed*, MED. ECON., Apr. 7, 1997, at 87.

Just as health plans should work, positively, on patterns of care that should be delivered, so must they, on a more negative side, strive to identify and remedy poor quality care. This is their third proposed area of major responsibility. As argued above, health plans neither can nor should try to second-guess every individual clinical encounter. To do so would require enormous resources—virtually an entire extra layer of physicians to check up on each action of physicians caring for patients at the clinical level, with perhaps yet another layer to monitor the monitors. More importantly, such intense supervision would be intrusive and unnecessary.¹⁹⁰ No supervision system can prevent all errors. Further, if the medical staff is chosen with reasonable care, such intimate scrutiny should be unnecessary.

Accordingly, health plans' target should be patterns in which a physician systematically fails to render an appropriate quality or quantity of care. As the American College of Physicians suggested regarding UM: "Evidence suggests that the principal process of review, the case-by-case review, may not be cost-effective and may not be conducive to improving quality."¹⁹¹ Instead, "the American College of Physicians recommends that routine case-by-case reviews be abandoned and replaced by profiling of patterns of care."¹⁹² Those profiles can look, on the positive side, to ensure that physicians are providing important forms of standard care. On the negative side, they can monitor adverse incidents to ascertain whether a given physician has simply committed an individual error or whether isolated incidents constitute a pattern.

When systematic deficiencies appear, plans can respond with additional education and training or supervision, or practice restrictions or, if necessary, personnel replacement. Other cases may show that the guidelines, not physicians' behavior, must change. The health plan's question is not so much whether a physician erred in a given instance, or whether that physician owes redress to the patient. Such personal debts from physicians to their patients are generally better addressed within classic malpractice tort law. Rather, the health plan's task is to determine whether a given physician should remain on its panel and, if so, what remedial actions should be taken to improve performance. Such evaluations might be undertaken directly by the MCO or may emerge from tradi-

190. See *supra* note 174.

191. American College of Physicians, *supra* note 128, at 423.

192. *Id.* at 426.

tional kinds of peer review. Either way, the process should be geared not toward punishment, but toward quality improvement.¹⁹³

In their fourth function, health plans literally practice medicine. This domain is unavoidable because the preceding three do not have clear or precise boundaries. Even if health plans ordinarily provide only general guidance on the optimal management of chronic illnesses; even if they are looking mainly for patterns of inadequate care among their physicians rather than trying to pinpoint every error or dubious judgment; and even if their business duties are not ordinarily "medical" in character; at certain points the health plan will be looking into a member's clinical care in a way that can only be described as practicing medicine, because the plan will be making medical judgments that directly determine, or at least are a substantial factor, in the patient's specific care and outcomes. Because of this inquiry health plans could find themselves practicing medicine in any of their first three domains.

In the first domain it should be noted that not all business decisions are strictly business. Again, because every medical decision is also a spending decision, controls on spending will often have medical implications. If the health plan takes those implications into account, then in at least some instances it practices medicine. If surgeons on its staff request that a certain piece of equipment such as a new type of laser be purchased, for instance, the MCO may need to undertake an independent evaluation of the surgeons' claims that this new laser will produce better outcomes than current procedures. If the MCO decides that these medical claims are not fully credible, and thereby declines to purchase it on medical grounds (rather than on cost or other grounds), its decision will directly affect the health care of the enrollees who would otherwise have been treated with that laser. In such cases the health plan may have practiced medicine in the course of making business decisions. These cases will be debatable, because the impact of the MCO's business decisions on individual patients' care and outcomes will be considerably more remote than in the other two domains. Nevertheless, it is possible at least to envision scenarios in which business decisions involve practicing medicine.

The more obvious opportunities for practicing medicine arise from the exercise of plans' prerogative to foster good practice patterns and address poor performance patterns. Within the second domain, if a physician indicates that one of his patients needs an

193. See David Blumenthal & Arnold M. Epstein, *The Role of Physicians in the Future of Quality of Management* (pt. 6), 335 *NEW ENG. J. MED.* 1328, 1329 (1996); Glenn Laffel & Donald M. Berwick, *Quality in Health Care*, 268 *JAMA* 407 (1992).

exception to the general guidelines, the health plan must scrutinize that case. It will make a medical judgment as to whether the physician's request is warranted, and its decision whether to cover the requested variation will in many cases have a major impact on the patient's care. In essence, any time an MCO must interpret guideline ambiguities in order to determine which care it will cover for a specific enrollee, or any time it must consider exceptions to its usual limits on covered care for a patient who does not fit the guidelines, there is a high probability that the plan will be practicing medicine. Note that these instances mainly arise in situations in which the MCO exercises direct utilization control over the care that is provided. Where the plan has transferred financial risk to physicians, as through capitation, physicians are usually free to provide as much care as they wish, so long as they provide no less than that to which the patient is contractually entitled. In these cases the physician, not the plan, makes the medical/financial judgments.

An MCO also will sometimes practice medicine in its third domain of control, as it monitors staff performance. If a physician's asthmatic patients generally do not do as well as expected, for instance, the health plan must investigate that physician's individual interventions for particular patients, and it must at certain points determine whether those decisions constituted good medicine or bad medicine. If the MCO then decides to work more closely with that physician, directing his actions to ensure that the care of subsequent individual patients comports more closely with its standards, it may in many instances be practicing medicine.

2. *Physicians*—If these are the kinds of things that health plans can and should control, physicians likewise have their distinctive domains. These will be outlined only briefly here, because this Article focuses primarily on MCOs. As noted above, physicians must have the freedom to exercise considerable clinical discretion so that they can examine patients, form diagnostic hypotheses, explore those hypotheses, discuss choices and their respective benefits and risks, and in the process build the personal, trusting relationship with each patient that is indispensable to good care. Physicians should not have to spend endless hours justifying ordinary decisions to MCOs, because the MCOs should be looking mainly for practice patterns, not moment-to-moment decisions.

Beyond these obvious patient-care duties, physicians also have a substantial responsibility to identify instances in which patients do not fit the health plan's guidelines. As noted, even the best clinical protocol will not fit every patient. The physician has the profes-

sional training and the responsibility to recognize such instances and to pursue acceptable alternatives on behalf of that individual.

More broadly, physicians also need to help plans recognize when the guidelines themselves do not work and need to be improved or replaced. It is a task that can only be fulfilled by those who live and work at the intersection between the general (the science and guidelines of care) and the particular (the patients).

3. *The Balance*—In sum, health plans and physicians each can claim a fairly distinctive role. MCOs' job is to find better ways to shape clinical patterns of practice, and to find minimally intrusive ways to draw physicians in that direction. MCOs cannot escape practicing medicine at certain points, but those occasions should be limited. Practicing medicine should be the exception, not the rule.

Although the foregoing is at best a rough sketch of the ways in which control might be distributed between physicians and health plans, it shows a sufficiently clear path to move into a discussion of liability. If the proper priority is to establish first who should be controlling what in the delivery of health care, and only thereafter to consider who should bear what sort of liability for adverse outcomes, it is now appropriate to move to that latter question. As noted, health plans and physicians should bear liability only for those aspects of care that they can and should control. As Part V demonstrates, MCOs should first pare down the extent to which they currently practice medicine, if their role is to focus on practice patterns as recommended here.

V. SCALING BACK MCOs' MEDICAL PRACTICE

If MCOs and physicians, respectively, should bear liability only for those aspects of health care that they can and should control, as per Part III; and if, per Part IV, MCOs should practice medicine sparingly rather than routinely; then the first task in discussing an appropriate liability allocation is to examine the extent to which MCOs currently practice medicine. As this Part proposes, health plans currently practice medicine much more than they should, primarily because health care contracts are largely founded on the concept of medical necessity. As long as health plans must first decide whether an intervention is medically necessary (thereby making a medical judgment) before they can make a coverage determination, and so long as financing is a prerequisite to receipt of

care for many patients (thereby causing these medical judgments to have a significant impact on patients' treatment and outcomes), plans will continue to practice medicine routinely rather than sparingly. For many reasons, this arrangement should change.

*A. Scaling Back Medical Practice:
Dropping "Medical Necessity"*

Virtually all health plans today define their benefits in terms of medical necessity. This has not always been the case. For many years, health plans covered almost any service that a physician chose to order, until it eventually became evident that some physician services were extravagant, exclusively for convenience, utterly untested, or dubious in a host of other ways. Not until the 1960s, in an attempt to curb costs, did health plans begin seriously to restrict what they would cover under the rubric of "medical necessity." Courts, in turn, tended not to enforce plans' denials of coverage because the term was so vague. Over time, plans attempted to carve out more explicit exclusions, such as for experimental or cosmetic care. Still, medical necessity has remained the cornerstone of health care contracts.¹⁹⁴

To be precise, health plan contracts do not actually contain language that expressly promises to cover all medically necessary health care. Rather, contracts typically identify the categories of services they cover, such as inpatient care and outpatient care (including hospital and health professional services, for both emergency and non-emergency situations); care for mental illness and substance abuse; prescription drugs; laboratory, radiology, and diagnostic services; home health care and hospice services; durable

194. As Hirshfeld and Harris have observed, "[w]hen a health plan agrees to cover health care services, the contract with the beneficiary generally specifies that the services must be paid for when they are reasonable and necessary for the diagnosis or treatment of an illness or injury suffered by the beneficiary." Hirshfeld & Harris, *supra* note 8, at 4; see also Gerard F. Anderson et al., *Medical Technology Assessment and Practice Guidelines: Their Day in Court*, 83 AM. J. PUB. HEALTH 1635, 1636 (1993); Bergthold, *supra* note 179, at 182-83; David M. Eddy, *Benefit Language: Criteria That Will Improve Quality While Reducing Costs*, 275 JAMA 650, 652 (1996) (noting that "unadorned" contract language limiting coverage to "medically necessary" or "appropriate" treatment has failed to limit liability for refusing treatment and suggesting that insurers adopt "specific criteria" illustrated with examples to clarify exactly what treatment will be paid for under an insurance contract); Hall & Anderson, *supra* note 30, at 1644-51; Wendy K. Mariner, *Patients' Rights After Health Care Reform: Who Decides What Is Medically Necessary?*, 84 AM. J. PUB. HEALTH 1515, 1516 (1994) (noting that "[p]rivate health insurance companies have relied on the concept of medical necessity to limit the services they will pay for in individual cases").

medical equipment; and rehabilitation.¹⁹⁵ Not all plans cover all categories and, for care within the accepted categories, plans typically carve out exceptions. Exclusions are usually for services that are “experimental,” “innovative,” or “not medically necessary.” By implication, however, as long as a service is within an accepted category and is medically necessary (that is, it is not excluded or unnecessary), it is covered.¹⁹⁶ One would be hard-pressed to find any health plan that explicitly denies services that it agrees are “medically necessary,” and that fall within a category the plan pledges to cover.

This implicit promise to cover all necessary services within the accepted categories is not limited to indemnity-style plans that govern resources via reimbursement decisions and explicit utilization management. The promise also applies to capitated arrangements and other forms of risk-sharing. An MCO might contract with primary care physicians (PCPs) under a capitation arrangement, for instance, requiring them to provide primary care services and a spectrum of laboratory, radiology, and specialist services. That capitation contract will ordinarily list the kinds of services physicians must cover in exchange for the set monthly per-patient fee.¹⁹⁷ Although such arrangements leave physicians considerable freedom (albeit at personal financial peril) to deliver the care they deem appropriate, in fact the contract the patient signs with the health plan will still contain the familiar categories of services, the same exclusions for experimental and medically unnecessary services, and the same implicit promise that, if a service within those categories is necessary, it will be covered. However specific or general the list may be, and however free these physicians may be to deliver more than what they are obligated to provide, they must at least provide medically necessary services of the covered types.

If health plans clearly owe their beneficiaries medically necessary care, however, it is not at all clear what medical necessity means. At one extreme, an intervention is only necessary if it is “*essential to*

195. See Rosenbaum et al., *supra* note 135, at 230.

196. See Hirshfeld & Thomason, *supra* note 8, at 4 (“When a health plan agrees to cover health care services, the contract with the beneficiary generally specifies that the services must be paid for when they are reasonable and necessary for the diagnosis or treatment of an illness or injury suffered by the beneficiary.”).

197. In some cases such listed services include procedures traditionally done by specialists, including dermatologic procedures such as skin biopsies, casting of undisplaced fractures, colonoscopies, sigmoidoscopy, joint aspiration and injections, stress tests, and the like. See James Novak, *How We Wrote Our Own Managed-Care Success Story*, MED. ECON., Aug. 10, 1998, at 116; Ken Terry, *Surprise! Capitation Can Be a Boon*, MED. ECON., Apr. 15, 1996, at 126; Karen Cheney, *What You Can Learn from an M.D. Mutiny in a Managed-Care Plan*, MONEY, Dec. 1995, at 21.

reach a goal of improving or curing a *disease*.”¹⁹⁸ This minimalist definition could preempt many interventions currently deemed standard—including such mundane things as anesthesia for painful office-based procedures. In contrast, Medicare’s definition of “reasonable and necessary” inquires whether the intervention is “safe and effective, not experimental, and appropriate.”¹⁹⁹ On this much broader approach, an intervention is necessary if it “works.”²⁰⁰ Commonly, “medically necessary means medically appropriate. It excludes experimental care, nonstandard treatments, treatment without any known benefit, and treatment such as cosmetic surgery not intended to correct or relieve a medical condition.”²⁰¹ It means “sufficiently accepted within the medical community to be covered as acceptable medical care.”²⁰²

198. William M. Glazer, *Psychiatry and Medical Necessity*, 22 *PSYCHIATRIC ANNALS* 362, 362 (1992).

199. Steinberg et al., *supra* note 179, at 144.

200. One of the most specific definitions comes from Florida’s workmen’s compensation law:

“Medically necessary” means any service or supply used to identify or treat an illness or injury which is appropriate to the patient’s diagnosis, consistent with the location of service and with the level of care provided. The service should be widely accepted by the practicing peer group, should be based on scientific criteria, and should be determined to be reasonably safe. The service may not be of an experimental, investigative, or research nature, except in those instances in which prior approval . . . has been obtained.

Mariner, *supra* note 194, at 1516–17 (citing FLA. STAT. § 440.13(1)(c), *quoted in Jones v. Petland Orlando S.*, 622 So. 2d 114 (Fla. Dist. Ct. App. 1993)). This more precise-looking definition is still almost hopelessly vague when one tries to define “appropriate,” “widely accepted,” “reasonably safe,” “experimental,” and similar phrases. *See also Eddy*, *supra* note 194, at 651–52; Helvestine, *supra* note 68, at 172–73.

201. Hall et al., *supra* note 56, at 1056; *see also* CLARK C. HAVIGHURST, *HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM* 15 (1995) (“Under the test of ‘medical necessity,’ which serves almost universally as the contractual touchstone of plan coverage, the criteria used to check the spending discretion of providers are almost exclusively medical, not economic.”).

202. Mariner, *supra* note 194, at 1516. Definitions of medical necessity include:

- Medicare excludes coverage for services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” Social Security Act, 42 U.S.C. § 1395y(a)(1) (1988).
- In the context of Medicaid, Minnesota specifies that covered services must:

A. be determined by prevailing community standards or customary practice and usage to: (1) be medically necessary; (2) be appropriate and effective for the medical needs of the recipient; (3) meet quality and timeliness standards; (4) be the most cost effective health service available for the medical needs of the recipient;

B. represent an effective and appropriate use of medical assistance funds.

MINN. R. 9505.0210 (1999).

Historically, health plans have tended to defer to the collective judgments of the profession to determine which interventions are necessary under which circumstances.²⁰³ However, in light of the term's vagueness and the difficulty of enforcing benefit limits, plans have increasingly felt compelled to adopt clinical guidelines of their own, together with specific procedures for determining the

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- The Florida Administrative Code provides the following definition:

Covered outpatient services must be medically necessary, preventive, diagnostic, therapeutic or palliative services. . . . Requested service must be reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent the worsening of conditions that threaten life, cause suffering or pain, result in illness or infirmity, or threaten to cause or aggravate a handicap, physical deformity, or malfunction, and there is no equally effective, more conservative or less costly course of treatment available.

FLA. ADMIN. CODE ANN. r. 10C-7.040 (1992).

- In South Dakota:

To be medically necessary, the covered service must meet the following conditions: (1) It is consistent with the recipient's symptoms, diagnosis, condition, or injury; (2) It is recognized as the prevailing standard and is consistent with generally accepted professional medical standards of the provider's peer group; (3) It is provided in response to a life-threatening condition; to treat pain, injury, illness or infection; to treat a condition that could result in physical or mental disability; or to achieve a level of physical or mental function consistent with prevailing community standards for diagnosis or condition; (4) It is not furnished primarily for the convenience of the recipient or the provider; and (5) There is no other equally effective course of treatment available or suitable for the recipient requesting the service which is more conservative or substantially less costly.

S.D. ADMIN. R. 67: 16:01:06.02 (1991).

- Finally, in California, a service is "medically necessary" or a "medical necessity" when it is "reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain." CAL. CODE REGS. tit. 22, § 51303(a) (2000) (incorporated by reference into 22 CAL. CODE REGS. tit. 22, § 51336 (2000)).
- Health plans' corporate definitions can be somewhat more specific. The Travelers Insurance Company has used this definition:

Company determines, in its discretion, if a service or supply is medically necessary for the diagnosis or treatment of an accidental injury or sickness. This determination . . . [considers] the following:

- It is appropriate and required for the diagnosis or treatment of the accidental injury or sickness.
- It is safe and effective according to accepted clinical evidence reported by generally recognized medical professional or publications.
- There is not a less intensive or more appropriate diagnostic or treatment alternative that could have been used in lieu of the service or supply given.

Doe v. Travelers Ins. Co., 971 F. Supp. 623, 629 (D. Mass. 1997), *aff'd in part, rev'd in part, vacated in part, and remanded in part, all on other grounds*, 167 F.3d 53 (1st Cir. 1999) (citing language from *The Traveler's Plan*, under which plaintiff was covered).

203. See Havighurst, *supra* note 201, at 14-15.

necessity of new technologies and innovative interventions.²⁰⁴ Such guidelines have not been universally welcomed. As noted throughout this Article, their use has prompted bitter accusations that MCOs are meddling in the clinical practice of medicine.

The problems with using “medical necessity” as the contractual cornerstone of health care benefits, however, go far deeper. There are three major problems that collectively constitute sufficient reason to discard the concept in favor of an alternative, namely guidelines-based contracting, as proposed in Part V.B below.²⁰⁵

First, the vagueness of “medical necessity” makes it very difficult for health plans to enforce denials of coverage—a problem that, in turn, makes it very difficult for plans to control their costs and thereby the price for those who pay premiums. Second, the concept does not fit the clinical realities of medicine so that as a benefits standard it requires continual second-guessing of, and interference with, physicians. Third, the standard currently leads to the mistreatment of patients in several ways: by cultivating over-expectations with the promise of sameness among various health plans that in fact deliver very different levels of benefits; by decreasing their benefits as the operational definition of “medical necessity” quietly shrinks; and by removing choices legitimately left to patients, through the imperative of “necessity.” Each of these deserves a closer look.

From health plans’ perspective, perhaps the biggest drawback to the medical necessity criterion is that its vagueness renders the benefits denials issued under its aegis almost impossible to defend in court. As a general principle of contract law, courts routinely construe ambiguities against contracts’ drafters.²⁰⁶ This doctrine of *contra proferentum* is based on a fairness principle: because the party writing the agreement had the opportunity to make the wording clear, the drafting party’s failure to do so should not work against the party who lacked this opportunity.²⁰⁷

204. In *Bucci v. Blue Cross-Blue Shield*, 764 F. Supp. 723 (D. Conn. 1991), Blue Cross-Blue Shield had implemented a five-factor “Technical Evaluation Criteria” (TEC). See *id.* at 731; see also discussion *supra* note 178. The court held the reliance on the TEC to be invalid on the ground that some portions were irrelevant, other portions subjective. See *Bucci*, 764 F. Supp. at 732; see also Berghold, *supra* note 179, at 183; Daniels & Sabin, *supra* note 179, at 28–29; Hall & Anderson, *supra* note 30, at 1683–89; Mariner, *supra* note 194, at 1516.

205. See *infra* notes 246–253 and accompanying text.

206. The court applied this principle in *Bucci*: “Ambiguities in the plan should be resolved against the insurer.” *Bucci*, 764 F. Supp. at 730. “If a court finds that an insurance policy is ambiguous, . . . an ambiguous policy will be construed in favor of the insured.” *Katskee v. Blue Cross/Blue Shield*, 515 N.W.2d 645, 649 (Neb. 1994); see also ROBERT H. JERRY, II, UNDERSTANDING INSURANCE LAW 125–36 (2d ed. 1996).

207. See Havighurst, *supra* note 201, at 182.

Given the vagueness of “medically necessary,” courts have often overturned health plans’ denials of benefits on this familiar contractual principle. Thus, in *Van Vactor v. Blue Cross Association*,²⁰⁸ the Illinois Supreme Court held that because “medically necessary” was ambiguous, and contract disputes must be construed in favor of the insured, the patient should receive coverage for inpatient removal of impacted wisdom teeth.²⁰⁹ In *McLaughlin v. Connecticut General Life Insurance Company*,²¹⁰ the California Supreme Court likewise cited *contra proferentum* to hold that, in view of the ambiguities inherent in “medical necessity,” immunoaugmentive therapy for terminal lung cancer should be covered.²¹¹ In *Ex Parte Blue Cross-Blue Shield*,²¹² the Alabama Supreme Court relied on the same reasoning to award coverage for inpatient care of osteoporosis-related fractures, while in *Group Hospitalization, Inc. v. Levin*²¹³ the District of Columbia appellate court awarded costs incurred for private nursing services for back pain. Similarly, a California appellate court held in *Hughes v. Blue Cross*²¹⁴ that when an insurer implemented a standard of medical necessity significantly different from prevailing community standards and did not properly investigate a claim, it stood to incur liability for bad faith.²¹⁵ One could list many more cases,²¹⁶ but the trend is clear. As long as courts honor *contra proferentum*, and as long as health plans rely mainly on such an utterly ambiguous concept as medical necessity to guide the great

208. 365 N.E.2d 638 (Ill. 1977).

209. See *id.* at 643.

210. 565 F. Supp. 434 (Cal. 1983).

211. See *id.* at 450–52.

212. 401 So. 2d 783 (Ala. 1981).

213. 305 A.2d 248 (D.C. 1973).

214. 245 Cal. Rptr. 273 (Ct. App. 1988).

215. Not every case goes against the health plan, of course. Sometimes a court is even willing to construe an interpretation of medical necessity as being plain enough to prevail. See, e.g., *Free v. Travelers Ins. Co.*, 551 F. Supp. 554 (D. Md. 1982); *Lockshin v. Blue Cross*, 434 N.E.2d 754 (Ohio Ct. App. 1980).

216. In *McGraw v. Prudential Insurance Co. of America*, 137 F.3d 1253 (10th Cir. 1998), Prudential Insurance denied physical therapy services for a patient with multiple sclerosis on the ground that it would not affect the course of the disease. Prudential’s criteria of medical necessity required that the service be provided by a doctor, that it be recognized as safe and effective for the particular illness or injury, that it be employed in ways consistent with medical standards, and that it not be educational, experimental, or investigational. See *id.* at 1256. The Tenth Circuit held that the denial of services was arbitrary and capricious, on the ground that the insurer had covertly modified its definition of medical necessity to incorporate an additional requirement that the treatment provide a measurable, substantial increase in functional ability. See *id.* at 1263.

On some occasions courts invoke government Medicare or Medicaid approaches to medical necessity in order to find for plaintiffs. See, e.g., *Thie v. Davis*, 688 N.E.2d 182, 187 (Ind. Ct. App. 1997).

majority of their benefits decisions, plans can expect their efforts to limit expenditures to be systematically thwarted.

This need not happen. Recently courts have been willing to uphold benefits denials where the contracts were clear.²¹⁷ In *Loyola University of Chicago v. Humana Insurance Co.*,²¹⁸ for example, surgeons performing coronary bypass surgery responded to an emergency situation by implanting an artificial heart as a bridge to the human heart transplant that was performed a month later. The insurer refused to cover the artificial heart on the ground that it was experimental, and also denied reimbursement for the human heart transplant because the patient failed to secure UM approval as required. The Seventh Circuit affirmed. "This is a contract case and the language of the benefit plan controls. Again, Loyola and Mr. Via were certainly free to attempt these life-saving procedures, but the benefits plan does not require Humana to pay for them."²¹⁹ The court noted:

As the plan unambiguously states, no benefits are payable without prior approval. It is undisputed that necessary records on Mr. Via's condition were not sent by Loyola until after the heart transplant and that the records were not received by Humana until after Mr. Via's death. . . . Although it seems callous for Humana to deny coverage for a life-saving procedure and thereafter deny all subsequent hospital expenses—in essence saying to Mr. Via "we will not cover you because you should be dead"—Humana's humanity is not the issue here. This is a contract case and the language of the benefit plan controls.²²⁰

217. See Morreim, *Contributive Justice*, *supra* note 40, at 254–56.

218. 996 F.2d 895 (7th Cir. 1993).

219. *Id.* at 903.

220. *Id.* The same Seventh Circuit panel ruled similarly in *Fuja v. Benefit Trust Life Insurance Co.*, 18 F.3d 1405 (7th Cir. 1994), in which a woman sought an autologous bone marrow transplant (ABMT) for advanced breast cancer. The insurance contract excluded research treatments, and the court found that ABMT for her disease was research. "Under the present state of the law, we are bound to interpret the language of the specific contract before us and cannot amend or expand the coverage contained therein." *Id.* at 1412. The court went on to observe: "Although we fully realize the heartache Mrs. Fuja's family has endured, as judges we are called upon to resolve the legal question presented in this appeal, i.e., interpreting the Benefit Trust insurance contract." *Id.* at 1407.

In the same vein, in *Free v. Travelers Insurance Co.*, a Maryland district court held that an insurer was not obligated to pay for the patient's laetrile:

The plaintiff's unfettered right to select a physician and follow his advice does not create a corresponding responsibility in the defendant to pay for every treatment so chosen. As one court noted, "it is simply not enough to show that some people, even

The Tenth Circuit echoed the theme in *McGee v. Equicor-Equitable HCA Corp.*,²²¹ upholding an HMO's refusal to pay for nursing home care for which prior UM approval had not been sought as required.

We are mindful that the objective in construing a health care agreement, as with general contract terms, is to ascertain and carry out the true intention of the parties. However, we do so giving the language its common and ordinary meaning *as a reasonable person in the position of the HMO participant*, not the actual participant, would have understood the words to mean.²²²

The court pointed out that “[w]hile it is readily apparent Mr. McGee sought the best possible care for his daughter, he was still obligated to work within the defined contractual borders of the HMO he elected to participate in.”²²³ These borders may be especially

experts, have a belief in [the] safety and effectiveness [of a particular drug]. A reasonable number of Americans will sincerely attest to the worth of almost any product or even idea.” . . . Finally, the Court notes that the plaintiff, by his own admission, was well aware that laetrile and nutritional therapy are disapproved of by the majority of cancer specialists. He was equally well informed of the accepted alternative, chemotherapy.

551 F. Supp. 554, 560 (D. Md. 1982) (citations omitted).

Similarly, in *McLeroy v. Blue Cross-Blue Shield*, a district court in Georgia pointed out that it was “well within the bargaining rights of the parties” to determine the conditions under which special alternative services might be provided. 825 F. Supp. 1064, 1071 (N.D. Ga. 1993).

In *Goepel v. Mail Handlers Benefit Plan*, a New Jersey district court held that the plaintiffs' written policy was clearly written, with adequate notice of policy changes, and enabled the plaintiffs to make an informed purchase. No. 93-3711, 1993 WL 384498, at *9 (D.N.J. Sept. 24, 1993). Significantly, the court also expressed an interest in the responsibilities of subscribers:

This Court is also troubled by the invitation to recognize a cause of action, not based on the fact that the policy was unclear, but rather, as plaintiffs suggest, on the premises that insureds (1) do not read the full brochure detailing policy coverage and (2) do not heed the admonition in the section on “How the Plan Changes” to review the entire policy.

Id. This decision was subsequently overturned by the Third Circuit, on grounds, not of its substance, but of jurisdiction: preemption from state to federal court should not have occurred automatically, and required further adjudication. *See Goepel v. National Postal Mail Handlers Union*, 36 F.3d 306, 313 (3d Cir. 1994).

221. 953 F.2d 1192, 1202 (10th Cir. 1992).

222. *Id.* (citing *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 112 (1989)). The Tenth Circuit did require the HMO to pay for some benefits that in fact met their utilization requirements.

223. *Id.* at 1207.

important in managed care. "HMOs are not traditional insurance companies designed to indemnify participants for services they unilaterally select at any geographic location. Instead, HMOs . . . provide comprehensive prepaid medical services within a defined geographic area, and with specific exceptions, only by participating medical professionals and facilities."²²⁴ Equicor, the defendant HMO, had made rehabilitation benefits contingent on periodic determinations by the patient's physician—a requirement Mr. McGee knew about but chose not to fulfill.

In a now-familiar vein, the Third Circuit upheld an insurer's requirement that the patient pay thirty percent of his medical bill because he failed to secure advance approval for his care. The patient knew at least a full day ahead of time that he would need to enter the hospital; his wife could have obtained precertification within the time required. Beyond that, he presented hospital admissions staff with an outdated insurance card that lacked current precertification information.²²⁵ A number of other recent cases likewise insist on faithfulness to contractual language.²²⁶

224. *Id.*

225. *See Nazay v. Miller*, 949 F.2d 1323, 1336 (3d Cir. 1991). The court noted that it is legitimate for those who pay for health care to attempt to contain their rising costs. *See id.* at 1328. In this case, a corporation gave teeth to its precertification requirement by imposing a 30% penalty on those who failed to comply. If this requirement were overruled, the corporation "and its employees would be deprived of an important weapon in their joint battle against rising healthcare costs." *Id.* at 1338.

226. In *Gee v. Utah State Retirement Board*, 842 P.2d 919, 920–22 (Utah Ct. App. 1992), the Utah Court of Appeals upheld an insurer's denial of coverage for removal of breast implants, holding that the policy was not ambiguous. "Insurance policies are contracts, and are interpreted under the same rules governing ordinary contracts. . . . [A] policy term is not ambiguous simply because one party ascribes a different meaning to it to suit his or her own interests." *Id.* at 920–21.

Other courts have expressed similar views. The Seventh Circuit has noted that "because of the plain language of the contract, we would have no choice but to affirm the denial of coverage even if, *arguendo*, we were to review that decision *de novo*." *Harris v. Mutual of Omaha Co.*, 992 F.2d 706, 713 (7th Cir. 1993).

The district court for the District of Columbia has held:

The plan is clear and not ambiguous. . . . The contract is clear. HDC-ABMT is not covered under the 1992 Plan. Accordingly, Blue Cross/Blue Shield's decision denying coverage and OPM's review and affirmance of that decision are rational. Denial of coverage is clearly not an arbitrary and capricious decision; indeed, because of the plain language of the contract, the Court would affirm denial of coverage even if that decision were reviewed *de novo*.

Arrington v. Group Hosp. & Med. Serv. Inc., 806 F. Supp. 287, 290–91 (D.D.C. 1992).

Many similar cases have upheld payers' denial of funding based on the plain language of the contract. *See Barnett v. Kaiser Found. Health Plan, Inc.*, 32 F.3d 413 (9th Cir. 1994); *Doe v. Group Hosp. & Med. Serv.*, 3 F.3d 80 (4th Cir. 1993); *Harris v. Blue Cross Blue Shield*, 995 F.2d 877 (8th Cir. 1993); *Nesseim v. Mail Handlers Benefit Plan*, 995 F.2d 804 (8th Cir. 1993); *Farley v. Benefit Trust Life Ins. Co.*, 979 F.2d 653 (8th Cir. 1992); *Healthcare Amer-*

Thus, although courts have been quite willing to uphold clear contracts (usually found where the contract has an explicit exclusion), many balk when the only basis for benefits denial is a fuzzy claim that "we consider this medically unnecessary."²²⁷ Therefore, a health plan that wants to draw and meaningfully enforce limits on its expenditures must provide a far more specific contractual basis.

The second flaw in the "medical necessity" concept concerns the ill fit between "necessary" and ordinary medical care. The problem is immediately obvious in the question now facetiously bandied about as health plans consider the recently approved drug for male impotence: how often per month (per week? per day?) is drug-assisted sexual intercourse "medically necessary"? Most medical decisions do not present clear choices of life versus death, nor juxtapose complete cures against pure quackery. Rather, the daily stuff of medicine is a continuum requiring a constant weighing of

ica Plans, Inc. v. Bossemeyer, 953 F. Supp. 1176 (D. Kan. 1996); McLeroy v. Blue Cross/Blue Shield, Inc., 825 F. Supp. 1064 (N.D. Ga. 1993); Goepel v. Mail Handlers Benefit Plan, No. 93-3711, 1993 WL 384498 (D.N.J. Sept. 24, 1993); Thomas v. Gulf Health Plan, Inc., 688 F. Supp. 590 (S.D. Ala. 1988); see also Adnan Varol, M.D. v. Blue Cross & Blue Shield, 708 F. Supp. 826 (E.D. Mich. 1989) (informing a group of psychiatrists that they were expected to adhere to their contract with an insurer, even though they now disagreed with its cost containment provisions); Sarchett v. Blue Shield, 729 P.2d 267 (Cal. 1987) (upholding insurer's right to deny payment, based on its own judgment of medical necessity); Madden v. Kaiser Found. Hosp., 552 P.2d 1178, 1185 (Cal. 1976) (holding that an employee who had chosen his HMO from among several options negotiated on his behalf by a state agency was bound by the arbitration clause to which he had agreed, and noting that "one who assents to a contract is bound by its provisions and cannot complain of unfamiliarity with the language").

227. Judges' favor for injured plaintiffs sometimes goes further than invoking *contra proferentum*. In a pattern dubbed "judge-made insurance," courts have sometimes stretched contractual language to award benefits when desperate individuals seek treatment that may be their only hope for survival. Even when contractual language is quite clear, courts sometimes have gone out of their way to favor the needy individual over the large insurer. In *Bailey v. Blue Cross/Blue Shield of Virginia*, 866 F. Supp. 277 (E.D. Va. 1994), for instance, a woman with advanced breast cancer sought high-dose chemotherapy with peripheral stem cell rescue (a form of bone marrow transplant). The insurer's policy language stated: "Autologous bone marrow transplants and other forms of stem cell rescue . . . with high dose chemotherapy and/or radiation are not covered." *Id.* at 280. Although the policy listed some exceptions to this exclusion, it explicitly stated that breast cancer was not such an exception. Nevertheless, the court denied defendant's motion for summary judgment on the ground that the policy was ambiguous. Typically judges in these cases will argue that the contract is ambiguous, that the ill patient may lose his life while the health plan loses only money, and that the patient will arguably prevail on the merits in any event.

For a more detailed discussion of "judge-made insurance" see generally PETER W. HUBER, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES 142-52 (1988); Kenneth S. Abraham, *Judge-Made Law and Judge-Made Insurance: Honoring the Reasonable Expectations of the Insured*, 67 VA. L. REV. 1151 (1981); John H. Ferguson et al., *Court-Ordered Reimbursement for Unproven Medical Technology: Circumventing Technology Assessment*, 269 JAMA 2116 (1993); Hall & Anderson, *supra* note 30; Frank P. James, *The Experimental Treatment Exclusion Clause: A Tool for Silent Rationing of Health Care?*, 12 J. LEGAL MED. 359 (1991).

uncertainties and values.²²⁸ For a patient needing hip replacement, one prosthetic joint may be longer-lasting but far costlier than an alternative. One antibiotic regimen may be far less costly than another, but with somewhat higher risks of damage to kidneys or liver. One antihypertensive regimen may be considerably more costly than an equally effective alternative, but with fewer side-effects and the enhanced convenience of once-a-day dosage rather than thrice-a-day may be more palatable. It is artificial precision to say that one is “necessary,” connoting “essential” or “indispensable”—and the other is “unnecessary,” suggesting “superfluous” or “pointless.” Various options have merits, and often no single approach is clearly “*the* correct” choice. A given option is better described as “a good idea in this case,” “reasonable, given the cost of the alternative,” “maybe a bit better than the alternative,” or “not ideal, but acceptable.” The question is whether a particular medical risk or monetary cost is worth incurring in order to achieve a desired level of symptomatic relief or functional improvement. A huge array of treatments fits this description: more or less worthwhile, but not “(un)necessary” in any ordinary sense. The patient will not die without it, or might even die from it (with this or that degree of risk), and alternatives can be reasonable even if each option has drawbacks.

More broadly, concepts like necessity, appropriateness, and effectiveness can only be defined relative to a goal.²²⁹ Antibiotics are not “effective” per se; they are effective against bacteria and, barring placebo effect, ineffective against viruses. It makes no sense for a physician to prescribe antibiotics if the goal is to eradicate a viral infection. But if the goal is to placate a relentlessly demanding patient who insists on antibiotics for his viral infection, it may at least superficially make sense to write the prescription. The choice

228. Hirshfeld and Thomason describe medical necessity as a continuum:

Ultimately, medical necessity can be thought of as a continuum, whereby services at one end of the continuum are clearly necessary for the diagnosis and treatment of an illness or injury, and services at the other end of the continuum are clearly unnecessary, and in between are services that have some degree of likelihood of benefiting a patient. As one moves along the continuum from clearly necessary to clearly unnecessary, the percentage of likelihood of a benefit from the provision of the health care involved decreases. The value judgment that must be made is how large the percentage of likelihood of a benefit should be for care to be provided. The closer that percentage is to 100%, the more likely it is that some individuals will be harmed by the withholding of care that could have benefited them.

Hirshfeld & Thomason, *supra* note 8, at 24–25 (citations omitted).

229. See Eddy, *supra* note 194, at 654–55; Robert D. Truog et al., *The Problem with Futility*, 326 NEW ENG. J. MED. 1560 (1992).

of goals, and of the prices that may or may not be worth paying in order to reach them, requires a level of clinical complexity that is not reflected in simplistic notions such as necessity. It would be far better to acknowledge these choices and uncertainties openly than to hide them under blanket categories connoting a façade of precision.²³⁰ Across a broad spectrum of such choices and trade-offs, people may legitimately come to different conclusions about what price is worth paying, medically and financially, to achieve what kinds of goals. To presume that a medical intervention is either necessary or unnecessary belies the legitimacy of such variation.

The problem marches from the conceptual drawing board into the clinical setting as health plans try to apply this ill-fitting notion to actual medical decisions. As long as health plans base their benefits decisions on medical necessity, they must make a medical decision in order to make an economic decision. Wherever this economic decision has a significant bearing on the actual decisions and outcomes experienced by patients, the health plan is practicing medicine—on a clinically odd basis, at that. Such routine second-guessing and intrusion into the clinical setting disrupts relationships and often is counterproductive.²³¹ A considerably less intrusive approach, “guidelines-based contracting” as outlined below,²³² would have plans specify what they do and do not cover.

In the third problem, patients can be harmed in unexpected ways when benefits are allocated according to the medical necessity concept. First, the concept invites enrollees to entertain high, uniform expectations. As long as virtually every plan implicitly appears to promise all “necessary” care within the covered categories, and as long as a person assumes (as many laymen do) that medicine is highly scientific and precise, then it is reasonable for health plan subscribers to expect that all of the plans based on medical necessity will provide the same benefits, aside from any explicit exclusions or other specified exceptions that might differentiate them. If, beyond this, subscribers invoke the most common conception of medical necessity—the definition that only requires an intervention to be safe, effective, and appropriate in order to be “necessary”—enrollees will believe they are entitled to “everything that works,” regardless of the price of their plan. Indeed, the very notion of medical necessity implies a scientific evaluation, to which

230. For further elaboration see Morreim, *Saving Lives*, *supra* note 113.

231. See *supra* Part IV.C.1.

232. See *infra* Part V.B.

economic and other normative considerations are irrelevant.²³³ It is a tall order for any plan that wants to provide care at an economical price.

The bright promise of high, uniform benefits could hardly be farther from reality. As noted above, “medical necessity” can range narrowly from only those interventions that will diagnose or cure disease, to broad versions encompassing virtually everything that works.²³⁴

Even a unified definition would not solve the problem. The federal Medicare program for the elderly and disabled, for example, ostensibly provides a uniform set of benefits to all enrollees, although various insurers act as the plan’s fiscal intermediaries. Yet in a study conducted by the General Accounting Office, Medicare payment for a chest x-ray was 451 times more likely to be denied in Illinois than in South Carolina; payment for a physician office visit was almost ten times more likely to be denied in Wisconsin than in California; and payment for real-time echocardiography was nearly one hundred times more likely to be denied by Transamerica Occidental than by Blue Shield of California.²³⁵

233. As Helvestine points out, health plans may even see an increased risk of liability if they permit their judgments of medical necessity to be influenced by economic considerations. See Helvestine, *supra* note 68, at 174.

234. See *supra* Part V.A.1.

235. See Michael Pretzer, *Hate Those Medicare Denials? Try Moving*, MED. ECON., Apr. 10, 1995, at 92–93. Data showed that for every 1000 services allowed:

- for office visits, Blue Shield (BS) of northern California denied 12.1, while Wisconsin Physicians’ Service (WPS) denied 109.7;
- for real-time echocardiography, Blue Cross/Blue Shield (BCBS) of Illinois denied zero, BS of California denied 2.2, and Transamerica Occidental (TO) denied 198.5;
- for myocardial perfusion imaging, BCBS of Illinois and WPS denied zero, while TO denied 252.3; and
- for ambulance with basic life support: BS of California denied 1.5, BCBS of South Carolina denied 1.5, and Connecticut General denied 413.2.

See *id.* at 93; see also Stephen C. Gleason, *Health System Deregulation: Some Aspects of Health Care System Reform Need Not Be Held Hostage*, 274 JAMA 1483, 1483 (1995); Wendy K. Mariner, *Business vs. Medical Ethics: Conflicting Standards for Managed Care*, 23 J.L. MED. & ETHICS 236 (1995).

This variability also has important implications for providers, who can be accused of fraud if they provide and bill for “unnecessary” services. As pointed out by one commentator

HCFA has elected . . . to allow each of its contractors to establish the medical necessity guidelines and parameters that will be applied in its service area. Thus, notwithstanding the national coverage “speed limit,” HCFA allows—indeed, has encouraged—carriers and fiscal intermediaries to set up what are essentially “speed traps” for the unwary by refusing to inform providers of local interpretations and parameters to be applied in processing their claims.

Just as the definition and practical implementation of “medically necessary” can vary widely from one plan or geographic region to another, so implementation can change quickly and quietly within a particular plan. One major area in which an erosion of benefits is particularly disturbing concerns interventions that restore or preserve quality of life. These interventions provide comfort and function, as distinct from the more dramatic life-and-death treatments. People do not often die from untreated cataracts, for instance, even if their lives are considerably disrupted by an inability to see well enough to read or drive. Yet patients in some prepaid health plans are significantly less likely to have cataract extraction than patients in fee-for-service (FFS) plans.²³⁶ In like manner, rehabilitation once deemed standard is also under scrutiny.²³⁷ Patients with strokes may be discharged to nursing homes rather than to rehabilitation facilities, with potentially less opportunity for improved function.²³⁸ A plan may decide without prior notice that epidural anesthesia is “unnecessary” for normal vaginal childbirth because, after all, the pain is only transient.²³⁹ In some cases, entire medical disciplines are under economic pressure because they focus mainly on quality of life. They range from ophthalmology to orthopedics, dermatology, mental health care, reconstructive plastic surgery, and end-of-life care.²⁴⁰

Timothy P. Blanchard, *Medicare Medical Necessity Determinations Revisited: Abuse of Discretion and Abuse of Process in the War Against Medicare Fraud and Abuse*, 43 ST. LOUIS U. L.J. 91, 102 (1999).

236. Less care does not necessarily mean worse care, of course, because the “artesian well of money” fee-for-service system rewarded excess. But at some point, less is worse. See Caroline L. Goldzweig et al., *Variations in Cataract Extraction Rates in Medicare Prepaid and Fee-for-Service Settings*, 277 JAMA 1765, 1767–68 (1997); Stephen A. Obstbaum, *Should Rates of Cataract Surgery Vary by Insurance Status?*, 277 JAMA 1807, 1807 (1997).

237. See *Adelson v. GTE Corp.*, 790 F. Supp. 1265 (D. Md. 1992).

238. See Sheldon M. Retchin et al., *Outcomes of Stroke Patients in Medicare Fee for Service and Managed Care*, 278 JAMA 119, 122–24 (1997); James R. Webster & Joseph Feinglass, *Stroke Patients, “Managed Care,” and Distributive Justice*, 278 JAMA 161, 161 (1997).

In *Bedrick v. Travelers Insurance Co.*, 93 F.3d 149 (4th Cir. 1996), the insurer for a boy with cerebral palsy refused to continue most of the coverage for his physical therapy, occupational therapy, and speech therapy because these would not improve the boy’s condition. Testimony that the services could preserve current function and prevent deterioration were to no avail until a federal court overturned the insurer’s denial.

239. See Edward Hirshfeld, *The Case for Physician Direction in Health Plans*, 3 ANNALS HEALTH L. 81, 93 (1994).

240. See generally Daniel B. Borenstein, *Does Managed Care Permit Appropriate Use of Psychotherapy?*, 47 PSYCHIATRIC SERVICES 971 (1996); Goldzweig et al., *supra* note 236; Clifford Warren Lober, *Dermatology: Positioned for Health Care Reform*, 132 ARCHIVES DERMATOLOGY 1065 (1996); Paul S. Russell & Lisa J. Kaplan, *The American Academy of Dermatology’s Response to Managed Care and Capitation*, 132 ARCHIVES DERMATOLOGY 1125 (1996); Robert K. Schreter, *Ten Trends in Managed Care and Their Impact on the Biopsychosocial Model*, 44 HOSP. & COMMUNITY PSYCHIATRY 325 (1993); Robert S. Stern, *Managed Care and the Treatment of Skin Diseases*,

As a health plan's (usually undisclosed) guidelines and thus its specific benefits shift underneath the vaguely-worded contract, the result can be a steady erosion in the plan's actual coverage. A subscriber cannot know precisely what she has purchased in a health plan. It may cover much less than she thinks, if administrators flesh out the slippery "necessity" concept differently than she expects. Where necessity is defined according to physician acceptance the iteration of what "works" can change as fleetingly as the fashions of consensus.²⁴¹ Interestingly, when health plans shrink their iteration of necessary services, patients rarely enjoy financial savings. Everyone but the patient seems to benefit as health plans, employers, and governments pocket the cash while patients endure greater discomfort and reduced function. Even where the benefit cuts aim mainly to avert premium increases, patients rarely have any voice in the trade-offs. Unfortunately, as long as the deleted interventions are dubbed "unnecessary," patients ostensibly are not being deprived of anything important, and the underlying, value-laden trade-offs remain unrecognized.

The notion of necessity also preempts choice. "Necessary" is an imperative. As noted by an Ohio appellate court borrowing from Webster's dictionary, it means: "essential, of an inevitable nature, inescapable, predetermined, compulsory, absolutely needed, required; the general tenor is that the word imports something which is indispensable or essential."²⁴² In medicine, people other than the patient make most of the important decisions regarding what should be covered and what should not.

Up to a point this reasoning is valid. If the fundamental objectives of health care are to save lives and preserve capacities for function, medical science has much to say regarding which sorts of care are essential, which are marginal, and which may actually harm those goals. But this analysis is hardly definitive. Necessity and effectiveness can only be defined relative to a goal.²⁴³ The principle of informed consent holds that the patient, not the health plan or the physician, should ordinarily choose the goals

132 ARCHIVES DERMATOLOGY 1039 (1996); The SUPPORT Principal Investigators, *A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients: The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT)*, 274 JAMA 1591 (1995).

241. See generally John F. Burnum, *Medical Practice a la Mode*, 317 NEW ENG. J. MED. 1220 (1987); Joseph E. Hardison, *To Be Complete*, 300 NEW ENG. J. MED. 193 (1979); James W. Mold & Howard F. Stein, *The Cascade Effect in the Clinical Care of Patients*, 314 NEW ENG. J. MED. 512 (1986); Edward T. Wong & Thomas L. Lincoln, *Ready! Fire! . . . Aim! An Inquiry into Laboratory Test Ordering*, 250 JAMA 2510 (1983).

242. *Lockshin v. Blue Cross*, 434 N.E.2d 754, 756 (Ohio Ct. App. 1980).

243. See Eddy, *supra* note 194, at 654-55.

and, within certain parameters, the means of treatment.²⁴⁴ Removal of cataracts may be “necessary” for someone annoyed by an inability to do his favorite things, unimportant for someone who enjoys her life as is, and pointless for patients in a permanent vegetative state. The key question is whether a particular medical risk or monetary cost is worth taking or paying in order to achieve a desired goal such as possible prolongation of life, symptomatic relief, or functional improvement.

In the healthcare context, calling an intervention “necessary” usually means the health plan must cover it and thus that subscribers must pay for it in the purchase price. When “necessity” is defined as “everything that works,” people can be forced to pay for care that many may deem excessive.²⁴⁵ Combine these features with the fact, noted above, that it is virtually impossible to know what a plan covers, and it becomes equally impossible to select a plan on the basis of what it does and does not cover. Consumers have virtually no control over what they buy.

*B. Better Approach: Explicit,
Guidelines-Based Contracting*

Instead of writing health plan contracts in broad terms such as medical necessity, and then fleshing them out with a set of covert, detailed-but-quietly-changeable clinical guidelines, health plans should simply drop the elusive notion of medical necessity, open their guidelines,²⁴⁶ describe the procedures by which they adjudicate disputes, and make these guidelines and procedures the explicit basis on which they contract with enrollees.

The basic ideas behind such guidelines-based contracting have been proposed by this author and by others, and thus will not be redescribed in detail here.²⁴⁷ For present purposes, it is useful to

244. See *Canterbury v. Spence*, 464 F.2d 772, 780, 790 (D.C. 1972); *Cobbs v. Grant*, 502 P.2d 1, 9 (Cal. 1972).

245. For further discussion of the ways in which health plans commonly require subscribers to purchase a level of care beyond what they might want, see HAVIGHURST, *supra* note 56.

246. At least one state already requires a degree of such openness. New Jersey requires that all health plans permit their participating providers “an opportunity to review and comment on all medical and surgical . . . protocols . . . of the carrier.” Health Care Quality Act, ch. 192, 1997 N.J. SESS. LAW SERV. 192 (West).

247. A number of commentators have challenged the way in which “medical necessity” is used in health care contracting. However, many of them propose not to drop the concept as recommended here, but to find a uniform definition alone or in combination with refining the procedural criteria by which health plans adjudicate uncertain cases. In other words,

note several major advantages of such an approach. Once the vagueness of medical necessity is replaced with the greater precision and clarity of open guidelines, the variation that already exists among plans and their coverage will become more obvious. Less costly plans may require a higher threshold of scientific validation and cost-effectiveness before accepting costly new drugs or other

they retain the notion that health plans are all implicitly striving to provide the same kind of care (the “necessary” care), but believe that the notion needs to be defined much more precisely. David Eddy, for instance, proposes to replace the terminology of medical necessity with an array of procedural criteria that could be used to consider the following: whether the intervention in question is used for a medical condition, whether there is sufficient evidence on which to draw conclusions about the intervention’s effects on health, whether there is evidence attesting to the likelihood that the intervention will actually work as intended, whether the benefits of the intervention are likely to outweigh its harms, and whether it is the most cost-effective available intervention. *See* Eddy, *supra* note 194, at 653.

Through this move, Eddy still looks for a one-size-fits-all approach to health benefits. He seeks only to make that single set of benefits clearer by replacing necessity language with procedures such as those he outlines. *See id.*; *see also* Bergthold, *supra* note 179.

Other commentators, including this author, propose that health plans should not collectively attempt to define a single product. Instead, a diversity of approaches should be accepted given that, as noted above, few interventions are “necessary” in any objective sense. Rather, they are more or less desirable, toward this or that goal, with greater or lesser scientific credibility. Once this is acknowledged, the health plan’s task is to expose its own particular approach to the trade-offs of medicine via opening guidelines and writing contracts on that basis. *See* Morreim, *Saving Lives*, *supra* note 113; E. Haavi Morreim, *Diverse and Perverse Incentives of Managed Care: Bringing Patients into Alignment*, 1 WIDENER L. SYMP. J. 89 (1996) [hereinafter Morreim, *Diverse and Perverse*]; Morreim, *Resource Limits*, *supra* note 40, at 47–52; Morreim, *Contributive Justice*, *supra* note 40.

Havighurst endorses the use of guidelines to spell out the details of health care contracts. Because there are many sets of guidelines now in use, enrollees would potentially have many options from which to choose. *See* HAVIGHURST, *supra* note 56, at 222; *see also* Hall & Anderson, *supra* note 30, at 1689–93; Paul E. Kalb, Note, *Controlling Health Care Costs by Controlling Technology: A Private Contractual Approach*, 99 YALE L.J. 1109, 1123 (1990).

In a compatible vein, Hadorn proposes to eliminate medical necessity in favor of a detailed description defining the most basic level of care, above which people could purchase more elaborate plans:

Basic benefit plans would provide coverage for all and only legitimate health care needs. ‘Needs,’ in turn, would be defined as services judged to have been *reasonably well demonstrated* to provide *significant* net health benefit to patients who receive them. Costs of care would not be directly considered in making judgments of necessary care, but would be addressed indirectly by eliminating coverage for many services that cannot meet the standard of demonstrated benefit. By restricting coverage to this subset of currently provided services, basic benefit plans could realize substantial cost savings while preserving patients’ access to truly needed, *basic* care.

Defining necessary services in this way will require the use of a special type of clinical guideline—‘necessary care guidelines’—to depict the specific clinical indications for which various services are to be deemed necessary, and therefore covered under basic-level plans. A complete set of necessary-care guidelines would then constitute a basic benefit plan.

Hadorn, *supra* note 164, at xi.

technologies, for instance, while costlier plans may offer a wider array of options. Arguably, all plans should provide some reasonable level of basic care—a point that will be presumed but not defended here. Beyond that, plans would simply disclose what they do and do not cover by basing contracts openly on their clinical guidelines.

Once this information is openly available, purchasers will be better able to compare health plans and to make choices that fit their own needs, values, and priorities—just as they do with other important choices in their lives.²⁴⁸ They can reasonably expect, for the duration of the contract, that they will know what they bought, and it will not silently erode under the cover of vague language. This is not to say that health plans must mail their entire compendium of guidelines to every current or prospective enrollee, or that subscribers must understand and affirm every clause of every guideline before the contract is valid. That would be impossible and unreasonable, and would go far beyond the level of information typically required for other contracts exchanging complex goods.²⁴⁹ Rather, each plan should provide a general description of its basic approach to benefits—its summary of plan benefits and its underlying coverage philosophy²⁵⁰—together with an assortment of case illustrations to show how that philosophy is actually implemented. To this the MCO can add information about how to inspect the complete guidelines (such as visiting a website).²⁵¹

248. See generally Morreim, *Saving Lives*, *supra* note 113; Morreim, *Diverse and Perverse*, *supra* note 247; Morreim, *Contributive Justice*, *supra* note 40; Morreim, *Resource Limits*, *supra* note 40. Critics might respond that some people would make foolish choices that could cost them their lives. In reply, such diversity does not preclude the setting of some reasonable basic level, below which no plan would be permitted to go. See Morreim, *Saving Lives*, *supra* note 113; Morreim, *Diverse and Perverse*, *supra* note 247; Morreim, *Resource Limits*, *supra* note 40, at 47–52.

249. See HAVIGHURST, *supra* note 56, at 181.

250. Kalb proposes three tiers of care from which patients might choose, each of which would represent a different resource philosophy and have its own set of guidelines. The most basic level would encompass care that has been shown to be safe, effective, and cost-effective. The next level would include interventions that, although also safe and effective, are not maximally cost-effective. The top level might encompass innovative treatments that have not yet been proven effective. See Kalb, *supra* note 247, at 1122.

Hall and Anderson propose a similar but broader set of tiers of health care, including care that has been deemed safe, effective, and cost beneficial; care that is safe and cost-effective; safe and effective but not cost-effective; safe and effective; safe but ineffective; safety in doubt; and unsafe. See Hall & Anderson, *supra* note 30, at 1689–93.

251. Part VI will further discuss such variations among guidelines. In addition to disclosing the guidelines' basic approach to care, it would seem appropriate for plans to provide information regarding how their guidelines were created. Those based on science may have a considerably different level of credibility than those created strictly by consensus of a few invited physicians.

Such openness might be expected to lead to improved guidelines. Part IV.A observed that many guidelines are not founded on good science, and many physicians have noted that guidelines sometimes make little clinical sense. However, once physicians and the public at large can examine and critique various sets of guidelines, better research and improved guides might follow.

Health plans, for their part, might anticipate that their enrollees would make more knowledgeable purchasing decisions.²⁵² It will be to MCOs' advantage if patients no longer expect that every plan, regardless of price, provides exactly the same level of benefits. More importantly from plans' perspective, guidelines-based contracts can expect greater deference from courts. *Contra proferentum* is difficult to invoke against clear and unambiguous contracts.²⁵³

VI. MEDICAL PRACTICE AND CORPORATE MALPRACTICE

This Part will not study all potential legal causes of action against health plans for rendering inferior quality of care.²⁵⁴ As noted pre-

252. The typical consumer, of course, will not choose among plans by carefully scrutinizing guidelines. Most people, after all, would find such scientifically esoteric details incomprehensible. But this does not preclude lucid descriptions of the basic ways in which each plan chooses what it will cover and what it will not. As noted, supporters of this general approach have looked to criteria like proven safety, effectiveness, cost-effectiveness, and the like, to distinguish between plans' resource philosophies. See HAVIGHURST, *supra* note 56; Hadorn, *supra* note 164, at xi; Morreim, *Saving Lives*, *supra* note 113; Hall & Anderson, *supra* note 30, at 1689-93; Kalb, *supra* note 247; Morreim, *Diverse and Perverse*, *supra* note 247; Morreim, *Resource Limits*, *supra* note 40, at 47-52; Morreim, *Contributive Justice*, *supra* note 40.

253. See Morreim, *Contributive Justice*, *supra* note 40. Relevant cases include: *Barnett v. Kaiser Foundation Health Plan, Inc.*, 32 F.3d 413 (9th Cir. 1994); *Fuja v. Benefit Trust Life Insurance Co.*, 18 F.3d 1405 (7th Cir. 1994); *Doe v. Group Hospital & Medical Service*, 3 F.3d 80 (4th Cir. 1993); *Loyola University v. Humana Insurance Co.*, 996 F.2d 895 (7th Cir. 1993); *Harris v. Mutual of Omaha Cos.*, 992 F.2d 706 (7th Cir. 1993); *Nesseim v. Mail Handlers Benefit Plan*, 995 F.2d 804 (8th Cir. 1993); *Harris v. Blue Cross Blue Shield*, 995 F.2d 877 (8th Cir. 1993); *Farley v. Benefit Trust Life Insurance Co.*, 979 F.2d 653 (8th Cir. 1992); *McGee v. Equicor-Equitable HCA Corp.*, 953 F.2d 1192 (10th Cir. 1992); *Goepel v. Mail Handlers Benefit Plan*, No. 93-3711, 1993 WL 384498 (D.N.J. Sept. 24, 1993); *McLeroy v. Blue Cross/Blue Shield, Inc.*, 825 F. Supp. 1064 (N.D. Ga. 1993); *Arrington v. Group Hospitalization & Medical Service*, 806 F. Supp. 287 (D.D.C. 1992); *Adnan Varol, M.D. v. Blue Cross & Blue Shield*, 708 F. Supp. 826 (E.D. Mich. 1989); *Thomas v. Gulf Health Plan, Inc.*, 688 F. Supp. 590 (S.D. Ala. 1988); *Sarchett v. Blue Shield*, 729 P.2d 267 (Cal. 1987); *Madden v. Kaiser Foundation Hospital*, 552 P.2d 1178 (Cal. 1976); *Williams v. HealthAmerica*, 535 N.E.2d 717 (Ohio Ct. App. 1987); and *Gee v. Utah State Retirement Board*, 842 P.2d 919 (Utah Ct. App. 1992).

254. Others have done so. See Chittenden, *supra* notes 11, 68. Chittenden's discussion includes brief reference to health plans' and physicians' duties to disclose their cost-containment and incentive systems. See Chittenden, *supra* note 11, at 483. Since that article was written, other cases have supported this potential cause of action, at least in ERISA cases. See *Herdrich v. Pegram*, 170 F.3d 683 (7th Cir. 1999), *cert. granted*, No.98-1949 1999

viously, the predominant avenues currently available are direct liability (mainly for failure to credential and monitor physician staff adequately, or for negligent design or implementation of the UR process) and indirect liability (for the tortious deeds of employees and ostensible agents).²⁵⁵ Rather, this part focuses on those cases in which health plans have literally practiced medicine. Some recent legislative actions appear to authorize placing medical malpractice liability on health plans.²⁵⁶ Texas' law is the first and best known:

(a) A health insurance carrier, health maintenance organization, or other managed care entity for a health care plan has the duty to exercise ordinary care when making health care treatment decisions and is liable for damages for harm to an insured or enrollee proximately caused by its failure to exercise such ordinary care.²⁵⁷

U.S. Lexis 4742 (Sept. 28, 1999); *Shea v. Esenstein*, 107 F.3d 625 (8th Cir. 1997); *Negron v. Patel*, 6 F. Supp. 2d 366 (E.D. Pa. 1998); *Drolet v. Healthsource, Inc.*, 968 F. Supp. 757 (D.N.H. 1997); *McConocha v. Blue Cross & Blue Shield*, 898 F. Supp. 545, 551 (N.D. Ohio 1995); *Neade v. Portes*, 710 N.E.2d 418 (Ill. App. Ct. 1999); *Nealy v. U.S. HealthCare HMO*, 711 N.E.2d 621 (N.Y. 1999). *But see Ehlman v. Kaiser Found. Health Plan*, 20 F. Supp. 2d 1008 (N.D. Tex. 1998); *Weiss v. CIGNA Healthcare, Inc.*, 972 F. Supp. 748 (S.D.N.Y. 1997); *D.A.B. v. Brown*, 570 N.W.2d 168 (Minn. Ct. App. 1997).

Sage and Helvestine also discuss liability. *See Sage*, *supra* note 68, at 173-75; Helvestine, *supra* note 68. Hall likewise discusses theories of liability, including tortious interference with advantageous relationships and fee-splitting. *See Hall*, *supra* note 8, at 460-502.

255. *See generally Schleier v. Kaiser Found. Health Plan*, 876 F.2d 174 (D.C. Cir. 1989); *Paterno v. Albuerno*, 855 F. Supp. 1263 (S.D. Fla. 1994); *Elsesser v. Hospital of Phila. College*, 802 F. Supp. 1286 (E.D. Pa. 1992); *Independence HMO, Inc. v. Smith*, 733 F. Supp. 983 (E.D. Pa. 1990); *Albain v. Flower Hosp.*, 553 N.E.2d 1038 (Ohio 1990); *McClellan v. HMO of Pa.*, 604 A.2d 1053 (Pa. Super. Ct. 1992); *Boyd v. Albert Einstein Med. Ctr.*, 547 A.2d 1229 (Pa. Super. Ct. 1988); *DeGenova v. Ansel*, 555 A.2d 147 (Pa. Super. Ct. 1988) (bringing an action against an insurer); *Dunn v. Praiss*, 606 A.2d 862 (N.J. Super. Ct. App. Div. 1992). A recent case upholding both corporate negligence and vicarious liability claims against an HMO is *Shannon v. McNulty*, 718 A.2d 828 (Pa. Super. Ct. 1998).

256. This development is to be distinguished from earlier cases in which courts have considered whether physicians acting in their capacity as MCO medical directors have practiced medicine. In Part II.A, three such cases were discussed: *Murphy v. Board of Medical Examiners*, 949 P.2d 530 (Ariz. Ct. App. 1997); *Hand v. Tavera*, 864 S.W.2d 678 (Tex. App. 1993); and *Morris v. District of Columbia Board of Medicine*, 701 A.2d 364 (D.C. 1997). These cases do not place malpractice liability on MCOs; their reach extends solely to physicians, and inquires whether UM activities fall within the ambit of medical practice.

257. TEX. CIV. PRAC. & REM. CODE ANN. § 88.002 (West 1999). The statute continues:

(b) A health insurance carrier, health maintenance organization, or other managed care entity for a health care plan is *also* liable for damages for harm to an insured or enrollee proximately caused by the health care treatment decisions made by its:

- (1) employees;
- (2) agents;

Since the Texas statute was enacted, other states including Georgia²⁵⁸ and Missouri²⁵⁹ have proposed or enacted similar provisions. When the Texas statute was challenged on ERISA grounds,²⁶⁰ several features of the statute were held to be preempted by ERISA.²⁶¹ However, the United States District Court for the Southern District of Texas held that ERISA did not preempt those clauses holding health plans liable for failing to exercise due care when making treatment decisions,²⁶² arguing that the statute refers to the quality, not quantity, of the care rendered.²⁶³ Although this Article will not elaborate on ERISA issues, the statute will assuredly

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- (3) ostensible agents; or
 - (4) representatives who are acting on its behalf and over whom it has the right to exercise influence or control or has actually exercised influence or control which result in the failure to exercise ordinary care.

Id. (emphasis added). Note that this second source of liability simply places a legislative endorsement on the vicarious liability health plans have already incurred for the misdeeds of their employees, agents, and ostensible agents.

256. See Ga. H.B. 732, 145th Gen. Assembly, Reg. Sess. (Ga. 1999); Ga. S. Res. 210, 145th Gen. Assembly, Reg. Sess. (Ga. 1999).

259. See Mo. H.B. 335, § A, 89th Gen. Assembly, 1st Reg. Sess. (Mo. 1997) (codified as amended at MO. ANN. STAT. § 354.505 (West 1999)). The bill deleted the following subsection from Missouri Revised Statute section 354.505: "Any [HMO] authorized under [s]ections 354.400 to 354.550 shall not be deemed to be practicing medicine and shall be exempt from the provisions of Chapter 334, R.S.Mo." *Id.* As Garrison observes:

Concurrent with the elimination of this provision, H.B. 335 adds HMOs to the definition of health care provider under Missouri's medical malpractice statutes. It also includes HMOs in the peer review protections of Chapter 537. The significance of these changes remains to be seen. According to a bulletin issued by the Department of Insurance, the Department interprets the amendment to Missouri Revised Statute section 354.505 as making HMOs subject to medical malpractice claims. There are, however, strong arguments that the amendment should not be interpreted to create a liability that would not otherwise exist.

Garrison, *supra* note 33, at 782-83.

260. See *Corporate Health Ins. Inc. v. Texas Dep't. of Ins.*, 12 F. Supp. 2d 597, 603 (S.D. Tex. 1998). For discussion of ERISA, see Morreim, *Resource Limits*, *supra* note 40, at 76-94; Morreim, *Contributive Justice*, *supra* note 40, at 251-52.

261. For example, the court preempted those parts that established an independent appeals process for coverage denials, forbade health plans to remove physicians because they had advocated for patients, and forbade indemnification or hold harmless clauses. See *Corporate Health Ins.*, 12 F. Supp. 2d at 630.

262. The statute defines a health care treatment decision as "a determination made when medical services are actually provided by the health care plan and a decision which affects the quality of the diagnosis, care, or treatment provided to the plan's insureds or enrollees." TEX. CIV. PRAC. & REM. CODE ANN. § 88.001 (West 1999).

263. See *Corporate Health Ins.*, 12 F. Supp. 2d at 611-20.

be relevant to non-ERISA plans, regardless how courts address the ERISA issues.²⁶⁴

We turn to the question whether and how malpractice tort claims might be applied to health plans' practice of medicine. As a prefatory point it is useful to note that once health plans abandon contractual reliance on "medical necessity" and embrace explicit guidelines-based contracting, they will vastly reduce the extent to which they practice medicine. In this revised setting the plan essentially says "if you purchase this plan, here is what you get:" Immediately, most of the instances in which health plans are currently practicing medicine by making medical judgments will become fairly straightforward matters of contract reading. The plan administrators look at the relevant guidelines and conclude: "see, here it is—you do(n't) get that." Where this is the case, the plan is subject to standard principles of contract law, not tort malpractice law. When the plan wrongly fails to provide what it clearly was obligated to cover, contract law can provide surprisingly adequate remedies.²⁶⁵

Not all contract interpretations will be clear and straightforward. Even the best clinical guidelines cannot cover every possible scenario. Sometimes they will be unclear about the case at hand, and in other cases they may be contrary to a patient's interests and will require a legitimate exception. As outlined in Part II,²⁶⁶ this scenario is a key instance in which an MCO will practice medicine. Accordingly, before any malpractice claim can succeed, a plaintiff must first show that the MCO was actually practicing medicine, and not just interpreting the contract. To recall the definition provided in this Article,²⁶⁷ practicing medicine involves two dimensions: (1) making a medical judgment that (2) has a significant impact on the patient's care and outcome. Both these dimensions require further discussion before turning to the mechanics of bringing a tort malpractice action against an MCO. Following that discussion, the remainder of this Part will consider some of the distinctive challenges that arise in bringing a malpractice action against an MCO.

264. For further discussion of ERISA and health plans' liability, see Morreim, *Resource Limits*, supra note 40, at 76–94.

265. See *id.* at 52–62.

266. See *supra* notes 18–67 and accompanying text.

267. See *supra* notes 68–112 and accompanying text.

A. Medical Practice

1. *Making Medical Judgments*—Clear guidelines that straightforwardly apply to a particular patient do not require the MCO to make medical judgments. If an otherwise healthy adult falls and bumps his head, but experiences no dizziness or loss of consciousness, a guideline might suggest a brief period of observation followed by instructions for rest and reexamination if symptoms change. If such a patient nevertheless demands a computed tomography (CT) scan, just to be sure his headache does not signify terrible trauma or a sudden onset of brain cancer, the MCO can point to the guideline and declare “see—here it is: you don’t get that.”

A well-crafted guideline will also provide alternate instructions for common variations of the situation, as where someone has experienced loss of consciousness, double vision, or similar symptoms. More broadly, guidelines commonly offer an array of options, not just one-size-fits-all mandates. Such flexible guides should adequately address the great majority of routine situations—and routine situations, by definition, represent the great majority of cases.²⁶⁸

Where guidelines are sufficiently clear and applicable to the particular patient, there should be little need for discussion.²⁶⁹ Note that in cases where a guideline is quite clear in permitting a patient access to a particular service or product, and the MCO nevertheless wrongfully denies it, the plan is engaging in breach of contract, not the practice of medicine. For instance, if the MCO’s drug formulary includes a particular medication the patient requests and a UM clerk mistakenly says the drug is not on the formulary, then the problem is a simple breach of contract.

268. If such guides are adequately disseminated, as by computer links with physician offices, ideally there should be no need for physicians to contact health plans frequently. Open guidelines should thus, at least in principle, ameliorate a significant portion of the “hassle-factor” currently permeating many physicians’ practices, as they or their staffs must spend large amounts of time arguing with clerks about invisible edicts.

269. In another option for streamlining the process, health plans might leave the most routine decisions to physicians and patients, and produce guidelines only for the costlier, more complex situations where some measure of uniformity is more important. In such a don’t-sweat-the-details arrangement, cost-containment at these lower levels could be achieved by placing patients under medical savings accounts or similar financial incentives. Where patients and physicians have reasons to consider the economic as well as the medical wisdom of proposed interventions, there is little need for health plans to intervene. For a more detailed description of such approaches, see Morreim, *Diverse and Perverse*, *supra* note 247, at 105–18; Morreim, *Saving Lives*, *supra* note 113.

At the same time, even the best guidelines will not cover every scenario. If the head-bumping patient is a child who also happens to have been gobbling up large doses of the anticoagulant (blood-thinner) pills prescribed for her grandmother's heart condition, the usual guidelines may be inapplicable because in this unusual scenario there is an increased danger of intracranial hemorrhage or other complications atypical of ordinary head-bumps. In atypical situations the MCO must combine two types of reasoning.

First, because the "letter" of the guideline is insufficient, the MCO must interpolate the "spirit" of the health plan's contract to apply to the present situation. If the contract is a generous, no-holds-barred plan, the MCO would probably have to approve whatever interventions would maximize the health and safety of the patient, regardless of cost. If the plan is more conservative, and generally restricts enrollees to the most cost-effective interventions among those that are likely to preserve the patient's life and health, the options will be more limited. In other words, it is one thing for the patient to request a flexibility that can be legitimately encompassed within the overall resource limits of the plan, and quite another to ask for a clearly higher level of care. Although MCOs' guidelines must be fundamentally medically sound, they need not cover every conceivable benefit for maximally optimal care. This periodic need to interpolate the spirit of the contract—that is, to interpret ambiguities as the guidelines are implemented in practice—is a standard phenomenon in contracts and contract law. In this process, the MCO is not necessarily making any medical judgments.

Second, a different kind of reasoning requires the MCO to discern, as it evaluates requests for outside-the-guidelines services, whether the proposed care is likely to help the patient, or whether some alternative would be as good or better, within the basic parameters of the plan. For these judgments the MCO must know what the patient's current condition is, which kinds of intervention have what probabilities of helping, with what risks, and other relevant factors. A request for a costly drug that is not on the formulary, for instance, will require information about what side-effects the patient has experienced with the approved drugs, or what symptoms indicate that these should not be tried, how likely the requested drug will avoid such problems, and so forth. In such situations the MCO is making medical judgments. These medical judgments can be made well or poorly, with adequate or inadequate information, and with a good or poor understanding of the clinical realities of diagnosis and treatment for people in this

patient's situation. In this context MCOs will be rightly judged for the adequacy of the factual and medical basis on which they made their medical judgment.

2. *Affecting Patient Care*—Aside from making medical judgments, practicing medicine requires that the judgment be implemented and have a significant impact on care and outcomes. To review briefly the discussion in Part II,²⁷⁰ two elements are important.

First, the denied intervention must at least plausibly be owed by the MCO to the enrollee. As noted,²⁷¹ where the health plan clearly does not owe an intervention, then even if the lack of funding prompts a denial of care and ultimately an adverse outcome, that outcome is not attributable to the plan. The MCO is no more responsible than any other bystander who also did not owe the intervention.²⁷² Undoubtedly, a significant area for litigation will focus on the ambiguous cases where coverage is unclear. But with reasonably clear guidelines instead of the fuzzy "medical necessity" standard, these instances should occur less often.

Second, the denial of resources must have a significant impact on decision making and thereby on outcomes. In many cases this will be obvious. Health care is often very costly, and physicians, hospitals, and other providers are increasingly reluctant to offer services with no assurance of payment. But the bare fact that an MCO has declined coverage does not, ipso facto, mean that the patient will be denied care. If the patient is affluent, or the cost of the service is easily affordable, or the denial only triggers a small increase in copayment, or other sources of funding can conveniently be found, or providers are content to render care without assurance of payment, then the MCO's denial is not necessarily decisive. More important from the standpoint of ascribing liability, an MCO's denial does not always mean a refusal of all coverage. Where the MCO's denial means only a marginal diminution of coverage—as when it pays eighty percent instead of ninety percent of the intervention—then, analogous to analysis looking for proportionate fault, the MCO may not bear as much causal responsibility as it would have, had its decision been a complete denial of all coverage.²⁷³

270. See *supra* notes 18–67 and accompanying text.

271. See *supra* Part II.C.

272. See Morreim, *supra* note 62.

273. In *Adnan Varol, M.D. v. Blue Cross & Blue Shield*, 708 F. Supp. 826 (E.D. Mich. 1989), a district court found that psychiatrists who had agreed to a managed care arrangement and then found its terms intrusive were nevertheless contractually bound. The court

For litigation purposes, courts may need to identify some general criteria to guide decisions about whether a health plan's denial of resources had sufficient impact on treatment decisions to constitute a "substantial factor". The analysis could be tuned to the individual in question, and inquire strictly whether that individual could easily have gotten treatment despite the denial of coverage. Or the analysis could inquire more broadly whether the "reasonable person" would have deemed the influence significant. In either case, the court will only inquire into this issue if it finds that the health plan did owe the patient the coverage in question. If coverage was not owed, then its denial was not a "substantial factor" in causing the treatment decision, no matter how badly the patient needed the treatment or the money.

B. Ascribing Malpractice

In the final analysis, then, MCOs can potentially be liable for medical malpractice. But this is only so only where the MCO has practiced medicine, and has done a poor job of it with the result that the patient is wrongly denied coverage he should have gotten, and the denial is a substantial factor in the patient's failure to

noted that even when authorization for services was denied, the providers still received most of their fee:

[T]he Program in no way prevents providers from obtaining full payment even for rendering services that are not concurrently reviewed or preapproved. If the treating psychiatrist renders the service, that psychiatrist can still obtain 80 percent of his fee directly from BCBSM and collect the balance from the patient. So the denial of approval does *not* have the effect plaintiffs have urged; it merely changes from whom providers collect the 20 percent.

Id. at 833. Although in this case the court's reasoning applied most directly to physicians, it also applied to patients, whom the physicians would expect to pay the difference. In the eyes of the court, a reasonably affluent patient can make the copayment, while a reasonably affluent physician can absorb the defaults of those who cannot.

In *Long v. Great West Life & Annuity Insurance Co.*, 957 P.2d 823 (Wyo. 1998), a denial of payment-authorization meant a far more substantial change in patients' cost-sharing, and might be expected to have a considerably greater impact on decisions about the patient's care. "Under the contract, surgery performed without authorization would result in a payment penalty. Authorized surgery was paid at 80% up to \$5000.00 less deductibles and then 100% over \$5000, while unauthorized surgery would only be paid at 60% for all costs." *Id.* at 825. Nevertheless, it might be noted in this case and in a number of others the patient actually received the treatment, paid out of pocket, and then sued afterward for these expenses and other alleged damages. See also *Lenox v. Healthwise of Ky., Ltd.*, 149 F.3d 453, 455 (6th Cir. 1998) (noting patient eventually underwent successful heart transplant despite insurer's denial of coverage); *Bast v. Prudential Ins. Co.*, 150 F.3d 1003 (9th Cir. 1998) (patient paid for initial stages of autologous bone marrow transplant after payer denied coverage).

receive the care he should have gotten, thereby precipitating an otherwise avoidable adverse outcome. The criteria for ascribing malpractice here, as elsewhere, are the usual tort criteria of duty and breach, injury, and causation.

The latter elements will not be a focus in this Article. Questions about the existence of an injury can be settled in the usual ways. Given the definition of medical practice offered, at least part of the causality issue will already have been addressed. In order to say that the MCO has actually practiced medicine, one must already have determined that the MCO made a medical judgment that affected the patient's care. Establishing that impact, as defined in Part II.C,²⁷⁴ requires a determination that the MCO's denial of coverage was a "substantial factor" in bringing about the treatment decision that was actually made. A further causal inquiry must, of course, establish that the denial, delay, or change in treatment, in turn, caused the patient's injury. This, like establishing the existence of an injury, is a routine task in malpractice tort litigation.

More interesting is the question what constitutes the MCO's duty of care when it makes medical judgments. The issues are too complex to permit exhaustive treatment here. But several observations can be made. To begin with, the usual way in which the medical standard of care is set, by appealing to physicians' prevailing practices, would not satisfactorily establish MCOs' duties. As suggested in Part III, physicians' practices are not necessarily optimal either medically or financially, and as argued in Part IV, MCOs should have significant opportunities to shape the care their enrollees receive. Indeed, this author has argued elsewhere that the prevailing-practice approach to the standard of care is an anachronism that must be dropped, even as the ruler by which to measure physicians.²⁷⁵

Rather, health plans' duty of care in practicing medicine should be understood as an obligation to bring sufficient knowledge, care, skill, judgment, efficiency, and effort to their tasks—a duty of expertise, as distinct from an obligation to deliver resources.²⁷⁶ In this sense, health plans' duties must for technical reasons be a bit different from expertise duties owed by physicians. A physician has an obligation to examine the patient carefully, for instance to listen carefully and knowledgeably to heart sounds, or to use a scalpel with precision so as to avoid damaging nearby tissue. Obviously an organization such as an MCO cannot literally perform such hands-

274. See *supra* notes 18–67 and accompanying text.

275. See Morreim, *Resource Limits*, *supra* note 40.

276. For further discussion of the distinction between expertise and resources, see *id.*

on functions. Accordingly, the MCO's duty of expertise must be drawn in terms of its judgments about the patient's medical situation, based on information it gathers from the attending physician and other sources.

As the MCO makes medical judgments, its duty of care begins with the obligation to obtain an adequate factual picture. The MCO should avoid drawing conclusions and should seek further information if it knows or suspects it does not have all the relevant facts.²⁷⁷ Further, the MCO's medical judgments should be based on advice from sufficient numbers of physician-consultants with adequate training in the relevant field(s). Thus, the MCO should not make a decision about the effectiveness of lung reduction surgery for emphysema by asking a dermatologist, nor should it ask a family practitioner to guide its judgments about which interventions are appropriate for pediatric intensive care.²⁷⁸ In the end, if the MCO undertakes sufficiently careful procedures, its own medical judgments should be at least as credible as the attending physician's.²⁷⁹

277. Sorting out problems surrounding inadequate factual information can pose interesting challenges. Where a deficit is due to an attending physician's recalcitrant refusal to furnish the necessary information, then arguably the blame and liability for any resulting adverse outcomes would shift to the physician. But reciprocally, where a health plan places onerous administrative burdens on its physician staff, the blame and liability can shift back toward the health plan. For further discussion, see *id.* at 64-67.

278. In a poignant case, a young California girl diagnosed with Wilm's tumor could be cured with surgery. The operation is technically demanding, however, and can only be successful if performed by a highly experienced surgeon. TakeCare Health Plan, the family's HMO, insisted that the surgery be done by a general surgeon with no experience in this particular procedure, rather than by the highly experienced pediatric surgeon whom the family had requested. The child eventually received the surgery from the qualified surgeon, and the HMO was penalized by the California Department of Corporations. See Hirshfeld & Thomason, *supra* note 8, at 36-37. Quite possibly, the HMO's error in this case stemmed at least partly from inadequate medical understanding and a failure to appreciate the need for specialized surgical expertise.

279. This potential for health plans to make medical judgments that improve upon attending physicians' judgments is rooted partly in the fact that so many ordinary physicians' actual practices are not well-founded on scientific research. See *supra* Part IV.B. Numerous researchers have documented that physicians' practices vary widely, without any particular relation to patients' underlying illnesses. See Guadagnoli et al., *supra* note 140, at 573; Leape et al., *Practice Volumes and Geographic Variation*, *supra* note 140, at 656 (supporting John Wennberg's hypothesis that geographic variation in use of surgical procedures results from referral and performance patterns in the area); Wennberg, *Paradox*, *supra* note 140, at 2568; Wennberg et al., *Hospital Use*, *supra* note 140, at 1172 (describing study of Boston and New Haven that found rates of hospital use gave no information on relative illness rates); Wennberg et al., *Invasive Cardiac Procedures*, *supra* note 140, at 1161; Wennberg et al., *Rationed*, *supra* note 140, at 1185.

A practical example illustrating that MCO judgments might sometimes be better than individual physician judgments comes from a recent Sacramento case. The attending physician for a woman with an ostensibly localized cancer of the cervix (squamous cell cancer *in situ*) wanted to treat her with a hysterectomy, i.e., removal of the entire uterus as well

Aside from individual medical judgments, the guidelines themselves might be a potential target for malpractice litigation, because MCOs must bring good medical reasoning to the process whereby they select and modify their guidelines over time. This is not to say that all plans must subscribe to the same guidelines. There is wide latitude for differences among plans, because there are many legitimate ways to make the risk-benefit and cost-value tradeoffs implicit throughout medical decision making.²⁸⁰ But it would be a mistake to infer that therefore every guideline is as credible as any other. As noted in Part III,²⁸¹ many of the guidelines in use today have little or no scientific foundation and precious little medical credibility. Accordingly, the guidelines themselves should reflect sound medical judgment.²⁸²

as the cervix, even though her cancer appeared to be completely confined to the original site. Humana, the patient's HMO, recommended an alternative. Removing just the affected cone of the cervix would be not only less expensive, but equally effective in terms of removing the cancer and distinctly safer, with decreased risks of bleeding, adverse anesthesia reactions, abdominal pains, and infections. If a pathologist's review of the removed tissue showed that the cancer was confined to the excised cone, nothing further need be done; if the review showed the cancer was not confined, a hysterectomy could then be undertaken. See Tom Philp, *When Juries Play Doctor, Verdicts Can Be Bitter Pills*, SACRAMENTO BEE, NOV. 9, 1998, at B7. The need for such decision making is evident in this regard:

When it comes to hysterectomies, hundreds of thousands of women have been saved from needless surgeries by health insurers and medical researchers who had the courage to challenge the practice patterns of doctors.

. . . .

Back in 1975, when insurers rarely scrutinized surgery proposals, American doctors performed 725,000 hysterectomies. Experts throughout the 1980s suggested that many hysterectomies were not necessary. Doctors now perform about 150,000 fewer hysterectomies every year. What's more, studies out of Dartmouth University have proven that doctors in certain sections of the country are far more likely to recommend surgery than doctors elsewhere. One's zip code rather than one's medical condition can be a better predictor of whether a doctor will recommend surgery.

Id. Relying not only on its own physicians, but also on an independent panel, the MCO thus offered a medical judgment that it deemed not just to be more consistent with the patient's contract, but medically superior to the attending physician's opinion. As the case turned out, the patient elected to follow her physician's more aggressive approach and paid \$14,000 out of pocket for the hysterectomy. Pathological review showed that her cancer was confined just to the cone of the cervix. Nevertheless, the patient sued the MCO and won a jury verdict of \$13.1 million. See *id.*

280. See Morreim, *Diverse and Perverse*, *supra* note 247; Morreim, *Resource Limits*, *supra* note 40; Morreim, *Saving Lives*, *supra* note 113.

281. See *supra* notes 68–112 and accompanying text.

282. A classic example of a guideline once included in one major commercial set of guidelines was marketed by the actuarial firm Milliman & Robertson to such firms as Cigna, Prudential, United Healthcare Corp, U.S. Healthcare Inc, and others. See George Anders, *Limits on Second-Eye Cataract Surgery Are Lifted by Major Actuarial Firm*, WALL ST. J., DEC. 15,

Tort evaluation in this area will once again focus largely on procedures. Relevant questions would include how the MCO chose or developed the guideline in question—whether there is any scientific basis, whether qualified physicians were invited to comment on it, and how readily the plan will consider changes if clinical experience shows the guideline to be seriously flawed.

Overall, when health plans practice medicine the focus of tort is on sufficiently careful procedures, a point that carries from the narrowest to the broadest level: the plan must use due care to ensure that it has medically accurate, adequate information about the patient; it must use due care to ensure that it has medically accurate, adequate information about the patient; it must use due care to ensure that its selection, adaptation, and ongoing revisions of guidelines are medically credible. The focus is on the MCO's policies, its procedures for implementing them, and the care and faithfulness with which it followed its own mandates.

CONCLUSION

The past decade has brought stunning changes in health care. Spiraling costs have slowed or leveled, even if only temporarily. But the price for that prized result was a measure of activism by health plans that has deeply concerned physicians and sometimes frightened the public. Although anti-managed care horror stories in the media have undoubtedly been exaggerated or distorted at least some of the time, some very real concerns have emerged concerning the proper role that MCOs should play in the daily delivery of clinical care. Simplistic answers will not suffice. It is not true that every time an MCO declines to cover a proposed intervention it has practiced medicine, let alone practiced it badly, or that it deserves to pay in tort just for disagreeing with a treating physician. At the same time, neither should MCOs be permitted blithely to escape accountability in those instances where they have truly practiced medicine, and done so in a substandard fashion. As proposed in this Article, excellence in health care requires first that we determine who, between health plans and physicians, should be controlling which aspects of care. In such a framework, health

1994, at B6. The guideline regarding cataract surgery indicated that “[a]fter one lens has been removed, removal of the other lens is only indicated in a relatively young person who requires binocular vision for vocational function.” *Id.* The flaws of such a guideline are as obvious: a frail, elderly person attempting to descend a staircase needs binocular vision at least as much as a younger working person. The guideline was eventually dropped. *See id.*

plans should focus, not on micro-management, but on patterns of care and on guidelines-based contracting that will sharply limit the instances in which they literally practice medicine. Even so, where MCOs do play doctor, they should be open to malpractice accountability, right alongside physicians.