Cost-Effectiveness Analysis in the Courts: Recent Trends and Future Prospects

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Abstract This article provides an initial look at how managed care organizations (MCOs) might incorporate cost-effectiveness analysis (CEA) into their decision-making process and how the courts might respond. Because so few medical liability cases directly involve CEA, we must look at other areas of the law to assess potential MCO liability for applying CEA. In general negligence cases, courts rely on a risk-benefit test to determine customary practice. Likewise, in product liability cases, courts use a risk-utility calculus to determine liability for product design defects. And in challenges to government regulation, courts examine how agencies use CEA to set regulatory policy. The results have been mixed. In product liability cases, CEA has led to some punitive damage awards against automobile manufacturers. But courts have integrated it in negligence cases without generating juror antipathy, and generally defer to agency expertise in how to incorporate CEA. The article discusses the implications of these cases for MCO use of CEA and outlines various options for setting the standard of care in the managed care era.

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Cost control is a primary objective of the managed care environment.[1] It is no longer possible to provide health care without regard to cost or patient demand. The question is not whether there will be cost containment, but how to structure and oversee its implementation. Neither the courts—to whom patients frequently turn when the general need for cost containment turns into the specific need to deny treatment—nor other policy makers can successfully resolve managed care disputes by ignoring or wishing away the fundamental fact of scarcity. At issue is how courts will respond to managed care's cost containment initiatives in developing liability principles for the managed care era.

A potentially significant cost containment approach is the use of cost-effectiveness analysis (CEA) in making clinical and payment decisions. This article provides an initial look at how managed care organizations (MCOs) might incorporate CEA into their decision-making process and how the courts might respond. We examine how courts have viewed CEA when used by private parties to set industry custom and by governmental agencies in promulgating regulations. We also consider what these judicial trends portend for future legal doctrine in health care.

At present, there is a lot of skirmishing over cost containment. MCOs seem reluctant to publicize the role of cost constraints in clinical and payment decisions, and the courts are slowly figuring out how to construe the reality of scarce resources in applying liability standards to MCOs. It probably won't be long before the skirmishing breaks out into direct conflict. In anticipation of the conflict, this essay suggests ways in which courts might incorporate CEA into the standard of care. We conclude that CEA should be treated as one piece of evidence to be considered by a jury rather than being used to determine the standard of care.

Organization of the Article

The next section discusses the concept of CEA, how it might be used in clinical decisions, and barriers to its use. Then we look at how CEA has been interpreted in the courts. After briefly describing how courts establish liability (the standard of care), we discuss how courts have used CEA in a range of case types, including nonmedical negligence litigation, medical malpractice cases, environmental law, and product liability cases. We then examine how CEA might arise in future health care cases and

1. We define cost containment initiatives as that set of managed care practices designed to reduce the costs of health care by encouraging providers to limit medical treatment. For more detailed consideration, see Gold et al. 1995.

how the courts might respond. We conclude with a discussion of what the standard of care should be in the managed care era.

Cost-Effectiveness Analysis (CEA)

Defining CEA

Cost-effectiveness is a widely used but imprecise term that means different things to various users. Like the term *medical necessity*, there is no common conceptual understanding of what it means or how it should be used (Gold et al. 1996). According to A. M. Garber et al. (1996: 26), "Cost-effectiveness analysis is a method designed to assess the comparative impacts of expenditures on different health interventions."[2] CEA assesses the advantages and disadvantages of alternative interventions to examine the inevitable trade-offs in resource allocation (Berger and Teutsch 2000). Even though the definition is seemingly straightforward, CEA is deceptively difficult to apply.

In assessing alternatives, CEA uses a ratio where the denominator is the gain in health (such as adverse reactions avoided) and the numerator is the incremental cost of obtaining the benefits. The denominator may be expressed in years of lives saved or undesirable outcomes averted. The primary advantage of CEA is the ability to compare two interventions aimed at the same outcome. But a disadvantage is that the denominator may omit important aspects of quality of life, satisfaction, different preferences, values, etc. (see, e.g., Goold 1996; Gold et al. 1995). Another problem is that by definition, cost-effectiveness analysis presupposes knowledge regarding the overall effectiveness of a given clinical intervention, which is often not known. This problem plagues many areas of clinical decision making, helping to explain why few clinical decisions are grounded explicitly or primarily on the results of a CEA.

CEA differs from cost-benefit analysis (CBA) and cost-utility analysis (CUA) in how the benefit is expressed.[3] In CEA, the common measure is one of nonmonetary effectiveness, while CBA is expressed in dollar terms and CUA is expressed in quality adjusted life years (Titlow et al. 2000). Because of discomfort with ascribing dollar values to health outcomes, CEA is more often used by health services researchers.

2. Eddy (1996: 653) adds that a clinical intervention "is considered cost-effective if there is no other available intervention that offers a clinically appropriate benefit at a lower cost."

3. Some economists treat CBA and CUA as a variant of CEA. Personal communication with Michael Chernew, 15 August 2000.

As an example, consider the debate over whether to provide yearly mammograms to women under fifty. According to one synthesis of the literature, yearly mammogram screening is not as cost-effective for women under fifty as it is for women between fifty and sixty-nine ($105,000 per cost of year gained for the former relative to less than $50,000 for the latter) (Salzmann, Karlikowske, and Phillips 1997; see also Eddy 1997; Hirth et al. 2000). Suppose that based on this information, a plan decides not to offer mammograms to women under fifty and that a forty-five-year-old then sues the plan for failure to detect her breast cancer. She alleges that the failure to screen resulted in a more advanced disease. The plan will argue that the money saved by not investing in the less cost-effective screening can better be allocated to more productive uses. The patient will argue that the use of cost-effectiveness ignores unmeasured benefits and that there is no widely accepted threshold for determining when a particular intervention should be provided (Hirth et al. 2000). Although other evidence will be presented, such as professional consensus statements, how the jury reacts to the plan's CEA will likely determine the decision.

Using CEA in Clinical Decisions

So far, there is little direct evidence that CEA is an integral aspect of clinical or payment decision making among managed care plans. For example, M. R. Gold et al. 1995 examined the state of the art in cost control mechanisms as of 1994 but do not mention CEA in their report. In a recent and thorough review of managed care practices, Gold (1999) makes no mention of CEA as an integral element in MCO cost containment practices. It seems as though CEA is more talked about than implemented (Prosser et al. 2000; Jacobson et al. 1997). Nonetheless, MCOs may be using CEA but implicitly and below the radar screen. For example, cost considerations could be incorporated implicitly into the development of clinical practice guidelines or in rendering utilization review decisions. Because MCOs are cost-conscious organizations, these considerations must enter into their decisions.

If CEA were to operate as well as its proponents expect, CEA would become a basis for clinical decision making so that the most cost-effective clinical alternative would be chosen. At this point, however, how MCOs might actually use CEA in making clinical or payment decisions is an evolving process. While the literature does not specify how that

process is working right now, there are several identifiable areas where CEA can be expected to emerge.

Benefit Packages. CEA could be used to determine the set of benefits to be offered to managed care subscribers. Plans might contract with employers to use CEA in making benefit determinations for subscribers. For example, the contract might state that based on CEA, yearly mammograms will only be provided for women over fifty.

Medical Necessity Determinations. Despite the continuing controversy over how to define and use the concept of medical necessity, it remains a commonly used concept for making clinical and insurance payment decisions. David M. Eddy has perhaps been the foremost proponent of including cost-effectiveness as an element of clinical decisions. Working with the National Institute for Health Care Management, Eddy (1996) developed a proposed approach that would require health plans to cover interventions based on the following criteria: (1) used for a medical condition; (2) sufficient evidence to draw conclusions about the effects on health outcomes (including the quality of life); (3) evidence that the intervention will produce the intended effects; (4) beneficial effects outweigh the harmful effects; and (5) the intervention is the most cost-effective method available to address the medical condition (NIHCM 1994). One way to incorporate CEA in clinical decisions is through the use of clinical practice guidelines based on cost-effectiveness criteria. Kaiser Permanente did so in developing guidelines for using contrast agents (liquid dyes used to improve the clarity of Xrays) without any resulting litigation (though not all physicians were exactly thrilled with the idea) (Eddy 1996; Jacobson and Rosenquist 1996).

It is not clear how widely CEA is incorporated into medical necessity decisions. One study found that some medical necessity definitions incorporate CEA but that respondents were divided as to its efficacy (Jacobson et al. 1997). The study found that administrators generally favored its use, while physicians (including plan medical directors) viewed it as an intrusion into their clinical autonomy. In contrast, a more recent study in California also found that only a few medical necessity contractual definitions included cost-effectiveness, but that private plan and medical group medical directors mentioned cost-effectiveness as a prominent criterion for clinical decision making (Singer et al. 1999). If confirmed by other studies, the Singer et al. results suggest that there is a gap between

what plans actually do and what is reported publicly or in the literature. Another important finding from the California study is that many respondents would approve an equally effective but more costly treatment "for fear of litigation or backlash if it were to be discovered that they had considered cost" (ibid: 57).[4]

Utilization Management. After a physician determines that a particular intervention is medically necessary, the MCO might then review the decision as part of its utilization management (UM) regime. At this point, the MCO could use a range of factors, including CEA, to determine whether the recommended intervention should be provided. Nothing in the literature shows that CEA is now an explicit component of the UM process, although it seems clear that cost considerations play an important role. Many of the studies cited above indicate that the incentives inherent in managed care are factored into the decision, including the use of clinical practice guidelines and preauthorization for high-cost medical interventions.

Pharmacoeconomics. A fourth area in which CEA could play a prominent role is in the emerging field of pharmacoeconomics. Because pharmaceutical costs are rising at such a rapid rate, many health care providers are turning to pharmacoeconomics to help them determine which pharmaceuticals to cover in the drug formulary. By definition, this process involves CEA. Most of these analyses are conducted by pharmacy benefit managers (PBMs) not by MCOs (Titlow et al. 2000; Rosoff 1998).

Indeed, a recent survey found that MCOs rely on information provided by PBMs, including CEA, literature reviews, drug utilization reviews, and recommendations for disease management programs (Titlow et al. 2000). The study also found that cost was only the third most often cited factor determining pharmacy coverage decisions, behind the drug safety profile and FDA approval. Costs were an important factor in shaping the overall formulary but not in deciding whether to cover individual pharmaceuticals. The authors noted that survey respondents "might have been reluctant to openly acknowledge the dominance of cost," but other data supported their findings (ibid.: 245; see, e.g., Jacobson and Rosenquist

4. Although the authors collected data from thirty-four plans and medical groups, the actual number of plan and group staff interviewed is not apparent in the final report, making it difficult to assess the validity of the reported results.

1996). Nevertheless, this raises the question of which entity would bear the potential liability if an MCO is sued for excluding a pharmaceutical based on a PBM's CEA.

Barriers to Using CEA in Medical Decisions

In theory, MCOs would appear to be perfect proponents and users of CEA. After all, the guiding concept of managed care is to provide high-quality care at a lower cost than in the fee-for-service system. Yet it appears that CEA is not widely used by MCOs, at least not explicitly or as reflected in the published literature. One of the few exceptions to this, as noted above, is the use of CEA in Kaiser Permanente's decision to use lower cost contrast agents for low-risk patients (Eddy 1992).

In a recent article, L. A. Prosser et al. (2000) suggest that serious barriers limit MCOs' use of CEA. They argue first that MCOs are not aware of the usefulness of CEA or, if they are aware, may still question its applicability. Clinical effectiveness, as opposed to cost-effectiveness, appears to be driving the decision-making process. Surprisingly, Prosser et al. argue that MCOs actually have limited incentives to use CEA. Right now, plans are able to achieve cost control through the other mechanisms, such as capitation, noted above that shift the cost control burden to physicians. That way, an MCO may have less risk of liability and be subject to less public anger.

Not surprisingly, Prosser et al. (ibid.) note the negative public perceptions (i.e., public relations problems) that could emanate from explicit use of CEA. Noting that Oregon had to retreat from using CEA in setting its priority list, the public may not be ready to accept an explicit CEA clinical approach.[5] Many MCOs are already reeling under the onslaught of the managed care backlash and may be reluctant to push much further. Physicians have also reacted negatively to including CEA in clinical practice guidelines as an intrusion into physician autonomy. Interestingly enough, Prosser et al. do not include litigation as a potential barrier. Given the recent jury verdict against General Motors for using CEA in deciding where to locate the gas tank (discussed below), it would be surprising if MCO administrators were not at least somewhat concerned about liability.

Currently, there are both methodological and process difficulties in

5. This, of course, creates some cognitive dissonance with the public's apparent desire to reduce health care costs. Perhaps it's the health care equivalent of the NIMBY syndrome (not in my backyard).

implementing CEA. The methodological problems include data timeliness, bias in the data sources, the lack of comparative studies, disputes over measuring costs and effectiveness, concerns about the subjectivity inherent in defining the denominator, and disagreement about the benchmark cost-effective threshold to be used (see, e.g., Hirth et al. 2000). CEA may undervalue health benefits and there may be limited evidence of clinical effectiveness for a wide variety of interventions. There is also no standard CEA methodology that can be pulled off the shelf to use, making it time-consuming to develop. Two editorials commenting on the Prosser et al. (2000) article are also cautious about using CEA based largely on the methodological problems involved (Livak, Long, and Schwartz 2000; Langley 2000).

The process barriers are equally daunting. For one thing, the quality of the analysis is an important consideration and often in doubt (Rennie and Luft 2000). For another, it is imperative that the process be transparent to gain public legitimacy. As Rennie and Luft (ibid.: 2159) argue: "The key requirement for any cost-effectiveness analysis is that the assumptions, models, and possible biases are well described, transparent, and fully supported by evidence, the strength of which is made easily available to any critical reader." Without this transparency, the essential aspects of patient understanding and informed consent cannot be fulfilled. Without patient understanding and informed consent, the process lacks public legitimacy.

CEA and Cost-Containment in the Courts

To date, there is little health care litigation interpreting the use of CEA. Eventually, MCOs will begin more explicit use of CEA in one or more of the areas just described, so it seems inevitable that courts will directly confront the issue. If challenged, MCOs might justify the denial of care to an individual patient by arguing that it would not be in the best interests of the patient population to provide benefits that are not cost-effective. Plaintiffs, on the other hand, may want to introduce CEAs to discredit the MCO by showing that the denial of care was not based on sound methodologies, undervalued care for the individual patient relative to the patient population, or was contrary to stated plan criteria.

These efforts will raise several questions. For trial courts, to what extent will this be a question of admissibility versus the weight of the evidence? (Admissibility is a judicial determination that evidence is relevant and can be introduced into trial. Once introduced into evidence, the jury's

responsibility is to weigh CEA against all the other evidence.) If the former, what criteria will be used to guide admissibility? If the latter, how can judges balance the probative value of the CEA with the potential prejudice against the defendant seen in automobile safety litigation? If admissible, should CEA be used to define the standard of care, or be treated as simply another piece of evidence for the jury to weigh?

One way to address these questions is to examine how courts have responded to CEA in other areas of the law and to other managed care cost containment innovations. In this section, we consider general liability decisions, medical liability cases, product liability cases, and cases challenging governmental regulation (particularly environmental issues). For those not familiar with the underlying legal standards, we first provide a brief overview of liability principles.

The Standard of Care

Establishing Liability. At its simplest, tort law (torts are civil wrongs such as negligence) establishes standards of behavior that individuals and businesses are expected to meet in avoiding unreasonable risk of harm to third persons. Each state's court system establishes it own body of common law negligence principles, although all states use the same general framework. This means that legal doctrine will vary across states, so that what may be negligent in one state will not be negligent in another.

To win a negligence case, the plaintiff must prove the following four elements by a preponderance of the evidence: (1) a duty of due care; (2) breach of that duty; (3) the conduct caused the injuries; and (4) the injury produced actual damages. To determine whether a defendant has breached his duty of due care, courts often look to custom in the industry, and, in the absence of custom, to reasonableness to set the standard of care. How would a reasonable person have acted under the circumstances? The reasonable person standard allows the jury to make an informed decision about whether the defendant's activity met the community's standard of due care or created an unreasonable risk of harm.

One of the hallmarks of the common law is its ability to adapt incrementally to changing social and economic circumstances. By deferring to industry custom, courts give the marketplace considerable flexibility to determine how and when to introduce the latest technology or safety advances. Not every conceivable safety precaution must be taken—only those that are justified by the costs of injury prevention. Thus the utility

or social value of the conduct must be weighed against the risks (United States v. Carroll Towing Co., 159 F.2d. 169 [2d Cir. 1947]; *Restatement [Third] of Torts: General Principles*, Article 4 [1999]). In negligence cases, the courts are free to overrule industry custom and impose more stringent standards of care if the industry is slow to adopt technologies or systems that would avoid injury (see, e.g., The T. J. Hooper, 60 F.2d 737 [2d Cir. 1932], *cert. denied*, 287 U.S. 662 [1933]).

Establishing Medical Liability. In medical liability cases, the standard of care is exclusively set by the medical profession itself based on what is customary and usual practice, as established through physician testimony and medical treatises. A typical statement of the law is that each physician must "exercise that degree of skill ordinarily employed, under similar circumstances, by the members of [the] profession" (Lauro v. The Travelers Insurance Co., 261 So.2d 261 [La. 1972]). In effect, this means that the same level of care must be provided to all patients, regardless of resource constraints. The primary reason why medical liability diverged from general negligence is deference to professionalism; courts did not feel capable of second-guessing customary medical practice. Instead, courts have consistently held that nonphysicians do not have sufficient training to establish customary and reasonable medical practices (Prosser 1978; Peters 2000).[6]

Most courts presume that a physician's failure to adhere to customary practice constitutes negligence. If there is more than one recognized course of treatment, most courts allow some flexibility in what is regarded as customary (known as the respectable minority rule). In relatively rare instances, courts will allow a plaintiff to challenge the adequacy of customary medical practice, resulting in a higher standard of care than that determined appropriate by the profession.

Custom and cost containment are not inherently in tension. The point of cost containment is to reduce the amount of inappropriate health care that led to the explosion in health care costs under the fee-for-service system. At a minimum, cost containment aims to change what has been the custom. The assumption is that what has been customary is in fact "too much" care, unjustified either from the standpoint of societal allo-

6. Philip Peters Jr. (2000) postulates that a trend among state courts is to move away from deference to the professional custom standard toward a "reasonable and prudent physician" standard. Even if Peters is correct, it is not clear how the emerging reasonable physician standard differs conceptually from professional custom and whether case outcomes are actually different in jurisdictions switching to the new approach.

cation of resources or, more often, from the standpoint of medically necessary care for the individual patient. In this sense, managed care is designed to influence how the standard of care will be set by physicians (by implementing, for example, treatment protocols). One of the common accusations against managed care is that it aims to depress the required standard of care too far, below an optimal level. Those who advocate a move away from the professionally determined standard of care are instead concerned that levels of care have been set too high and argue that resource intensity does not necessarily equal quality of care (Hall 1997; Havighurst 1995; Epstein 1997; Morreim 1997).

CEA and Cost-Benefit Analysis (CBA) in General Negligence Cases

The use of CBA and CEA in litigation grew from legal standards governing general negligence. Well into the twentieth century, there was little mention of any standardized formula for calculating the proper amount of precautions necessary to avoid claims of negligence. The reasonable or "prudent man" standard dominated both in academic discussions and in the courtroom, although there were pockets of what could be considered CBA scattered throughout the case law (Green 1997; see, e.g., The T. J. Hooper, 60 F.2d 737 [2d Cir. 1932]).

In the most famous case in which a cost-benefit approach was explicitly adopted, *United States v. Carroll Towing* (159 F.2d 169 [2d Cir. 1947]), the defendant owned a tug and was moving a line of unmanned barges out to sea when one broke loose and collided with a nearby tanker. The tanker's propeller punctured the hull of the barge, which then began to take on water. Eventually the barge sank, along with its cargo. Faced with the absence of precedent determining when barge owners were liable for not maintaining watch to ensure that their vessels did not break away from their berths, Judge Learned Hand (159 F.2d 169, 173 [2d Cir. 1947]) reasoned:

> Since there are occasions when every vessel will break from her moorings, and since, if she does, she becomes a menace to those about her; the owner's duty, as in other similar situations, to provide against resulting injuries is a function of three variables: (1) the probability that she will break away; (2) the gravity of the resulting injury, if she does; (3) the burden of adequate precautions. Possibly it serves to bring this notion into relief to state it in algebraic terms: if the proba-

> bility be called P; the injury, L; and the burden, B; liability depends upon whether B is less than L multiplied by P: i.e., whether B is less than PL.

In short, negligence occurs when the burden (cost) of investing in accident prevention is less than the expected liability ($P \times L$). Likewise, if the cost is greater than the expected liability, the defendant would not be negligent. Conceptually this formula makes sense, and its similarity to modern cost-benefit analysis formulas is readily apparent. Additionally, it is an easy-to-grasp (if not always easy to apply) guideline that allows for a great amount of flexibility. Of course, it suffers from the same problems that plague all cost-benefit and cost-effectiveness analyses, but that has not hindered its adoption by the courts.

The Hand formula and its derivations now dominate general negligence law. Just eighteen years after the decision in *Carroll Towing*, Section 291 of the *Restatement (Second) of Torts* (1965)[7] provided a risk-benefit test for unreasonable conduct and negligence, reflecting the standard put forth by Judge Hand. And the current draft (1999) of the *Restatement (Third) of Torts* clearly expects negligence cases to be decided based on a risk-benefit test (General Principles, Article 4, Comment d). The *Carroll Towing* analysis has also become "a staple of the law and economic scholarship addressing tort law" (Green 1997).

But even so, the common jury charge to this day involves some variant of the "reasonable man under like circumstances" standard and not a firm admonition to weigh costs or risks against benefits. Thus what remains very murky is whether the Hand formula is actually used to establish the standard of care, is just implicit in the reasonable man jury instruction, or is used by appellate courts in reviewing case outcomes.

CEA and Cost-Containment in Medical Liability Cases

Departures from the Professional Standard. On occasion, courts have deviated from the standard professional paradigm in medical liability cases. Two instances where courts have relied on CEA or resource constraints to establish a different direction are particularly interesting and instructive. Neither departure has had much doctrinal impact, but the

7. Restatements of the law are summaries of cases and commentaries on where the law should go prepared by leading scholars under the auspices of the American Law Institute. Many courts adopt the restatements in resolving litigation.

cases suggest directions courts might take if CEA becomes widely implemented.

One of the very few medical liability cases to consider CEA in setting the standard of care is *Helling v. Carey* (519 P.2d 981 [Wash. 1974]).[8] This case involved a physician's failure to provide a glaucoma screening test to a patient under forty years of age when professional custom was to screen only patients over forty because of the low incidence of glaucoma in persons under age forty. After the patient developed glaucoma, she sued the physician, arguing that since the screening test was relatively inexpensive and accurate, it should have been provided regardless of the prevailing professional custom. While the court did not explicitly rely on a CEA, it noted the test's low cost relative to potential benefits as a reason for overruling professional custom. As a result, some commentators have argued that the case represents the application of CEA in medical liability (see, e.g., Schwartz and Komesar 1978).

At the same time, commentators have criticized *Helling* on many dimensions (see, e.g., Wiley 1981).[9] For our purposes, perhaps the most telling criticism is that the court essentially used its own calculation to require a more stringent standard of care than determined by professional custom (Schuck 1981). At least implicitly, the profession had factored CEA into deciding not to provide the test to those under forty. A few subsequent courts have followed the *Helling* analysis (see, e.g., Hood v. Phillips, 554 S.W.2d 160 [Tex. 1977]), but most have rejected its holding, retaining the professional custom model in establishing the standard of care.

A more nuanced departure from the standard model occurred in *Hall v. Hilbun* (466 So.2d. 856 [Miss. 1985: 872]), a case alleging negligence in postoperative care. The underlying issue was whether local or national standards of care should prevail. In considering that issue, the court discussed differences in resources across hospitals and geographical regions. In adopting the national standard, the court nevertheless distinguished between technical skills and knowledge, which should not vary across professionals, and resource availability, which varies substantially across institutions. The court determined that the duty of care would be "based upon the adept use of such medical facilities, services, equipment,

8. The case was subsequently superseded by the Washington state legislature.

9. For example, the test has a high false-positive rate and early detection does not always alter the outcome (Fortess and Kapp 1985). On the other hand, the fact that the physician ignored the plaintiff's repeated complaints suggests a violation of the standard of care regardless of CEA.

and options as are reasonably available." Under this standard, for example, a physician practicing in a rural area would not be faulted for failing to use a CAT scan if the equipment were not reasonably available.

Without saying so explicitly, the resource use–technical skill distinction could easily be expanded to incorporate CEA or CBA. Arguably, if resources are constrained, MCOs should be able to use CEA to determine the most efficient use of those resources. Unlike *Helling*, where the court substituted its judgment for the profession's, *Hilbun* retains the professional standard of care but explicitly permits the profession to factor resource constraints in setting the standard of care. So far, few courts have seized on this rationale to develop a bifurcated standard of care (Morreim 1987).[10]

Cost Containment and ERISA. Legal challenges to managed care's cost containment innovations cannot be fully understood without taking into account the courts' responses to the Employee Retirement Income Security Act (ERISA). ERISA covers health care benefits established by self-insured employers (with few exceptions, such as for governmental employees). When an ERISA plan contracts with an MCO to provide health care, the MCO is treated as being covered by ERISA.

Traditionally, states are responsible for regulating health care delivery, and litigation against health care providers is usually resolved under state law. Medical liability lawsuits are rarely heard in federal courts.[11] ERISA alters the traditional approach by preempting state law, which means that state laws purporting to regulate health plans may not be enforced in any court (Nealy v. U.S. Healthcare, 711 N.E.2d 621 [N.Y. 1999]). In this context, state laws include legislation and regulations, such as those mandating particular benefit coverage, and most medical liability actions challenging MCO decisions to delay or deny care. Because ERISA limits the ability of state courts to hear these challenges, while simultaneously limiting a patient's legal remedies (i.e., damages), the result is to insulate cost containment initiatives from sustained legal challenges. Thus challenges to delayed or denied care by an ERISA-covered plan are usually preempted, meaning that the patient can only recover the amount of the denied benefit.[12]

The Supreme Court recently held that subscribers may not challenge

10. Haavi Morreim has been an avid proponent of the bifurcated standard of care.

11. Federal medical liability jurisdiction almost always results from diversity of citizenship (litigants residing in different states) rather than from raising a federal question.

12. For more detailed consideration, see Jacobson and Pomfret 2000.

managed care's financial incentives in court. In *Herdrich v. Pegram* (154 F.3d 362, 373 [7th Cir. 1998]; see also, 170 F.3d 683 [7th Cir. 1999][13]), the lower court held that a patient could sue for breach of fiduciary duty when alleging that the physicians' financial incentives caused a deprivation of needed medical care. The Supreme Court reversed the decision in *Pegram v. Herdrich* (120 S. Ct. 2143 [2000]), holding that challenges to the financial incentives should be resolved by the legislative branch and limiting the ability to bring breach of fiduciary duty cases.

Legal Challenges to Cost Containment Initiatives. Although there is very limited health care litigation directly raising or challenging the use of CEA, courts have begun to confront challenges to cost containment initiatives. The scholarly literature on how courts have responded to these challenges to date is relatively limited and reaches mixed conclusions.

Mark Hall (1988) first assessed early cost containment initiatives (such as prior authorization, physician payment incentives, and physician selection), adopted by hospitals (largely in a fee-for-service context) in the 1980s, and the courts' responses to them and concluded that cost containment innovations would not survive judicial scrutiny (see also, Anderson, Hall, and Smith 1998). Similarly, Gerard Anderson (1992) argued that courts have expanded their influence over health policy by, for example, overturning insurers' coverage decisions and favoring hospitals, as opposed to states, in Medicaid rate-setting cases under the Boren Amendment.[14] Other commentators have also argued that courts have tended to side with individual patients against insurers in deciding whether expensive technologies are covered benefits (Ferguson, Dubinsky, and Kirsch 1993).

Haavi Morreim (1995) analyzed more recent judicial decisions and concluded that courts have become much more receptive to cost containment than Hall predicted. Morreim postulated that courts were resolving the tension between managed care policies that favor patient populations at the expense of individual access to services in favor of cost containment initiatives. In at least two cases, the courts made this trade-off explicitly (Doe v. SEPTA, 72 F.3d 1133 [3d Cir. 1995]; Creason v. State Department of Health Services, 957 P.2d 1323 [Cal. 1998]). Likewise, one of the authors (PDJ) analyzed a range of challenges to cost con-

13. *En banc* decision affirming the three-judge panel, dissenting opinion.

14. The Boren Amendment provided the states with greater flexibility in setting Medicaid reimbursement rates to reduce rising Medicaid costs. The question for the courts is whether the rates set bear a reasonable relationship to the costs of providing the care.

tainment initiatives and concluded that courts are indeed deferring to the market and to legislative policy favoring cost containment (Jacobson 1999). In response, Hall (1999) criticized this analysis for ignoring (or minimizing) instances where courts have impeded cost containment objectives, especially in cases where MCOs are not protected by ERISA preemption.

In part, the latter dispute is over the speed of judicial internalization of cost constraints and in part over what the trends really show. In our view, the courts are following the traditional incremental manner in which the common law adapts to changes in the underlying social and economic environment. Where we view the courts as gradually incorporating cost containment into their decisions, Hall seems to advocate for a much more radical transformation than courts generally follow and thus interprets the changes that have occurred as being minimal (Jacobson 1999; Jacobson and Pomfret 1999). Ironically, the Supreme Court's opinion in *Pegram v. Herdrich* confirms both views. The decision clearly accepts the role of cost containment as a legitimate objective, confirming the trends noted by Morreim and Jacobson, but also forecloses further ERISA challenges to financial incentives, thus accelerating the transformation Hall supports.

One might also argue that the *Pegram* case makes it easier for MCOs to apply CEA. If so, how it is applied by payers and providers is likely to be a vital issue. For example, in *Kawaauhau v. Geiger* (172 B.R. 916, 923 [Bankr. E.D. Mo. 1994]),[15] a physician prescribed oral penicillin instead of the more effective intravenous penicillin because he alleged that the patient had expressed a desire to keep costs low. At trial, the patient denied that this exchange occurred, and there was no evidence that the physician informed the patient of the consequences of the lower-cost approach. While the physician did not use CEA in making the decision, the court's response to the explicit trade-off between cost and clinical effectiveness is cautionary: "administering penicillin orally because [it] costs less . . . despite the possible consequences, . . . offends even a person lacking formal medical training." Nevertheless, *Pegram* potentially changes the litigation environment in ways that will favor the use of CEA.

Medical Necessity Decisions. Neither CEA nor costs generally have played a significant role in benefit denial or medical necessity disputes.

15. Reversed on other grounds in *Kawaauhau v. Geiger*, 523 U.S. 57 (1998).

Most of these cases are decided based on interpretations of contractual language and are highly fact-specific determinations (Singer et al. 1999).[16] Courts may discuss cost concerns, but cost or CEA rarely forms the basis of the decision, at least in part because health care contracts rarely include when and how specific techniques (such as CEA) will or should be applied (ibid.).[17] To be sure, medical necessity provisions do not inherently exclude CEA, but a patient might challenge its use if not informed of how it might influence clinical decisions.[18]

In the ERISA context, a plan administrator's determination of medical necessity is given deference if the benefit contract specifically gives the plan administrator discretion in approving clinical decisions (Dowden v. Blue Cross & Blue Shield of Texas, Inc., 126 F.3d 641, 644 ([5th Cir. 1997]). The deference is not absolute and varies inversely in intensity with the financial incentives under which the plan administrator operates (Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 115 [1989]). Courts have not yet decided the issue of what deference would be granted if plan administrators were to rely on CEA in medical necessity determinations.

Product Liability

Product liability litigation has been heavily influenced by CEA/CBA concepts. An explicit risk-utility analysis (RUA) has become the dominant form of analysis for resolving product liability cases (Wade 1973; see also Saratoga Fishing Co. v. Marco Seattle Inc., 69 F.3d 1432, 1440 [9th Cir. 1995]). RUA evolved from the Hand formula proposed originally in *Carroll Towing* (see, e.g., *Saratoga Fishing Co*., 69 F.3d 1432; Liriano v. Hobart, 132 F.3d 123,131 [2d Cir. 1998]) and is used in product liability litigation, especially design defect cases, to weigh the benefits of a product against its risks. Among other aspects, RUA considers the usefulness or desirability of a product; safety aspects of a product; availability of substitutes; and the possibility of improving safety without decreasing usefulness or increasing cost (Epstein 1987). The multifactorial nature of RUA makes it difficult to apply. In fact, a 1997 computer survey of cases involving product-defect balancing tests in prescription drug cases

16. In their review of 203 judicial decisions involving clinical appropriateness criteria in medical necessity challenges, Anderson, Hall, and Smith (1998) make no mention of cost as a factor in case outcomes.

17. Singer et al. (1999: 66) note that "whether this relates to the tendency to pursue cases only when large amounts of money are at stake or whether disputes over lower cost treatments are settled at an earlier stage is not clear."

18. We thank Arnold Rosoff for this observation.

showed that courts had adopted numerous balancing tests, not all of which were compatible with each other or with the *Restatement (Second) of Torts* (Owen 1997).

Practically speaking, the effect of RUA has been to bring strict liability cases for product design defects closer to the standards used in traditional negligence cases. When striking a balance between risk and utility, at some point the consideration of cost must come into play, and some courts have ruled that CEA is an integral part of RUA. In *Proes v. Honda Motor Co.* (31 F.3d 543 [7th Cir. 1994]), for instance, the plaintiff claimed she had been thrown from her car during an accident due to the failure of a defectively designed seat belt (see also, Prentis v. Yale Manufacturing Co., 427 Mich. 670, 688 [Mich. 1984]). The court noted that to prove the defendant's negligence, the plaintiff needed to show that another seat belt design "not only could have prevented the injury but also was cost-effective under general negligence principles" (i.e., that there were no other alternatives that were more cost-effective).

Despite this case, MCOs may rightly be concerned about juror responses to CEA as opposed to how appellate judges will ultimately incorporate CEA into the standard of care. Two examples demonstrate the concern.

In the first instance, *Grimshaw v. Ford Motor Co.* (119 Cal. App. 3d 757, 174 Cal. Rptr. 348 [Cal. App. 1981]),[19] the plaintiff was a passenger in a 1972 Pinto when the car stalled on a freeway and was subsequently hit from behind. The force of the rear impact caused the gas tank to explode, severely burning the plaintiff and killing the driver. The plaintiff sued on the basis of negligence and strict liability for product design defects. During the trial, a CEA dealing with the safety of the Pinto gas tank surfaced. According to Ford's analysis, 180 burn deaths could be avoided if $137 million were spent on safety enhancements. Ford placed the value of each of the 180 lives at $200,000, for a total of $36 million (Green 1997; The T. J. Hooper, 60 F.2d 737 [2d Cir. 1932]). Total net savings realized by delaying safety improvements was $101 million. The CEA was never allowed into evidence at trial, and the jury never saw it. However, the jury heard testimony that pointed to the existence of the CEA, and it was made clear that Ford had weighed human lives against its profits (*Grimshaw*, 119 Cal. App. 3d at 813). The jury regarded this evidence as a "smoking gun" indicating Ford's culpability. The jury

19. For an excellent analysis of the underlying issues in this case, see Schwartz 1991. For additional case examples, see Viscusi 2000.

found for the plaintiff and awarded $125 million in punitive damages. Commenting on the defendant's behavior, the court had this to say:

> Through the results of the crash tests, Ford knew that the Pinto's fuel tank and rear structure would expose consumers to serious injury or death in a 20- to 30-mile-per-hour collision. There was evidence that Ford could have corrected the hazardous design defects at minimal cost but decided to defer correction of the shortcomings by engaging in a cost-benefit analysis balancing human lives and limbs against corporate profits. Ford's institutional mentality was shown to be one of callous indifference to public safety. There was substantial evidence that Ford's conduct constituted "conscious disregard" of the probability of injury to members of the consuming public.

More recently, a jury severely punished General Motors for using CEA to justify not pursuing safety-oriented design changes concerning the location of the gas tank in certain car models (Pollack 1999: A7). In July 1999, the jury awarded $4.8 billion in punitive damages for severe burns following the explosion of a car's fuel tank in a rear-end collision (although it is likely that the verdict will be substantially reduced on appeal). According to published reports, the trial testimony showed that GM could have moved the fuel tank at a cost of $8.59 per car. An internal memo written by a GM engineer estimated that fuel tank fires cost GM only $2.40 per vehicle. In a subsequent statement, GM argued that the fuel-tank placement met all regulatory standards. But "jurors told reporters that they felt the company had valued human life too lightly. 'We're just like numbers, I feel, to them,' one juror [said]" (ibid.). As in the *Grimshaw* case, the jury treated the internal memo as a smoking gun of culpability.

These cases suggest that MCOs face a daunting challenge to use CEA without conveying the impression that they treat individual lives cavalierly. As discussed below, internal memos such as those cited in the GM case are likely to expose MCO officials and physicians to withering cross-examination.[20]

20. In commenting on this article, Daniel W. Shuman asked whether it is fair to compare these automobile cases to CEA in health care. Because the auto case memos suggest a clear financial trade-off between the costs safety relative to paying for loss of life, while health care CEA makes trade-offs at the margin regarding net health benefits, the two may be very different. However inexact the analogy, it is a fair comparison. Inappropriately denied care may result in disability or premature mortality, so the practical effect may be similar.

CEA in Cases Challenging Government Regulation

CBA and CEA are used extensively in government rulemaking. For example, Executive Order No. 12,866 (3 Code of Federal Regulations 638 [1994])[21] requires regulatory agencies to conduct cost-benefit analysis on proposed regulations to ensure "that the benefits of the intended regulation justify its costs." Agencies are expected to consider "both quantifiable measures . . . and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider" and then select the regulatory approach "that [maximizes] net benefits (including potential economic, departmental, public health and safety, and other advantages; distributed impacts; and equity)." Once a regulatory course of action is chosen, agencies are also required to conduct a CEA to ensure the regulation is designed in the "most cost-effective manner to achieve the regulatory objective." The problem is that the executive order does not mandate a singular decision-making metric.

Environmental and occupational safety and health regulation are the areas most likely to invoke CEA, in part because of the nature of these issues and in part because Congress determines what standard an agency should use in the regulatory process.[22] For example, Congress prohibits or limits CBA under the Clean Air Act but allows costs to be considered under the Superfund program. Other environmental statutes, such as the Toxic Substances Control Act (TSCA) and the legislation establishing the Occupational Safety and Health Administration (OSHA), mandate amount to risk-utility standards, so that regulators must inherently balance risk and cost. None of the statutes instructs the regulators on how to conduct CBA or CEA, nor do they prohibit an agency from using these analyses. Since affected industries always produce economic analyses, which agencies are required to consider during the rule-making process, the reality is that the agencies almost always must examine the costs and benefits of any given regulation.

The courts generally defer to regulatory agency expertise, but agency decisions must be well reasoned and not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with a law" (Administrative Procedures Act, 5 United States Code 706[2][A]). (See also, Competitive

21. Issued by President Clinton on 30 September 1993.

22. Health care, and especially health care financing, would be another expected regulatory use of CEA. However, the HCFA recently backed away from using CEA in its proposed criteria for making coverage decisions. See *Federal Register*, vol. 65, no. 95, Tuesday, 16 May 2000, pp. 31124–31129.

Enterprise Institute v. NHTSA, 956 F.2d. 321, 327 [D.C. Cir. 1992]). Agency actions must be supported by substantial evidence when the record is viewed as a whole, and agencies must explain the rationale and factual basis underlying their decisions.[23] Within that framework, agencies have a great amount of discretion when constructing CBAs and CEAs during the rule-making process. The scope of review that courts are afforded over agency decisions is narrow, and courts must not substitute their own judgment for that of the agency, particularly in matters requiring technical expertise. Thus one court noted the following in reference to regulatory agency CBAs:

> Such cost-benefit analyses epitomize the types of decisions that are most appropriately entrusted to the expertise of an agency; certainly appellate briefs and arguments would ill-equip a court that would seek to balance for itself the myriad considerations involved in any complex administrative policy decision. (Office of Communication of the United Church of Christ v. FCC, 707 F.2d 1413, 1440 [D.C. Cir. 1983])

When courts find a regulatory decision of an agency to be arbitrary or capricious, or otherwise in violation of the law, the regulation is remanded to the agency for further consideration. At no point do the courts usurp the ultimate decision-making powers of regulatory agencies, and there seems to be no general desire on the part of the courts to do so. Usually, courts focus on reviewing the process agencies use to reach a final conclusion, not the conclusion itself.

But courts do not hesitate to question the methodology and the reasoning used by agencies in constructing cost-benefit analyses. In *Corrosion Proof Fittings v. EPA* (947 F.2d 1201 [5th Cir. 1991]), the court was highly critical of the CBA methodology used by the EPA to justify a complete regulatory ban of asbestos. The court was "troubled" by the EPA's strategy of discounting the future calculated costs while simultaneously failing to discount future calculated benefits, thus significantly skewing the analysis and calling its validity into question. The court was also bothered by the EPA's "cavalier" attitude toward manipulating its CBA data to support its preconceived position on banning asbestos, and also criticized the agency's failure to consider the lack of substitute products and the impact that the ban would have on the industry and consumers.

23. Industrial Union Department v. American Petroleum Institute, 448 U.S. 607 (1980); American Textile Manufacturers Institute v. Donovan, 452 U.S. 490 (1981).

Some courts have gone even further in arguing that regulatory activity must take into account the possibility that regulations may improve safety in one area but reduce it in another. Known conceptually as "richer is safer" or health-health trade-offs, the notion is that regulations imposed to save lives can also have the effect of costing lives, either through lost jobs or through substitution of less safe products. The problem occurs when reducing one health risk simultaneously increases another health risk, or prices some consumers out of the market for safer products (see, e.g., Sunstein 1996).[24]

Take, for example, challenges to fuel economy standards. In *Competitive Enterprise Institute v. NHTSA* (956 F.2d 321 [D.C. Cir. 1992]), a group of national automobile lobbyists petitioned the National Highway Traffic and Safety Administration (NHTSA) to lower the pollution emission standards for cars built in 1990. The NHTSA had the authority to relax the standards but declined to do so based in part on an agency CBA indicating that the higher emission standards produced a total net benefit. The plaintiff filed suit claiming the agency had failed to assess the impact of additional automobile accident fatalities that were being caused by downsizing cars in response to the stricter emission standards (because larger, more expensive cars have better safety records). The court was highly critical of the reasoning used by the NHTSA throughout its rule-making process but was most distressed at the agency's failure to include the additional fatalities in its cost-benefit analysis, stating:

> Even if the 27.5 mpg standard for model year 1990 kills "only" several dozen people a year, NHTSA must exercise its discretion; that means conducting a serious analysis of the data and deciding whether the associated fuel savings are worth the lives lost. When the government regulates in a way that prices many of its citizens out of access to large-car safety, it owes them reasonable candor. If it provides that, the affected citizens at least know that the government has faced up to the meaning of its choice. The requirement of reasoned decision-making ensures this result and prevents officials from cowering behind bureaucratic mumbo-jumbo. (*Competitive Enterprise Institute*, 956 F.2d at 327)

Following remand to the NHTSA, the agency considered the safety implications of higher fuel economy standards. Although still skeptical,

24. See also, International Union, United Auto Workers v. OSHA, 938 F.2d 1310 (D.C. Cir. 1991) (Williams, J., concurring at p. 1326: "And larger incomes enable people to lead safer lives.").

a different three-judge panel upheld the NHTSA, ruling that the agency's action was adequately supported by the record (Competitive Enterprise Institute v. National Highway Traffic Safety Administration, 45 F.3d 481 [D.C. Cir. 1995]).

Applying the health-health trade-offs question to managed care, if this reasoning were to be followed, MCOs might be able to argue successfully that the need to preserve plan assets for the patient population justifies CEA. That is, CEA is the most effective mechanism for making trade-offs between the needs of individual patients and the patient population.

Analysis

The judicial responses to CEA in general, medical, and product liability and government regulatory cases show mixed results, but some potentially interesting comparisons. Perhaps most revealing is the distinction between the government regulation and product liability cases. In the former, the courts are quite receptive to the government's application of CEA and, in some instances, even encouraging the government to be more aggressive in using it to justify regulatory policies. But in the product liability area, jurors are severely punishing private parties for their explicit use of CEA in making product design choices and trade-offs.

One possible explanation for this disparity may be that government agencies are entitled to considerable judicial deference while private parties are not. Courts give deference to other branches of government that they are not compelled or inclined to provide to private parties. Because courts will review MCO CEAs under common law principles, the statutory framework of government regulation cases will not apply. Nevertheless, it provides some insight into how courts view CEA and CBA and suggests that CEA is judicially viable. For one thing, judges have not reflexively opposed CBA and CEA. For another, when transposed into a common law context, courts may well defer to the market, as argued earlier. If so, a potential strategy is to work through Medicare/Medicaid managed care to introduce CEA and allow courts to develop a standard of care that defers to congressional policy regarding CEA. Then, CEA could migrate to nongovernmental programs in a manner that avoids the "smoking gun" problem. In view of the Supreme Court's strong endorsement of managed care's cost containment strategies, this approach seems plausible.

A second interesting comparison emerges between the general negli-

gence and medical liability cases. Whatever one may think of deference to custom as a liability standard, the courts' willingness to use CEA/CBA in these cases can just as easily lead to a higher standard of care as to a lower standard. There is no guarantee that allowing costs to be factored into the standard of care will reduce the level of care provided. Ironically, CEA or CBA can be used by the courts to require the latest technology or a more stringent (i.e., costly) standard of care. This negates the assumption that by incorporating CEA into medical decision making, MCOs will be able to provide lower levels of care where the benefits are commensurate with the costs.

These areas also take differing approaches to setting the standard of care. In general negligence cases, the Hand formula, when used, essentially establishes the standard of care. The same applies to RUA in design-defect product liability cases. Yet in medical liability litigation, costs have not been factored into setting the standard of care and the closest analog, clinical practice guidelines, have been used as one piece of evidence for the jury to weigh.

Our analysis leaves several important questions unaddressed. First, how extensively have the courts used CEA/CBA/RUA in reality, either to establish the standard of care or as one piece of evidence to determine industry custom? When scholars discuss the Hand test, is it more of an abstraction or an actual analytical tool used to resolve cases? In product liability cases, RUA seems to have become the standard of care, and perhaps in general negligence cases as well. But our tentative conclusion is that trial courts do not often use CEA when instructing juries. They still give juries instructions based on the reasonable person standard, even in product liability cases. If so, are juries actually using CEA or CBA to establish liability standards? Law and economics scholars contend, controversially, that this is exactly what jurors do when they determine what constitutes reasonable care, regardless of the judge's specific instructions. While the theory of negligence as equivalent to efficiency is ascendant in academia, it does not appear to be matched by how judges speak to juries. Unless judges make it explicit that juries should use efficiency criteria (including CEA) to determine whether the standard of care was met, the full force of the Hand test is unlikely to be attained.

Second, when used, does the CEA/CBA/RUA benefit plaintiffs or defendants? If jurors are not instructed to use it, then it would be difficult to discern which side benefits. Two nonmutually exclusive possibilities come to mind. Some studies suggest that jurors exhibit hindsight bias, where people overestimate the *ex ante* risks and underestimate the *ex*

ante benefits when viewed after an injury occurs (*ex post* at the trial) (Hastie and Viscusi 1998). When confronted *ex post* with real-life victims, jurors may overestimate the risks than when presented *ex ante* with hypothetical examples. For instance, jurors might assume that the patient might have lived if the MCO had only provided the treatment. If correct, this suggests that plaintiffs would benefit more because the CEA ratio would understate the costs and overstate the benefits, hence favoring liability. As argued above, the juror responses to CEA in product liability cases are not promising for explicit application of CEA as a cost containment approach. However, Richard Lempert (1999) raises serious doubt about the validity and likelihood of significant hindsight bias. Lempert also argues that judges may not respond differently than juries and that juries may well be skeptical of plaintiffs' contentions and may not punish defendants.[25]

At the same time, jurors may respond differently to CEA as opposed to CBA. When framed in terms of effectiveness, jurors may understand that what is at stake is to provide the most effective care at an affordable price. A focus on effectiveness may resonate with jurors as being the dominant concern, not costs. For example, if defendants show that they used CEA to place a higher value on reducing harm, juries may react more favorably. In contrast, jurors may think of CBA as just a cost-savings mechanism and react negatively. Therefore, how the evidence is presented, and the skill of the attorney, may determine the jury's response, since the same item could be favorably interpreted for either side.

Third, contract provisions could provide a distinction between the product liability cases and CEA in health care. Health insurers could bargain to include CEA in the health benefits contract, which could well alter the judicial outcome by forcing patients to sue for breach of contract rather than for tort damages (or by permitting courts to dismiss negligence claims). So far, there is no evidence that CEA is an explicit term in many health insurance contracts. If included, one potential difference from the product liability cases would be that when buying a car, there is no contractual term describing how CEA will be conducted.

Fourth, why do courts seem to have integrated CEA/CBA/RUA rela-

25. Lempert is also skeptical of the "deep pocket" effect, where jurors punish the party with the greatest financial assets. Personal communication, 10 April 2000. Viscusi (2000) conducted a subsequent jury judgment survey using different scenarios. In some scenarios, respondents were asked to react to situations where corporations used CBA; in others, CBA was not used. Mock jurors awarded 50 percent greater damage amounts when CBA was used. However, Peters (2000) echoing Lempert (1999), argues that policy makers should proceed cautiously to enact reform proposals that would systematically favor defendants.

tively easily in negligence and government regulation cases, while similar techniques have engendered considerable jury hostility in product liability cases? The answer to this question may provide the key to the potential integration of CEA into managed care decisions.

Fifth, what role might the classic divide between statistical lives and identified lives play in these case comparisons? In the government regulation cases, the emphasis is population statistics, not identified individuals. In the other areas covered, juries might identify with the named individual who brings the litigation and testifies.

The Future

The Spark

If it is correct that MCOs have been reluctant to use CEA explicitly, what will be the spark that sets it off? And, once in use, will it make a difference? The spark could come from several sources.

The Courts. First, the courts could signal a willingness to incorporate CEA into the standard of care. As noted above, courts have already signaled their willingness to internalize cost containment strategies, confirmed by the *Pegram v. Herdrich* decision. As long as the CEA is conducted according to standard methodologies by qualified experts, admissibility should not be a problem. The crucial issue will be how judges instruct juries on the weight the CEA evidence should be given and whether CEA should set the standard of care. In our view, CEA should be viewed as one piece of evidence for the jury to consider and should not set the standard of care.

An analogy would be how courts have considered (or should consider) clinical practice guidelines, as discussed in Arnold Rosoff's article in this issue. As Rosoff (1995) and others have argued (Brennan 1991), it is unlikely that courts will rely solely on guidelines to set the standard of care but will allow the jury to weigh them as one piece of evidence in determining liability. Given the physician judgment inherent in any clinical situation, the potential multiplicity of competing and conflicting guidelines, the usual lack of certainty inherent in the guidelines development process, and direct physician testimony, it is improbable that any guideline will suffice to set the standard of care.

The same reasoning holds for CEA. The use of CEA should not be an automatic defense to medical liability; nor, however, should using CEA in and of itself lead to liability. Because there is limited scientific evi-

dence of clinical effectiveness, both sides will use CEA and derive opposite conclusions as to whether the treatment should have been provided. CEA alone will not define the standard of care. The jury should be instructed that CEA is an entirely appropriate method for plans and physicians to use in making clinical decisions, but it is only one factor among many to take into account. Thus, if the jury finds that the CEA was poorly executed, it is free to give other evidence greater weight.

In the alternative, the courts could simply abandon the professional custom standard and switch to the standard of care for nonmedical liability cases, where deference to custom is not as strong. Of the two paths discussed earlier, *Helling and Hilbun*, the more likely is to incorporate CEA into an evolving standard of care that distinguishes between resource constraints and technical skill. Haavi Morreim (1997) has been a leading proponent of this approach. Morreim argues that both health plans and physicians owe patients the traditional standard of administrative or medical expertise concerning professional knowledge and skill. But since both plans and physicians operate under resource constraints, Morreim would rely on the terms of the contract to set the levels of expected resource use. This provides deference to MCOs in deciding which CEA methods are appropriate and avoids the judicial capacity concerns noted below. As the history of the *Helling* case suggests, placing judges at the forefront of CEA may not be the best strategy. In any event, the distinction between technical skill and resource utilization is unlikely to be as clear as Morreim maintains.

Institutional Capacity. A question that has received considerable scholarly and judicial attention is the judiciary's capacity for evaluating whether to admit CEA and other complex statistical analyses into evidence. As Daniel W. Shuman argues in his essay, the courts have not aggressively accepted the Supreme Court's invitation to act as a gatekeeper. One possibility is for judges to retain outside expertise to evaluate the qualifications of proposed witnesses and to assess their methodologies for purposes of admissibility only. Then the jury would weigh the evidence once admitted.

MCOs. Second, MCOs could begin more explicit use of CEA. Ideally, the spark should emanate from MCOs rather than courts. Nothing prevents the medical profession from incorporating resource constraints into customary medical practice.

In this case, the role of the courts should not be to force the market to

implement any particular cost containment strategy. Rather, the impetus should be among MCOs and other stakeholders to determine when and how CEA should become an integral part of managed care decision making. Then the courts can react on a case-by-case basis to establish whether and how CEA should be incorporated into the standard of care.

Contractual Arrangements. Third, one way to facilitate the goal of applying CEA to clinical decisions is to include explicit authorization for using CEA in managed care contracts. Employers can negotiate with plans over the terms under which CEA would be conducted, and MCOs can include these provisions in the contracts with subscribers. The contract should include how and when CEA will be used, processes for patient appeals, and information explaining the implications to subscribers. Several legal scholars, most prominently Clark Havighurst (1995) and Mark Hall (1997), and economists have advocated the contractual approach (Epstein 1997; Morreim 1997).

The rationale for the primacy of contract is that consumers can directly exercise sovereignty over cost, quality, and service. As an instrument of market arrangements, contract will force health care providers to compete on both price and quality to retain customers. Paul Rubin (1999: 27) notes that purchasers have an incentive to choose an efficient plan, defined as "one that provides all cost-justified care and no more," and that contracts allow individuals to decide how much they desire to spend on health care relative to other commodities. As long as patients understand what benefits will or will not be provided when they get sick, and how costs or CEA will be factored into clinical decisions, patients should be able to select plans providing fewer benefits at lower cost.[26] In this way, the market will set the desired benefit-cost levels through a series of contractual arrangements.

The Standard of Care in the Managed Care Era

Once the spark is ignited, how should the courts set the applicable standard of care? In their otherwise excellent recitation of the barriers to using CEA, Prosser et al. (2000) missed one important problem: how the courts might interpret it. The question is whether MCOs can implement CEA without providing plaintiffs' attorneys with an evidentiary smoking

26. As Catherine McLaughlin and Paul Ginsburg (1998) argue, subscribers usually do not negotiate directly over the contractual terms but are represented by employers, and subscribers are ususally uninformed about contractual provisions.

gun. This raises the broader question of what the standard of care should be for MCOs. As a normative proposition, should MCOs be immune from negligence actions based on reasonable cost containment programs? As an empirical proposition, will the imposition of liability unduly constrain the development of cost containment programs? If CEA becomes a standard for clinical decisions, will courts shift from the dominant tort law paradigm to contract law in resolving disputes?

From a conceptual perspective, there is no reason why MCOs should be automatically absolved from the adverse consequences of their economic decisions. One issue is whether the standard should continue to be based in tort or should shift to contract law. Despite the urging of several commentators (Morreim 1995; Havighurst 1995), courts have only hinted at the possibility of shifting to contract-based determinations (see, e.g., Dukes v. U.S. Healthcare, 57 F.3d 350 [3d Cir. 1995]). Numerous commentators have argued in favor of enterprise liability where the MCO would assume legal responsibility for any negligent outcomes. Enterprise liability would further solidify the MCOs's control over medical care but would give them greater flexibility to bargain with employers to include CEA (see, e.g., Havighurst 1997; Abraham and Weiler 1994; Sage 1997).

While a full discussion of potential MCO liability standards is beyond the scope of this article, there is no reason why MCOs should be prevented from arguing that the proper negligence standard should incorporate cost-based decisions.[27] In essence, juries should be able to decide whether the MCO has balanced the benefits of preserving assets for the patient population relative to the harm incurred by the individual patient, as in any other industry. In considering the standard of care for MCOs, courts could adopt one of several possibilities.[28]

First, in 1975, Randy Bovbjerg argued that the liability standard for HMOs should be based on standard practices among similar organizations. Bovbjerg contended that it would not be desirable to hold HMOs to customary standards of the fee-for-service system when HMOs were organized on a different model. Doing so could undermine HMOs's cost control strategies. When this concept was introduced, it really only applied to HMOs. With the expansion of MCO types since then, it might be a more difficult concept to apply. Still, the core idea that the standard of care for MCOs would adjust for cost containment strategies remains

27. "There is no theoretical impediment to configuring a medical malpractice standard that is . . . sensitive to available patient resources" (Henderson and Sciciliano 1994: 1395).

28. We are indebted to Arnold Rosoff for suggesting this line of analysis.

attractive and is consistent with the arguments above allowing for the profession to incorporate cost constraints into clinical decisions. The Illinois Supreme Court adopted a similar approach in *Jones v. Chicago HMO Ltd.* (730 N.E.2d 1119, 1129 [Ill. 2000]), stating that "an HMO must act as would a 'reasonably careful' HMO under the circumstances."

Second, the standard could be based on whether the plan made a reasonable attempt at applying CEA. Similar to the deference standard seen in government regulation cases, courts would accept that MCOs make cost-quality-access trade-offs and would only intervene if the CEA were conducted in an arbitrary and capricious manner. In this sense, the courts' primary role would be to ensure that fair processes were followed.[29]

Third, courts could reverse their deference to professional custom and resolve liability questions under traditional negligence standards. This would place cost-benefit trade-offs at the core of the judicial inquiry. An advantage is that MCOs could explicitly invoke CEA and other cost containment efforts as a defense. A disadvantage is that the court may second-guess the appropriateness of the methods and impose a higher standard of care, as in *Helling v. Carey*. Certainly, the potential for liability places a constraint on the extent of cost containment. But in doing so, the courts would simply be playing their traditional role in setting limits and in monitoring private economic relations. By imposing general negligence standards, the courts would not be impeding cost containment initiatives. They would instead be requiring plans to weigh the costs and benefits of implementing cost controls given potential adverse medical outcomes.

Fourth, courts might revert to the physician dominated standard of care seen under fee-for-service litigation where the physician's duty is to treat the individual patient and to increase the probability of a good outcome without worrying about resource constraints. In this approach, CEA would constitute a lower standard of care unless it became part of customary practice.

A fifth possibility is that courts could abandon tort altogether in favor of contract. As noted earlier, this is the preferred solution for many legal scholars and economists. To be viable, the contract would need to clearly specify the use of CEA, how it will be implemented and how patients will be informed about its use. Absent more explicit contractual arrangements between plans and employers, there is no reason to believe that courts

29. P. D. Jacobson and M. T. Cahill (2000) have proposed a similar strategy for resolving conflicts of interest under fiduciary duty concepts.

will shift to contract on their own (Jacobson and Pomfret 1999). This would change if, over time, plans and subscribers bargained for lower cost plans with lower benefit levels based on explicit CEA or other cost containment strategies. Courts would then be compelled to address the use of CEA from a contractual, as opposed to a tort, perspective.[30]

Sixth, courts could abandon both tort and contract to develop a standard based on fiduciary duty (Jacobson and Cahill 2000). This standard would force the courts to develop criteria for balancing between individual patient needs and preserving resources for the patient population. Although the Supreme Court has now foreclosed fiduciary challenges under ERISA in *Pegram v. Herdrich*, nothing prevents state courts from developing a common law of fiduciary duty in managed care litigation that survives an ERISA preemption challenge.

Finally, courts could develop alternative standards that combine tort and contract approaches. Various scholarly strategies for bridging tort and contract are described by Jacobson and N. M. Patil (2000), such as the bifurcate standard of care described earlier.[31]

Right now, ERISA preemption may limit state court experimentation with different standards of care. But to the extent that state courts hear more managed care cases, it seems likely that variation across states among the above options will emerge. Judges will look to legal scholars and health policy analysts and researchers for guidance on the health care policy and delivery implications of each standard.

Avoiding the Smoking Gun. Even if one accepts this approach, it still leaves unanswered the question of how plans can use CEA without either providing the smoking gun for a jury verdict or engendering a public backlash. In some ways, responding to the backlash may define how the former will be resolved. If plans can develop ways to bring the public into the decision-making process, there is less likelihood that individuals will sue, and less likelihood that juries will punish the use of CEAs.

Suppose courts eventually rule that CEA is admissible as one piece of

30. In response to this point, Shuman (in this issue) argues that this should be a contracts issue and that our approach essentially allows courts to rewrite contracts under the guise of tort law. From a normative perspective, one of the authors has argued against using a contract regime in health care litigation (Jacobson and Patil 2000). As an empirical proposition, we are not aware of instances where employers have negotiated contracts with MCOs to incorporate CEA. Absent some contractual language about the use of CEA, if an MCO uses CEA to deny care, the subsequent challenge lies in tort, not contract.

31. Jacobson and Cahill (2000) argue that a breach of fiduciary standard is more useful than either tort or contract in the managed care context.

evidence to determine the standard of care (in the same way that courts seem to be handling guidelines). Can this be introduced without prejudicing the jury against the MCO? As the Ford and GM cases illustrate, juries may have an inherent dislike of CEA when carried out by private parties who are maximizing profits at the expense of lives. The problem is likely to occur on cross-examination. In interviews regarding the cost-effectiveness of contrast agents, physicians who argued in favor of using the more expensive technology worried about being cross-examined as follows: "Dr. X, do you mean to tell me that this patient died (or suffered a severe reaction) because you wouldn't spend $150 to protect the patient's safety?" (Jacobson and Rosenquist 1996). As the GM gas tank case suggests, this is likely to be as much of a problem for MCOs as for physicians, particularly at a time when the public is generally skeptical, if not suspicious, of managed care's economic motives.

One possible approach is for judges to provide explicit instructions to the jury on how to weigh CEA evidence and where CEA fits in setting the standard of care. But this problem will not easily be solved. As Gary Schwartz (1991: 1041) observed in commenting on the *Grimshaw* case: "It seems sensible to recognize in all of this an instance of the 'two cultures' problem. A culture has developed around public policy analysts that sees the risk-benefit criterion as obviously acceptable; but the culture of public opinion itself tends to regard that criterion as distressing. Indeed, the outcome of the subsequent GM gas tank case suggests that the gulf between the two cultures remains wide."

Another possible approach is to develop a CEA certification process, perhaps under the auspices of the Agency for Healthcare Quality and Research (AHRQ) or the Institute of Medicine (IOM). CEAs certified by the responsible entity would be admissible, while CEAs not certified would be inadmissible.

Conclusion

In a 1988 article, Jacobson and John Rosenquist (1988: 1589) argued that medical professionals should not be held liable for the failure to use new technologies that were not cost-effective, stating that "nothing prevents the profession from factoring in resource constraints in defining the level of technology that will become customary practice." Surprisingly, the technology discussed in that article, contrast agents, never generated the anticipated litigation, so there was no test of whether the suggested approach would be persuasive in an appropriate case. For that test to

occur, CEA needs to be implemented. Sooner or later, the dictates of cost containment will compel more widespread use of CEA. Then the courts can decide whether to defer to the profession or to consider medical liability under general negligence principles that take cost-effectiveness into account.

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