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ACCESS TO INVESTIGATIONAL TREATMENTS

*Mary Ader**

I. THE ISSUE

STRIFE OVER THE SCOPE of health benefits persists. It permeates our courts, our legislatures, and our lives, eluding satisfactory solutions. Each day health plans are called on to design, draft, administer, and defend their benefit contracts in the face of astonishing technological advances, vigilante consumerism, and unprecedented judicial and legislative intervention. Nowhere is the controversy over coverage more acute than over access to investigational treatments.

Many factors have fueled this controversy. First, health plan beneficiaries, often with life-threatening diseases, expect their health plans to pay for potentially life-saving treatments, even though these treatments are still under investigation in various research programs. When health plans invoke the investigational exclusion to deny coverage, and balk at financing medical research (as opposed to paying for mainstream medical care), then the plan beneficiary may well choose to litigate the issue. Second, researchers and providers of care, faced with dwindling research revenues from other sources, are anxious to acquire third-party payment to help support their medical research. And third, state legislatures often resort to enacting mandated benefits legislation requiring third-party payors to pay for such research.

Historically, health plans have generally paid only for treatment that works, not for medical research. Perhaps it is now time for health plans to reassess this position, to help resolve the controversies over emerging technology, not through the courts and legislatures on an ad hoc basis, but rather through supporting the quest for scientific evidence through clinical trials. This approach would seem to be more constructive, more systematic. This Arti-

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cle examines some of the legal and medical issues involved in this debate, and offers some suggestions for future directions and conflict resolution.

II. THE OBJECTIVE

Our imperative is to chart a rational course to which all interested parties can subscribe — researchers and providers, payors and arrangers, patients and policyholders, lawyers and legislators. The objective is to establish a *modus vivendi* that acknowledges and addresses all their respective concerns. This undertaking, however, is far more complex than many of us may realize. It requires us to synthesize science, law, and public policy, and to put science first and foremost. This kind of preemption may be discomfiting to some, particularly those accustomed to legal leveraging. Nevertheless, it requires us all to submit to the authority — indeed the supremacy — of scientific data over legislative, journalistic, and judicial pronouncements.

III. THE CONTEXT

The ability to manage access to emerging medical technology is critical both to society in general and also to the three main parties to the health care transaction — patient, provider, and payor. It is critical in three different ways. First, it is critical to managing the delivery of quality medical care. We must deliver care that helps the patient, not care that may hurt the patient. We must ensure that the benefits of the treatment outweigh the harms. Second, it is critical to managing the financial constraints of delivering a quality health care benefit. We must be able to deliver the benefit within the budget (the premiums collected for the contracts issued). Third, it is critical to managing the legal risks of the failure to describe the benefits accurately and deliver them efficiently. Therefore, in the interests of quality medical care, delivered on budget, beyond legal challenge, it is prudent to develop criteria and mechanisms for determining access to investigational treatments.

In developing these principles of access to investigational treatment, we must recognize that in any rational health care system, there are limits on affordability. This creates at least two fundamental tensions. First, there is the tension between the insatiable demand for new technology and the need to establish — scientifically — safety and efficacy prior to diffusion. There is a

risk that our capacity to demand new technology may now be outpacing our capacity to assess its clinical usefulness. Second, there is the tension between the availability of these technological advances and their attendant costs. Our capacity to produce new technology may now be outpacing our capacity to pay for it. So we have to set reasonable limits. How to capture the benefit of new technology, and not lose it amidst budgetary constraints, presents both a challenge and an opportunity to the proponents of managed care.

IV. THIRD-PARTY PAYOR RESPONSES

Third-party payors have attempted to set reasonable limits in two major ways. The first method is a greater reliance on technology assessment. Payors, and their accounts, want value for their money. They want to pay for what works. Technology assessment is one means to this end. Technology assessment is performed by about seventy organizations nationwide: the major insurers do it; as do some medical societies; the federal government; and various research organizations. The key product is a secondary medical technology assessment that consists of a document that summarizes the current state of knowledge concerning the technology in question, including divergent evidence, areas of controversy, and gaps in the knowledge base. It describes safety, efficacy, and appropriate use based on the available evidence. If there is insufficient scientific evidence from which to draw conclusions as to safety and efficacy and as to improvement in health outcomes — such as length of life, ability to function, and quality of life — then payors and their accounts are likely to require the development of such evidence before the technology flows into mainstream payment.

In this way, technology assessment addresses not the *cost* of emerging technologies, but more significantly, *value* for money. The vital role that technology assessment plays in determining sound medical policy has generally been underrated, and sometimes even ignored or flouted by courts and legislatures. We need to make more effort to prevent these oversights, to make the process of technology assessment intelligible to a wider audience, and to educate the populace about this pivotal means of delivering quality health care.

The second method of defining reasonable limits has been for payors to tighten and enforce their exclusions from coverage,

particularly their investigational and medical necessity exclusions. These two exclusions, and the concepts that they represent, are sometimes confused, and sometimes used interchangeably. However, they do serve different, but equally valid, purposes.

Medical necessity exclusions, in essence, address the issue of the appropriateness of care for a given diagnosis, including the appropriate level of care. For example, does this diagnosis require six months of acute hospital care? In this length of stay medically necessary? Most medical necessity lawsuits are, in fact, length of stay disputes, and happen to be mostly psychiatric.¹ What this suggests is that there may be more uncertainty over the diagnosis and treatment of mental illness than there is over the concept of medical necessity as such. The definitional problem lies in the term "mental illness," not in "medical necessity." Although the concept of medical necessity has been much maligned, it does attempt to address the important concept of efficiency.

Investigational exclusions, by contrast, are designed to address the issues of safety and efficacy. They should do this by looking to the status of the technology. The language of the exclusion should, therefore, contain objective criteria that correlate to the existence of the continuing investigation of the technology. The question to be answered is: given this patient and this diagnosis, is there enough evidence to establish that this treatment works? Or is the evidence still being developed? Still inconclusive? If the procedure is still under investigation, it is investigational, warranting the Scottish verdict, "not proven." Technology assessments, when available, should determine the outcome of this inquiry. In terms of coverage, most accounts do not want to pay for technologies that have not yet proven their value. In terms of public policy and the need to conduct promising medical research, we need to develop means of financing patient access to such research.

1. See, e.g., *Hughes v. Blue Cross*, 248 Cal. Repr. 172 (1988); *cert. denied*, 110 S. Ct. 2200 (1990); *Salley v. E.I. DuPont & Co.*, 966 F.2d 1011 (5th Cir. 1992). A significant medical necessity case that did not involve psychiatric treatment is *Katskee v. Blue Cross and Blue Shield*, No. 5-92-1022 (Neb. Sup. Ct., May 6, 1994). The plaintiff had a genetic predisposition to cancer — breast-ovarian carcinoma syndrome — and the court found that this was an "illness" within the meaning of the contract, and that radical prophylactic surgery to remove the uterus, ovaries and fallopian tubes should not be denied on medical necessity grounds.

V. THE IMPACT OF ASSESSMENTS AND EXCLUSIONS

When third-party payment is not forthcoming by virtue of an assessment or exclusion, what impact does this have on the technology, and on the quality of care? First, payment decisions based on technology assessments and/or benefit exclusions may in fact delay the diffusion of technologies eventually found to be medically appropriate.² Sometimes there are prolonged periods of uncertainty for technologies eventually proven to be beneficial (cochlear implants for children for example). This occurs even though payors are committed to paying quickly to please their customers, and to the improvement of the quality of their services. Second, and conversely, the benefits of new technologies may ultimately prove to be small or nonexistent. Here, the decision to pay may promote ineffective or even harmful technologies (for instance, thalidomide; bowel removal for epilepsy; the freezing of gastric ulcers; and the Garren gastric bubble). Safety should always be the first consideration.

Finding the right balance is not always straightforward, and can be controversial. Currently, a number of technologies seem to fall into a "grey" area of payment confusion and litigation, such as high-dose chemotherapy with autologous bone marrow transplant (HDC-ABMT) for breast cancer; growth hormones for short-statured children; home uterine monitoring to detect early labor; PET scans;³ and radial keratotomy.⁴ Tomorrow's technologies, such as gene therapy, are already on the horizon. Does every technological advance have to be accompanied by payment battles, played out in the courts and the media? Surely these are singularly inappropriate forums for determining access to investigational treatments, given the nature of the scientific issues that such treatments present.

VI. ACCESS THROUGH LITIGATION

During the past few years, hundreds of patients have sought

2. Given a choice of possible treatments, providers generally opt for the one that the third-party payor reimburses. Therefore, until the newer technologies are proven safe and effective and hence, reimbursable, providers are reluctant to prescribe them.

3. Positron Emission Tomography (PET) uses a radioactive isotope to show areas of brain activity.

4. Radial keratotomy is a refractive surgery for the permanent correction of myopia (nearsightedness) and/or astigmatism.

access to investigational treatments through the courts.⁵ Many of these patients have been successful, for a variety of reasons, including the sympathy factor, inadequate and ambiguous contract language, and alleged negligent medical review by the benefit plan.⁶ As a result of this litigation compelling access to investigational treatments, benefit plans have tightened their exclusionary language and strengthened their medical review processes.

Nevertheless, the litigation continues, leaving unanswered some fundamental questions. Should health plans exclude investigational treatment to begin with? If so, how should health plans define "investigational?" How should they determine whether a particular treatment meets the definition? To health care payors, it seems that these questions have been the subject of much misunderstanding to those outside the health care payment business — patients, providers, the media, and the courts.

However, on certain key points the cases are instructive, and send a clear message to health plans that if they wish to exclude investigational treatments, their investigational exclusions need to contain, at a minimum, four elements: (i) sound criteria for making the decisions; (ii) a description of the decision-making process; (iii) language that is not ambiguous; and (iv) language that is sufficient to put the subscriber on notice of what is and what is not covered.⁷ This is easier said than done. To courts called upon to review complex medical and methodological questions, ambiguity in contract language will be construed against payors. Therefore, what is meant by "investigational" needs to be precisely defined in the contract and specifically related to enforceable criteria.

5. See, e.g., *Harris v. Blue Cross and Blue Shield*, 729 F. Supp. 49 (N.D. Tex. 1991); *Cole v. Blue Cross and Blue Shield*, 738 F. Supp. 42 (D. Mass. 1990). For an extensive compilation of these cases, see ADER & LEWIS, *INVESTIGATIONAL EXCLUSIONS: A SUMMARY OF THE CASELAW* (1995).

6. Where the plaintiff is seeking treatment for a life-threatening disease and the defendant is a deep-pocket defendant such as an insurance company, these facts tend to influence the outcome of litigation, regardless of the contract language at issue. In this David versus Goliath context, courts have often found the contract language ambiguous, see *Bailey v. Blue Cross & Blue Shield*, 866 F. Supp. 227 (E.D. Va. 1994), or found the medical review process deficient or inadequate in some way, see, e.g., *Bucci v. Blue Cross & Blue Shield*, 764 F. Supp. 728 (D. Conn. 1991). See also ADER & LEWIS, *supra* note 5.

7. See, e.g., *Doza v. Crum & Forster*, 716 F. Supp. 131 (D. N.J. 1989); *Hurowitz v. Blue Cross & Blue Shield*, No. 90-451 (E.D. Va. 1990); *Waldrup v. Connecticut Mut. Life Ins. Co.*, 566 So. 2d 434 (La. App. 1990). See also ADER & LEWIS, *supra* note 5.

Health plans have adopted different approaches to the problem of how to develop standards or criteria for determining investigational status. Some are better than others, but all have fallen victim to judicial disapproval at some time or another. The first approach is to accept the standard of "professional consensus." This, however, runs the risk of becoming the consensus of the *relevant* professionals, which in turn may become the consensus of the treatment's *proponents*.⁸ From the payor's perspective, this is a slippery slope.

A second approach is to reference and adopt the positions of other entities, such as the federal Office of Technology Assessment, the National Institutes of Health, or the AMA. This, too, is problematical. The entity selected may not have a position on a particular technology; the entity's position may be unclear, out-of-date, or in conflict with the position of other entities; and the subscriber still may not receive adequate notice of what is or is not covered.⁹

The third approach is to use scientific criteria, such as those used in the technology assessment program of the Blue Cross and Blue Shield Association.¹⁰ This approach recognizes that

8. See Dozsa, 716 F.Supp. at 131.

9. Waldrip, 566 So. 2d at 434.

10. The five Blue Cross and Blue Shield Association TEC criteria are:

1. The technology must have final approval from the appropriate government regulatory bodies.

- This criterion applies to drugs, biological products, devices and diagnostics.
- A drug or biological product must have final approval from the Food and Drug Administration.
- A device must have final approval from the Food and Drug Administration for those specific indications and methods of use that Blue Cross and Blue Shield Association is evaluating.
- Any approval that is granted as an interim step in the FDA regulatory process is not sufficient.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

- The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
- The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition there should be evidence or a convincing argument based on established medical facts that such measurement or alteration affects the health outcomes.
- Opinions and evaluations by national medical associations, consensus, or other technology evaluation bodies are evaluated according to the quality of the supporting evidence and rationale.

3. The technology must improve the net health outcome.
- The technology's beneficial effects on health outcomes should outweigh any harmful

there is a difference between the systematic generation of objective data and authoritative opinion. The latter may prevail in lawsuits in the short run, but must inevitably yield to the former in the long run.¹¹

For health plans that want to cover only those treatments proven to work, the scientific criteria approach, geared to the systematic generation of objective data, appears to be the superior one. Such plans would presumably specifically exclude treatments performed in Phase I, II, or III clinical trials under protocols that reference determinations of safety, efficacy, toxicity, and comparisons to conventional alternatives; and treatments that called for Institutional Review Board (IRB) approval and consent to investigational treatment.

Regardless of a health plan's approach and objective, its contract language will always be at risk of legal challenge on grounds of ambiguity, and its medical review process on grounds of timeliness, comprehensiveness, and currency. The burden of vigilance here, the courts say, falls on the health plan.¹² All of

effects on health outcomes.

4. The technology must be as beneficial as any established alternatives.

- The technology should improve the net health outcome as much as or more than established alternatives.

5. The improvement must be attainable outside the investigational settings.

- When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy criteria #3 and #4.

11. Some courts have decried the health plans' failure to specify the *quantum* of evidence required, and have called for specific thresholds of statistical success in terms of cure or survival rates. *See Pirozzi v. Blue Cross & Blue Shield*, 741 F. Supp. 586 (E.D. Va. 1990); *Reiff v. Blue Cross & Blue Shield*, No. CIV 90-583-S (E.D. Okla., 1991); *Bucci*, 764 F. Supp. at 728. With all due respect to these courts, such a standard — for all diseases, all technologies, and all times — simply could not be met; it would be utterly impracticable even to attempt to embrace all these in a single health benefit contract. Although these particular courts condemned the lack of standards for determining statistical success, at least one other court, looking at the numbers, took a different view. *Evans v. HMO Col., Inc.*, No. 91 CV 3797 (Colo. Dist. Ct., 1991). Here, the plaintiff sought benefits for HDC-ABMT for the treatment of cervical cancer. The court found it significant that the procedure had been performed on only six patients at one research facility. It said: "The University of Nebraska is the only one that has been trying to find out if this is going to work on this kind of solid cancerous form [N]obody knows yet. Everybody agrees that six is far too few to make a judgment on."

Ironically, "going by the numbers" has been condemned by one court. In reviewing *in vitro* fertilization, a court found it arbitrary and capricious for a plan to grant or deny coverage based solely on a success ratio (in this case, less than 50% successful). *Reilly v. Blue Cross & Blue Shield United*, 846 F.2d 416 (7th Cir. 1988).

12. Contract language does not always contemplate new medical developments. *See, e.g., Bailey*, 866 F. Supp. at 277; *Calhoun v. Complete Health Inc.*, No. 94-556, 1994 WL 448986 (S.D. Ala. 1994); *McLaughlin v. Williams*, 801 F. Supp. 633 (S.D. Fla. 1992).

this makes access to investigational treatment through litigation unpredictable and costly. Worse, the clinical issues of safety and efficacy are lost through loophole lawyering that focuses on how to interpret a benefit, not how to benefit an insured.

VII. BEYOND LITIGATION: ACCESS TO CLINICAL TRIALS

Parties to litigation over investigational exclusions often find themselves, literally as well as metaphorically, locked in mortal combat in the courts. When potentially life-saving treatment is at stake, trial courts are likely to rule in favor of the plaintiff. Defendants rarely appeal.¹³ Health plans have responded to this in a variety of ways: they have strengthened the general investigational exclusion; developed procedure-specific exclusions for certain treatments; been more selective in those cases they choose to take to trial; and offered riders for investigational treatments for inclusion at account option. All of these responses have contributed to minimizing the element of uncertainty inherent in benefit interpretation.

What these responses do not do, however, is answer the fundamental question raised earlier: should health plans be in the business of excluding all investigational treatment in the first place? Expressed differently, is there a legitimate role for health plans in paying for certain kinds of investigational treatment? If so, what might this be? How might it be described for benefit contract purposes?

With these questions in mind, it might be prudent for health plans to begin to think about two categories of investigational treatment, and pay separate attention to life-threatening diseases. Where the disease is life-threatening, where conventional therapy has failed, where, but for the investigational therapy, life expectancy is limited, and where the investigational therapy is the only possibility of preserving life, then health plans may wish to consider developing humane, worthwhile alternatives to claims denials. The funding of clinical trials would be a logical place to begin.

The case law shows that the investigational exclusion is an effective and appropriate barrier to payment for unorthodox treat-

13. See ADER & LEWIS, *supra* note 5.

ments, such as coffee enemas and tomato therapies.¹⁴ If this is all it accomplishes, it is worth maintaining. However, for potentially life-saving treatments, the case law suggests a trend that may render standard medical coverage language insufficient to protect against claims for investigational treatments, particularly in the context of the terminally ill, where the treatment is prescribed by legitimate providers and performed in leading institutions after conventional therapy has failed.¹⁵ Even the finest of investigational exclusions and decision-making processes will face an uphill battle in court in life-threatening cases where the plan is characterized as asking the court for a death sentence for the subscriber.¹⁶

This is frustrating for health plans, many of which are not-for-profit and which have in good faith set their premiums for their products based on their contracts as written and the actuarial principles behind them. Moreover, despite misguided attempts by plaintiffs and the press to depict health plans as latter-day Scrooges, the reality is that health plans routinely pay enormous sums for appropriate noninvestigational treatment. HDC-ABMT, for example, is a therapy that is routinely paid for in the treatment of at least six forms of cancers for which it is known to be effective.

Therefore, the real issue to be addressed is not the enforceability of the investigational exclusion, nor its wordsmithing, but rather how medical research is to be financed. In earlier days, cancer and heart disease were first in line for relatively abundant research funds. Today, governmental sources are subject to budget constraints; new diseases have unprecedented political clout; burgeoning techno-med consumes an increasing proportion of the health care dollar; and hospitals and physicians look to medical research programs to solve patient census problems and contribute to the bottom line. Health plans are now being tapped to fill the void.

Is the cost of medical research now to be borne by health plans? If so, then two conclusions follow. First, health care pre-

14. Requests for payment for these kinds of therapies are often denied by the plan's medical director, without recourse to the courts. *See Free v. Travellers*, 551 F. Supp. 554 (D. Md. 1982) (Laetrile treatments and vitamin regimens); *Henne v. Mutual of Omaha*, No. 81, 1359 (D. D.C. 1983) (unpublished opinion).

15. *See Pirozzi*, 741 F. Supp. at 586.

16. *Id.*

miums could increase in the short run. Second, health plans should begin to consider developing constructive payment mechanisms for investigational procedures, and to steer them into research studies in a timely manner. For example, they might rewrite their benefit contracts to cover certain forms of investigational treatment when provided in well-conceived clinical trials under specified terms and conditions. Plans would then be able to pool the resulting data and learn something for the money expended. This approach would stimulate valuable research and yield useful information. It would represent a new era of collaboration and cooperation between payers and providers. Above all, it would move the debate from the legal to the medical arena, where it belongs. A logical place to begin this process would be for plans to engage in selective contracting with specified institutions for promising treatments (for example, Phase III trials, representing a stage in the research that shows "substantial promise"). This option would entail coverage only when the procedure was performed at specified institutions (or institutions that met specified criteria).

Variations on this "Exclusive Provider Organization" theme, and suggested contractual components of it, might include: contributing to controlled clinical trials, under research protocols (national if possible, to elicit comparable data), within a designated time frame, with data analysis, cost-sharing, and risk-sharing. All of these components are designed to reinforce the *research* and *investigational* nature of the procedure at issue. Cost-sharing and risk-sharing might take a variety of forms (two-way, plan-provider; or even three-way, plan/provider/subscriber). An example of such an approach is the Blue Cross and Blue Shield System's Demonstration Project for HDC-ABMT for breast cancer. The Blue Cross and Blue Shield Association, in conjunction with the National Cancer Institute (NCI), is currently sponsoring a Demonstration Project for HDC-ABMT for breast cancer. The Blue Cross and Blue Shield Plans expect to contribute about \$40 million to this randomized controlled clinical trial over the next several years. The Demonstration Project supports a series of four national Phase III trials. The NCI Trials are intended for the eventual enrollment of 1500 women and are currently being conducted at eighty-six medical research institutions. Blue Cross Blue Shield Association has contracts with forty-two of these institutions. The research protocols governing each of the NCI Trials were designed and approved by clinical trial co-

operative groups, voluntary associations of cancer research institutions that conduct clinical trials executed uniformly among member institutions. The research protocols have been approved by the NCI, and the trials are randomized, so that the outcomes of the treatments can be scientifically compared. Randomized trials are ethical only where the researchers do not know whether the experimental therapy, the standard therapy, or either therapy is superior. This five-year Demonstration Project should be completed in 1996.

Another example of this kind of contracting is the Blue Cross Blue Shield Association multiple myeloma trial program. This program is modelled after the Breast Cancer Demonstration Project, and includes unique contracts with a network of qualified institutions, access to trials that are approved by a national research organization, a fixed contribution rate negotiated with each institution, and a centralized patient management and tracking system.

A final example of this kind of contracting is the Blue Cross Blue Shield Association's response to the September, 1994 federal government mandate that all carriers in the Federal Employee Health Benefits Program cover high dose chemotherapy with autologous bone marrow transplantation for three diagnoses: breast cancer, multiple myeloma, and epithelial ovarian cancer. The Blue Cross Blue Shield Association has developed a "Clinical Trials Benefit," which covers these services, and allogeneic bone marrow transplants for multiple myeloma, when performed in a clinical trial.

Clinical trials are the only way to resolve the relative efficacy of new technologies and the only way to ensure that the patient is being treated as safely as possible by the most competent physicians. If there *is* a point at which medicine, economics, common law, and common sense intersect, then the funding of clinical trials is that point. There *are* periods of scientific uncertainty. These issues can only be resolved scientifically, if at all. A court order or a state mandate to pay or an account mandate to pay is not responsive to this dilemma.

This leaves one final issue: how should we select clinical trials that are worth financing and incorporating into the health care benefit? Not all clinical trials are of the same value. The trials selected should be those that undergo the most rigorous protocol review process and receive thorough study oversight. For HDC-ABMT for breast cancer, for example, the most strenuous

level of protocol review and oversight is received by NCI-sponsored therapeutic clinical trials conducted by the Clinical Trials Cooperative Groups. Trials approved by other NCI programs or other research entities recognized by the NCI for Cancer Center support grants could be ranked second in importance for health plan consideration. Trials approved only by a hospital IRB and funded by the institution or pharmaceutical companies or other local sponsors should be ranked lowest in importance for health plan consideration.

Patients should always be treated in the highest "phase" of a trial for which they are eligible, since this is the phase most likely to yield a positive health outcome for that patient. Within the hierarchy of trial phases, Phase III multi-center controlled trials comparing investigational agents to standard therapy should receive the highest priority for health plans. Phase II trials which determine anti-tumor activity of agents generally in single-site trials should be ranked second in importance to Phase III trials for health plan support. Phase I trials which attempt to establish therapeutic effect and safe dosage should generally be supported by the research sponsor and not by payors.

Some may argue that to embrace this approach in a benefit contract would cause health care premiums to skyrocket. However, any such premium increases implemented in the short term may well be tempered in the long run by the elimination of payment for procedures that the research determined were not effective, and by the swifter channeling of patients to treatments that the research determined were effective. It is more productive for health plans to steer their members into well-conceived clinical trials than into ill-conceived judicial ones.

