

## THE LIMITED REGULATORY POTENTIAL OF MEDICAL TECHNOLOGY ASSESSMENT

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### I. TREATING THE SYMPTOM INSTEAD OF THE DISEASE

Expensive new technology is routinely blamed for our health care cost explosion.<sup>1</sup> Predictably, curbing its entry has become increasingly advocated in this and other developed nations. True, there are other popular culprits. Our populations need more health care because they are larger and older than before. And they can afford more care because they have higher disposable income. But these factors explain a relatively small portion of cost increases. Population increases cannot explain why inflation-adjusted expenditures have increased nine-fold *per person*.<sup>2</sup> An older (and thus sicker) profile of patients explains only two percent of this increase, and greater income explains only five percent.<sup>3</sup> And even if these factors were to blame to a

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<sup>1</sup> For one of the most thoughtful versions of such an argument, see Alan M. Garber, *Can Technology Assessment Control Health Spending?*, *Health Aff.*, Summer 1994, at 115.

<sup>2</sup> See David M. Cutler, *Technology, Health Costs, and the NIH 3* (Sept. 1995) (unpublished manuscript) (on file with the Virginia Law Review Association) (in constant 1990 dollars, 1990 health care expenditures in the United States were 8.9 times higher per person than in 1940).

<sup>3</sup> *Id.* at 4-5 & tbl. 2. Another explanation is that service industries naturally grow relative to other industries because productivity increases more slowly in services, *id.* at 6, but this does not explain why health care is growing much more rapidly than other services. Moreover, even if we assume *zero* productivity growth in medicine, that would explain only 19% of the nine-fold increase in expenditures per person. *Id.* at 7. Other commonly-named cost culprits include insurance, administrative expense, provider organization, government reimbursement and regulation, medical inflation,

greater extent, we presumably would not want to “correct” them by eliminating some of our population or reducing its longevity and income. No, technology is the natural target.

Yet I doubt technology regulation can do much about the cost escalation problem. The technology we get reflects the incentive structure for using it. If that incentive structure continues to embody an absolutist imperative that encourages the provision of all medical care having positive net health benefits regardless of cost, then we will continue to see innovations that marginally improve medical outcomes despite great cost. This is what I have called the “Field of Dreams” problem of health care innovation: If we’ll pay for it, it will come.<sup>4</sup> Technology assessment is a poor substitute for the incentives to trade off cost and benefit that are missing in an absolutist system. It treats the symptom rather than the underlying disease.

But, you might think, my description of our medical incentive structure is hopelessly outdated. We now live in a world of capitated payments, competition, for-profit hospitals, managed care, integrated providers, utilization review, and fixed payments for all treatment of a given diagnosis. Cost pressures are everywhere. True. But this should not change our analysis of the regulatory potential of medical technology assessment.

To begin with, any shift to cost-sensitive means of financing and providing health care *decreases*, not increases, the need to restrict the entry of expensive new technologies. If recent changes and new cost pressures have indeed moved us to an incentive structure that encourages providers to trade off the benefits and costs of care, then providers would have little incentive to use overly expensive technology and researchers little incentive to create it. That would mean medical technology assessment has even less regulatory potential than one otherwise might have thought.

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poor market information, tax subsidies, defensive medicine, waste and abuse, and excessive intensity or complexity of treatment. However, because these problems all reflect or stem from the root problem of the health care system’s incentive structure (as to some extent does slow productivity growth), I do not treat them separately. Moreover, Professor Cutler’s careful analysis suggests that even treating such factors as separate causes explains only 50% of the nine-fold increase. *Id.* at 9 & tbl. 2.

<sup>4</sup> Einer Elhauge, *Allocating Health Care Morally*, 82 Cal. L. Rev. 1449, 1543 (1994); Einer Elhauge, *Medi-Choice*, *New Republic*, Nov. 13, 1995, at 24, 26.

More important, reports of this shift are much exaggerated. We have not in fact shifted to an incentive structure that encourages cost-benefit tradeoffs. While our new regime may encourage market actors to minimize the cost of providing all beneficial care, Part II shows that it does not legally allow them to deviate from the goal of providing all care having a positive benefit. At every turn, in doctrines too widespread and manifold to dismiss as the product of wayward decisions, the legal framework that structures industry incentives discourages the trading-off of benefits and costs. Even the most ambitious reform proposals retain this absolutist imperative. This is the underlying disease we have not yet cured and cannot cure with regulatory technology assessment.

Of course, technology assessment might be not regulatory but informational. The informational variant aims merely to assess what the technology actually does and (sometimes) how much it costs.<sup>5</sup> As Part III discusses, this aim seems relatively helpful. But the record of actual achievement in helping buyers make cost-benefit tradeoffs is disappointing. Partly this is because reliable information has the elements of a public good, elements that perhaps surprisingly undermine its provision by publicly-funded actors as well as by the market. And those with the strongest incentives to create product information—the product sellers—have the least incentive to be accurate or reliable. But the strongest reason is probably that our current health care regime leaves little or no incentive for technology buyers to *use* such information to make cost-benefit tradeoffs. Indeed, under our absolutist system, informational technology assessment typically *exacerbates* cost problems by encouraging the use of innovations that confer relatively small marginal benefits at much higher cost.

Unlike the informational variant, regulatory technology assessment would take the next step of imposing some pressure not to use or develop negatively assessed technology.<sup>6</sup> Sometimes this takes the form of a prohibition on the sale or use of

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<sup>5</sup> See Garber, *supra* note 1, at 120 (noting that some major approaches to medical technology assessment avoid cost considerations).

<sup>6</sup> See Frederick Schauer, *Playing by the Rules* 5 (1991) (noting that the distinctive feature of mandatory rules is that they create some sort of pressure to follow them).

technology absent regulatory approval.<sup>7</sup> Or a negative assessment might mean that a provider's use of the technology would be regarded as malpractice.<sup>8</sup> Other times, it is simply a prohibition on government reimbursement for the disfavored technology.<sup>9</sup> Or perhaps the point is enabling private insurers and providers to deny the disfavored technology by lifting the threat of liability for such denials.<sup>10</sup> Although these examples have important differences, the common distinctive element is that all of them aim to improve the operation of the health care industry by discouraging an entry of disfavored new technological inputs that would otherwise occur. I will thus refer to all such efforts as regulatory technology assessment throughout this Article.<sup>11</sup>

Plainly, regulatory technology assessment can and often does pursue goals other than making cost-benefit tradeoffs: namely,

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<sup>7</sup> See, e.g., Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 351-360l (1994).

<sup>8</sup> See generally Clark C. Havighurst, Practice Guidelines as Legal Standards Governing Physician Liability, *Law & Contemp. Probs.*, Spring 1991, at 87 (noting likely influence of practice guidelines on malpractice standards).

<sup>9</sup> Such decisions have been made by Medicare administrators, see Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. 4302, 4307-08 (1989) (to be codified at 42 C.F.R. pts. 400, 405) (proposed Jan. 30, 1989), as well as by the Office of Healthcare Technology Assessment (OHTA) at the Agency for Health Care Policy and Research (AHCPR), see Sean R. Tunis & Hellen Gelband, Health Care Technology in the United States, 30 *Health Pol'y* 335, 359-61 (1994). See also Clark C. Havighurst, Practice Guidelines for Medical Care: The Policy Rationale, 34 *St. Louis U. L.J.* 777, 788 & n.33 (1990) (noting that guidelines are likely to influence Medicare and Medicaid reimbursement policies); Office of Technology Assessment, *Identifying Health Technologies That Work* 36 (1994) (noting preliminary agreement whereby Canadian national health insurance would not cover services outside guidelines).

<sup>10</sup> See Barry R. Furrow et al., *Health Law* § 6-2(a), at 241 & n.29 (1995) (collecting state statutes immunizing physicians from malpractice liability); Mark A. Hall & Gerard F. Anderson, Health Insurers' Assessment of Medical Necessity, 140 *U. Pa. L. Rev.* 1637, 1687-89 (1992) (proposing that insurers could contract out of covering negatively assessed procedures); Havighurst, *supra* note 8, at 87, 91-93 & n.19, 95 (noting likely influence of practice guidelines on malpractice and insurance law standards); Office of Technology Assessment, *supra* note 9, at 2, 35, 140 (noting that one major purpose of technology assessment and practice guidelines is to enable insurers and physicians to deny disapproved technologies without legal liability and describing laws in Maine, Vermont, and Minnesota allowing it to be used as a defense in malpractice cases).

<sup>11</sup> Indeed, much of the critique (surprisingly) applies also to nonregulatory efforts to simply cut off government research funding to negatively assessed technologies.

screening out new technologies that are “medically ineffective” in that they have no net health benefit at all or, more recently, those that are “cost ineffective” in that they cost more without conferring any greater health benefit.<sup>12</sup> Such goals, as discussed in Part IV, are more modest and achievable than a goal of making cost-benefit tradeoffs. They are also highly important goals under a regime with fee-for-service financing, since such financing encourages the provision of additional or more expensive care whether or not it has greater health benefits. Still, even these more modest regulatory goals face conceptual and practical problems likely to undermine their achievement. Furthermore, like regulatory cost-benefit assessment, they are less important if we are moving to a reformed system that instills incentives to minimize costs. Medical providers under such a system already have no incentive to use technologies that are harmful, ineffective or impose additional costs without benefit to patients: Such technologies cost the providers money without offering any real attraction to their customers.

In any event, eliminating technology that is unsafe, unbeneficial or cost-ineffective is unlikely to do much to curb health care cost increases.<sup>13</sup> What has really made technology assessment promising and provocative is the goal of preventing the entry of technology whose cost exceeds its benefit, at least when the cost-benefit disparity is large. It is on such regulatory cost-benefit assessment that this Article will focus.

Regulatory efforts to curb technology whose cost exceeds its benefits will likely fail for three general reasons. First, as I discuss in Part V, regulators are unlikely to actually weigh health benefits against monetary costs. To the extent that regulators are chosen for their technical expertise, such expertise does not help them because cost-benefit tradeoffs require value judgments that are not susceptible to objective scientific determination. Indeed, medical expertise can be antithetical to making such tradeoffs. To the extent we make regulators politically responsive, they have few incentives to make cost-benefit tradeoffs because most political input predictably comes from those

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<sup>12</sup> These terms are defined in more detail in the introduction to Part II, *infra*.

<sup>13</sup> See *infra* Section II.C.1.

favoring the entry of medically beneficial technology. Thus, it is not surprising that, in practice, efforts to curb new technology normally try only to screen out new machines, medicines, or procedures that have dubious health benefits or (sometimes) those that deliver no additional health benefit, but do so at a higher cost. This imposes little restraint on the absolutist imperative that is the root cause of the cost-escalation.

Second, even if regulators did seriously attempt to weigh health benefits against monetary costs, they would face the enormous technical problems I outline in Part VI. The costs and benefits of technology are not static. They vary with output and regions, among individuals and across time. No centralized regulator could possibly implement regulations that effectively adjust for all these factors and shift quickly with time and region as the factors change.

Third, efforts to curb new technology are unlikely to contain the spending pressures created by an absolutist incentive structure. As I discuss in Part VII, such an incentive structure creates pressures likely to overwhelm any regulatory dam. Even if regulations stem the flow of expensive new technology, efforts to improve health outcomes at any cost will simply be displaced to unregulated areas. More intensive use will be made of old technology, or research will focus on hard to regulate innovations such as new surgical procedures.<sup>14</sup>

Finally, in Part VIII, I explain why any shift to a cost-minimizing medical regime suggests that regulatory technology assessment would have even less potential in the future. Even if such a shift were to occur, the first two problems with regulatory

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<sup>14</sup>The technology assessment literature generally defines "medical technology" as including not only machinery, devices, and drugs but also medical practices and procedures. See, e.g., H. David Banta & Bryan R. Luce, *Health Care Technology and Its Assessment: An International Perspective* 8-9 (1993); Office of Technology Assessment, *supra* note 9, at 131. This definition usefully emphasizes that innovation and cost increases can occur from changes in any of those areas. But it somewhat confusingly seems to eliminate any distinction between technology and health care. In any event, despite agencies' predictable tendency to interpret their jurisdiction broadly, regulatory authority over technology entry is generally limited to technologies with some physical manifestation, typically produced by mass manufacturing. And whether or not the authority is so limited, entry regulations are easiest to enforce against such manufactured technologies, so they prove the most frequent target.

technology assessment identified above would still apply: Regulators would still have philosophical and technical problems making such cost-benefit tradeoffs. However, the third problem identified above would change. Providers and researchers would no longer have incentives to circumvent curbs on expensive technology. But they would also have no incentive to use excessively costly technologies to begin with, making the curb unnecessary. No, if regulatory technology assessment is justifiable at all, the case is strongest under an absolutist provide-any-beneficial-care regime. Conversely, if we cannot justify it even under such an absolutist regime, it seems plain that it would not be justifiable under a less than purely absolutist regime.

## II. PROFESSIONAL ABSOLUTISM AND MODERN MEDICINE: THE UNDERLYING DISEASE

The possible goals of any health care system can usefully be categorized into four levels. The first level is what I will call *medical effectiveness*, eliminating all harmful and unnecessary care. For purposes of this Article, care is harmful if it provides a lower benefit to the individual patient than other care options (including no care) and unnecessary if it provides no benefit improvement over less (or no) care. This level demands that the relative net benefits of care ( $B$ ) exceed zero.

The second level is what I will call *cost effectiveness*, reducing the cost of whatever care we do provide.<sup>15</sup> That is, given some program of treatment producing benefit  $B$ , the costs of care ( $C$ ) should be minimized. This would include, for example, substituting cheaper generic drugs for more expensive ones when they produce exactly the same health benefit. It would not include cost cuts that fail to maximize patient health. It thus does not conflict aspirationally with medical effectiveness. But it was not a traditional goal of medicine. And in practice, considering costs may distract what would otherwise be undivided attention on maximizing the health of patients.

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<sup>15</sup> Although current literature unfortunately sometimes uses the term "cost effectiveness" to refer to cost-benefit analysis, the above is the dominant usage in technology assessment. See Office of Technology Assessment, *supra* note 9, at 108.

The third level is *allocative effectiveness*, making sure that, out of any fixed budget for health care, we allocate it to the treatments and patients that generate the greatest health benefit. In other words, given some costs (preferably minimized), the benefits of care should be maximized. This involves morally controversial judgments about when health benefits to some persons should be denied to provide greater health benefits to other persons.<sup>16</sup> The need to make such tradeoffs at all indicates that the resources provided must have been insufficient to fulfill the goal of medical effectiveness. Thus, for purposes of long-term planning, the two goals conflict in the sense that achieving medical effectiveness moots questions of allocative effectiveness. But, in the short run, making triage-like allocative tradeoffs to cope with temporary shortfalls in resources has not been understood to pose a conflict as long as it is understood that the long-term solution is to add resources.<sup>17</sup>

The fourth level is *social effectiveness*, making sure that the benefits of any health care (preferably maximized) actually exceed the costs of that care (preferably minimized) given other possible social goods that could be obtained with those resources. This goal seems particularly attractive because equal expenditures on other social goods (like food, education, and shelter) can provide a greater *health* benefit than marginal expenditures on health care,<sup>18</sup> let alone greater benefits along other dimensions of life. But social effectiveness directly conflicts with medical effectiveness in both the long and short run because it requires the denial of health care with relative net positive health benefits if the costs are too great.

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<sup>16</sup> See generally Elhauge, *Allocating Health Care Morally*, supra note 4, at 1496-1526.

<sup>17</sup> Id. at 1494-95.

<sup>18</sup> Id. at 1460-61.



We can express these goals algebraically in Table 1.

Table 1

Medical Effectiveness	$B > 0$
Cost Effectiveness	$C(B) \rightarrow C_{min}$
Allocative Effectiveness	$B(C) \rightarrow B_{max}$
Social Effectiveness	$B_{max} > C_{min}$

This helps provide a framework to understand current changes in modern medicine. In a nutshell, my descriptive thesis is that, despite the outcry about enormous wrenching changes in medicine, all we have effectively done is move from having the sole goal of medical effectiveness to adding the goal of cost effectiveness as well. The goal of allocative effectiveness remains largely unpursued in the United States, though it is more seriously pursued in other nations. And, despite occasional limited endeavors at cost-benefit tradeoffs, no nation (and certainly not the United States) effectively pursues them in the systematic fashion that would be necessary to achieve social effectiveness. From a broad perspective, then, the change in goals has been limited. More important, it has been doomed to defeat because, without making cost-benefit tradeoffs, no nation can hope to end medical cost escalation. For the root cause of such escalation is the pursuit of medical effectiveness to achieve ever more marginal health benefits.

I begin, in Section II.A, with a somewhat stylized description of the traditional medical paradigm of professional self-regulation and full reimbursement—where the aim is to provide all beneficial care. To be sure, this has never been a completely accurate description of any health care system, but it will serve as a valuable heuristic device to emphasize tendencies. In particular, I describe this paradigm as pursuing an “absolutist” imperative of providing *any* care with  $B > 0$  even though I recog-

nize that all health care systems (at “the bedside” and elsewhere) manage to forgo some care with truly *de minimis* advantages. Such *de minimis* exceptions do not, however, alter the thrust of the system and should not distract us from the implications of that dominant thrust. The costs of pursuing ever more marginal health benefits above the *de minimis* line has more than sufficed to have the cost spiral implications I describe, especially since even *de minimis* limitations are not always insisted upon.

Section II.B then describes the modern paradigm of competition and capitation. I argue that, despite the introduction of such cost pressures, cost-minimization efforts in the United States are still legally subject to the constraint of providing all beneficial care. This constraint appears in too many different legal doctrines to dismiss as a mistake or to believe that one or two doctrinal changes could fix the problem. And its continued retention in even the boldest reform proposals belies any notion that it will soon lie behind us. In Section II.C, I discuss why we might have a regime that simultaneously imposes cost pressures and prohibits institutions from responding to them by making cost-benefit tradeoffs.

The proposition that modern medicine still does not countenance the denial of beneficial care runs so contrary to conventional wisdom that it may provoke resistance in the reader. The talk everywhere is about how cost pressures and organizational changes are forcing a revolution in traditional forms of medical practice. One might thus conclude that my description of the law must be overdrawn. Such a conclusion, however, mistakes direction for destination. That medical practice has had to begin considering costs more than ever before is a dramatic change. But it does not mean that cost considerations are legally permitted to change practice when it would adversely affect the health of patients.

In a similar vein, conventional wisdom might lead one to conclude that, even if my legal description is accurate, such laws must be so widely ignored as to make them inaccurate indicators of what actually happens. Examples abound in the newspapers (and common experience) of cases where beneficial care is denied to save costs. And of course the fact that something (here

denying beneficial care) is outlawed does not mean that people do not do it, especially when cost pressures give them incentives to do so. But neither does it mean that they make rational cost-benefit tradeoffs. It may merely mean they deny beneficial care when they think they can get away with it. The types of care whose denial is most likely to go unnoticed or unprotested need not bear any relation to the types of care that are least cost-justified. The illegality of medical cost-benefit tradeoffs can and does skew the provision of care even if it does not assure that all beneficial care is actually provided.<sup>19</sup>

In any event, the skeptical reader who comes to this Article believing such examples are widespread enough to overturn my general description of the health care system is invited to keep in mind some data about trends at a more macro level. Although cost pressures and HMO market share have grown since the 1970s, national health care expenditures have continued to escalate unabated, running roughly twice as great as the growth of the rest of the economy year after year into the 1990s.<sup>20</sup> The 1980s featured an explosion in managed care growth, and the early 1980s the introduction of fixed DRG (diagnosis-related group) payments by Medicare. Yet the real rate of increase in health care spending *rose* between the first and second half of the 1980s.<sup>21</sup> The rise in biomedical research was even greater: It increased 348 percent during the 1980s.<sup>22</sup> Nor have HMOs and fee-for-service insurers experienced any significant difference in the rate of growth of either their premiums<sup>23</sup> or their demand for physicians.<sup>24</sup> And HMOs and fee-for-service insurers have been

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<sup>19</sup> See *infra* Section II.C.

<sup>20</sup> See, e.g., Elhauge, *Medi-Choice*, *supra* note 4, at 24.

<sup>21</sup> See Garber, *supra* note 1, at 117-18.

<sup>22</sup> See Banta & Luce, *supra* note 14, at 18.

<sup>23</sup> See Cutler, *supra* note 2, at 22-23; Joseph P. Newhouse et al., *Are Fee-for-Service Costs Increasing Faster Than HMO Costs?*, 23 *Medical Care* 960, 962 (1985).

<sup>24</sup> See William B. Schwartz & Daniel N. Mendelson, *Eliminating Waste and Inefficiency Can Do Little to Contain Costs*, *Health Aff.*, Spring (I) 1994, at 224, 231 (observing that not only have HMOs' per capita demand for physicians matched the fee-for-service sector since the 1950s, the increase in physicians employed per enrollee has outstripped the increase in supply of physicians since 1984 at one of the most prominent staff-model HMOs).

shown to provide similar health outcomes.<sup>25</sup> Similarly, despite even more thorough cost containment efforts in other developed nations with quite different insurance arrangements and far more control over costs paid through national health care systems, the rate of growth in those other nations has been quite similar to that in the United States.<sup>26</sup>

This Article provides an explanation for this phenomenon: The root cause of the cost escalation is a refusal to trade off costs and benefits that remains largely unaltered. It is incumbent on those who believe new cost pressures, HMO expansions, bedside rationing and the like do (legally or practically) allow cost-benefit tradeoffs to be made to develop an alternative explanation for these macro trends.<sup>27</sup> And to explain as well more micro trends, like the increasing use of a clot-dissolver that costs seven to thirty times more than a competing product and whose one percent benefit over it was so small as to be statistically insignificant.<sup>28</sup>

#### A. *The Professional Paradigm*

The professional paradigm in its purest form requires that health care resources be allocated solely on medical grounds. If the care improves the health of the patient, it should be provided. Otherwise, it should not. Such an allocative policy might rest on claims about the immorality of denying beneficial health care.<sup>29</sup> It might also, or alternatively, rest on market defects in health care.

Unlike consumers in most other markets, patients lack sufficient knowledge to ascertain what service they want, how valu-

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<sup>25</sup> See Joseph P. Newhouse, *Free For All? Lessons From the RAND Health Insurance Experiment* 283 (1993).

<sup>26</sup> See Charles D. Baker, *Health Care in the United States (We Have Met the Enemy and He Is Us) 7-7A* (June 7, 1995) (unpublished manuscript) (on file with the Virginia Law Review Association); Cutler, *supra* note 2, at 23.

<sup>27</sup> Of course, to the extent cost-benefit tradeoffs are being made, the analysis in Part VIII would still mean that medical technology assessment has limited regulatory potential.

<sup>28</sup> See *infra* Part III.

<sup>29</sup> See Elhauge, *Allocating Health Care Morally*, *supra* note 4, at 1457-65 (discussing moral basis for absolutist claim and differences from traditional professionalism).

able it is, and whether they received a quality version of it. This makes patients dependent on the advice of their physicians, who have financial incentives to exploit them both by skimping on quality and by either ordering unnecessary or harmful care (if paid fee-for-service) or denying necessary care (if paid a fixed amount). To curb such incentives, professionalism seeks to replace ordinary profit-seeking market behavior with an objective scientific and professional norm.

Professional groups enforce such a norm in various ways. They screen out poor quality physicians through control over medical education, licensing boards, hospital staffs and accrediting bodies. They police harmful or unnecessary medical practices through the same bodies and by issuing ethical standards of medical practice. Traditional professional ethics also restricted advertising to prevent competitive-minded physicians from persuading ignorant consumers to purchase cut-rate or unnecessary medical treatments. And demands for professional autonomy protect against non-physician interference with medical decisions.

In the United States, the law historically not only left these means of self-regulation free from antitrust scrutiny, but also lent them the aid of legal enforcement. It gave physicians power over the necessary governmental boards, prohibited professional advertising, incorporated professional norms into malpractice standards, and required institutional structures that preserved professional autonomy.

Most important, professional groups seek to instill within each physician (particularly during medical school and residency) a commitment to put the health of his patients above any financial considerations. The Hippocratic Oath is the most famous manifestation of this commitment. Those conforming with this commitment will not only ignore their own financial interests but also order every health service that offers any positive net health benefit, no matter how small the benefit or how large the cost.<sup>30</sup> The most forthright physicians are explicit

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<sup>30</sup> See, e.g., Dan W. Brock, *Distribution of Health Care and Individual Liberty*, in *2 Securing Access to Health Care: The Ethical Implications of Differences in the Availability of Health Services*, 239, 255 (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research ed., 1983)

about this. As one physician put it: "A physician who changes his or her way of practicing medicine because of cost rather than purely medical considerations has indeed embarked on the 'slippery slope' of compromised ethics and waffled priorities."<sup>31</sup> As another insisted: "[T]he physician cannot serve two masters—his patient and society's coffers. . . . We [in the medical profession] should be prepared to argue for spending whatever is necessary for effective medical care."<sup>32</sup>

The professionalism paradigm is generally coupled with a preference for nonprofit hospitals.<sup>33</sup> For-profit hospitals, like non-professionals, are presumed likely to take advantage of market imperfections instead of correcting them. Although nonprofits can also make profits, they cannot distribute them to investors, and thus arguably have less financial incentive to abuse patient ignorance. Indeed, because they lack investors with a financial stake in exerting control, nonprofits are generally controlled by the physicians who comprise the hospital medical staff.<sup>34</sup> Thus, nonprofits should be expected not to interfere with professional norms.

Integral to the professional approach is an insurance regime that covers the financial cost of all beneficial care. Traditionally

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(observing that "an old and strong tradition" demands that "treatment recommendations are to be dictated solely by the patient's medical needs and not by financial considerations. The recommended treatment is then to be the alternative that provides the maximal sum of medical benefits minus medical risks, without regard to the financial costs of different or additional procedures."); Paul T. Menzel, *Strong Medicine: The Ethical Rationing of Health Care* 3 (1990) (noting that "health-care providers . . . cannot deny patients something they think would genuinely help."); Marcia Angell, *Cost Containment and the Physician*, 254 *JAMA* 1203, 1206 (1985) (observing that "[i]f very expensive care is indicated, then the physician should do his utmost to obtain it for the patient"); Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 *Am. Econ. Rev.* 941, 966 (1963) (maintaining that the "safest course" for the physician is to "give the . . . 'best' treatment of the day. Compromise in quality, even for the purpose of saving the patient money, is to risk an imputation of failure to live up to the social bond.").

<sup>31</sup> Erich H. Loewy, *Cost Should Not Be a Factor in Medical Care*, 302 *New Eng. J. Med.* 697 (1980).

<sup>32</sup> Angell, *supra* note 30, at 1206-07.

<sup>33</sup> See Arrow, *supra* note 30, at 950.

<sup>34</sup> Physicians normally cannot form a majority of the nonprofit's board of directors, but historically the other directors (lacking a financial stake) have generally deferred to the physicians' judgment. Robert C. Clark, *Does the Nonprofit Form Fit the Hospital Industry?*, 93 *Harv. L. Rev.* 1416, 1445 & n.80 (1980).

this took the form of fee-for-service reimbursement, where the price of any service deemed “medically necessary and appropriate” by a physician was covered by the insurer. Physicians and hospitals organized Blue Shield and Blue Cross around this principle and successfully lobbied to have Medicare and Medicaid based on the same approach when initially enacted.<sup>35</sup> The result was to remove any incentive the physician might have to skimp on the services provided and to eliminate any serious conflict between patient incentives and professional norms.

Indeed, professionalism and insurance have something of a symbiotic relationship. By covering medical expenses at the time of purchase, insurance makes professionals more attractive to consumers by lessening their apparent cost. More fundamentally, because insurance would produce massive incentives to overconsume even in a non-professional free market, it lessens any overconsumption effect flowing from professionalism. An insured consumer will wish to purchase health care even though its costs exceed its benefits, and will thus have less to fear from a professional allocation. Because insurance lessens the increase in overconsumption that can be attributed to professional control, the ability of professionalism to limit unnecessary or harmful care will, relatively, loom larger to the consumer and society.

For its part, by limiting consumption to medically beneficial care, professionalism may actually make the business of medical insurance more feasible for insurers. Medical insurance is an insurance against the costs of making a particular kind of purchase. This is a peculiar form of insurance. One cannot, for example, buy insurance against the costs of purchasing a car.<sup>36</sup> The

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<sup>35</sup> See Judith M. Feder, *Medicare: The Politics of Federal Hospital Insurance* 143-56 (1977); Paul Starr, *The Social Transformation of American Medicine* 295-98, 306-10 (1982) (describing how hospitals formed Blue Cross and physicians formed Blue Shield). Commercial insurers at that time also demonstrated little interest in imposing effective cost controls on medical providers. See Herman M. Somers & Anne R. Somers, *Doctors, Patients, and Health Insurance* 414-15 (1961). In addition to using parallel coverage standards, Medicare was and is largely administered by Blue Cross, Blue Shield, and commercial insurers. See Furrow et al., *supra* note 10, § 13-3, at 563.

<sup>36</sup> One can, on the other hand, purchase automobile and homeowner’s insurance to cover the cost of repairing injuries to one’s car or home from an insurable event. But such forms of casualty insurance differ from medical insurance for several reasons.

First, in medical care the diagnosis is often highly uncertain, the correct treatment

reason is because a car consumer can control his purchases. Professional physicians, in contrast, provide some cap on medical expenditures: By complying with their professional ethic, they certify that a given treatment is necessary in the sense that it does provide some positive health benefit. This at least protects insurers from paying for a host of dubious or harmful medical treatments.

Further, precisely because it does make physicians independent from insurers, professionalism helps insurers make a credible commitment to consumers to provide any health care with positive benefits. After all, it is in the insurers' financial interest to deny care even when the benefits exceed the costs. Without someone to make an independent determination that the insurer should provide reimbursement, consumers might well

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a matter of debate, and no treatment may work for certain. See Alain C. Enthoven, *Health Plan 1-12* (1980). In contrast, if you smash a fender, the problem is plain and the right repair is obvious and will fix the problem. This makes health care expenditures for any particular illness far more open-ended.

Second, the casualty insurer need make only one payment for each insurable event, like an accident or fire. There is no similar limit in medical insurance. If the patient who gets ill remains uncured by an initial round of treatment, she is entitled to additional medical care even if the insurance already paid for the first round. And this is unfortunately inevitable because the reality of our mortality means we cannot permanently save a life or cure poor health; we can only put off death and illness until a future point when new diseases may be even more expensive to treat. See Elhauge, *Allocating Health Care Morally*, *supra* note 4, at 1460. Nor need medical insurance be activated by any insurable event like a new illness: Medical treatments to improve a continuing health problem are also generally covered. It is thus much more like automobile or homeowner's insurance that covered any improvement one could make in one's transportation or housing: With that sort of insurance we would all buy expensive cars and homes.

Third, the automobile or homeowner's insurer normally fixes the sum paid based on the insurer's appraisal of the monetary cost of the damage, with a ceiling at the value of the automobile or home. In contrast, medical insurance does not appraise the damage from a medical illness and pay a fixed sum for the patient to procure treatment. Nor is the amount of payment capped by an appraisal of the value of a human life or of curing the illness. In part this is no doubt because there is no way for an insurer to attach a monetary value to life or health. Even if he could, the cost of compensating all injuries to life or health—even when they were untreatable—would be prohibitive. In addition, giving fixed monetary payments to those suffering a medical condition would result in administrative and incentive problems, including creating incentives to exaggerate illnesses, become sick or forgo treatments, and undermining incentives to be productive. See *id.* at 1487-90. To eliminate these problems, insurers traditionally have instead insured not for the disvalue of the medical problem but for the costs of all medical care professionals would provide.



doubt that insurers would actually pay for beneficial care. Professional independence may therefore help to make medical insurance more attractive to consumers.

Many of the anticompetitive aspects of professional regulation also seem to benefit insurers. Restrictions on advertising, for example, help curb what would otherwise be an almost limitless expansion of insurance payouts.<sup>37</sup> Limits on the number of physicians allowed to practice do the same.<sup>38</sup> And restrictions on commercial or for-profit practice discourages entrepreneurs from fully exploiting the opportunities of open-ended funding. In turn, the existence of open-ended funding lessens the undesirability of these curbs on advertising, entry and for-profit practice.

Finally, professionalism makes insurance more financially attractive. To the extent that the professional paradigm already determines which medical services are purchased (because professionals make purchase decisions on patients' behalf), insurance imposes no new moral hazard costs. Without insurance, the professional would still have the consumer purchase any health care that has positive health benefits. Insurance will not produce any further incentive to overconsume because even fully informed consumers have no desire to purchase health care without positive benefits. In reality, of course, a professional treating an uninsured patient will face the budgetary limit imposed by the patient's wealth. But patients' general tendency to overconsume because of their reliance on professional judgment will mean that insurance will involve less additional moral hazard costs and thus seem relatively more attractive.

Of course, in combination, professionalism and insurance cannot escape the blame for the overconsumption that results from supplying all beneficial care without regard to its cost.<sup>39</sup>

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<sup>37</sup> Because health care that could improve health marginally is almost limitless, advertising the availability of such care in an insured environment would produce an almost limitless expansion in demand and thus insurance payouts.

<sup>38</sup> If physicians were not limited in number, one would expect more and more to enter the market to provide any unmet beneficial care covered by insurers.

<sup>39</sup> One might object that two causes of overconsumption cannot limit each other. But my point is simply that if, for independent reasons, insurance is in place and produces 90% of the possible overconsumption, then adding professionalism can only add the final 10%. Likewise, if, for independent reasons, professionalism is in place

But in combination they also have combined benefits: the financial protection provided by insurance and the limits on unnecessary and harmful care provided by professionalism. Moreover, if one accepts the underlying theory of professionalism, overconsumption would exist even in a competitive non-professional uninsured system because non-professional physicians could use their informational advantage over consumers to order costly, but mildly beneficial services. To that extent, neither professionalism nor insurance is to blame for the overconsumption; it results because no person has the knowledge and incentives to make the necessary cost-benefit tradeoffs.

When is such a system of professional resource allocation likely to be desirable? When the amount of harmful and unnecessary care eliminated is high, and the amount of small marginal benefit care added is low. The former turns in part on the extent to which physicians have sufficiently internalized the professional ethic to rise above their self-interest.<sup>40</sup> If the actual financial incentives faced by physicians subvert this ethic, professionalism will have little benefit.

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and produces 90% of the possible overconsumption, then adding insurance can only add the final 10%. Both exacerbate the overconsumption effect of the other. But it remains true that the overconsumption cost that can be blamed on either is drastically lessened if we take the other as a given.

<sup>40</sup> Much relatively recent evidence has tended to undermine any internalization argument. See, e.g., Bruce J. Hillman et al., *Frequency and Costs of Diagnostic Imaging in Office Practice—A Comparison of Self-Referring and Radiologist-Referring Physicians*, 323 *New Eng. J. Med.* 1604, 1606, 1608 (1990) (finding that physicians with a financial interest in the imaging equipment ordered diagnostic imaging four times more frequently than those physicians who referred patients to radiologists, and that for those physicians not referring, the charges associated with imaging were often higher); Office of Technology Assessment, *supra* note 9, at 179 (citing studies demonstrating that economic incentives alter physician practice).

Notwithstanding assertions at the conference, nothing to the contrary was shown by the famous RAND study that randomly assigned patients to fee-for-service and capitated systems. The study found that health outcomes were the same in both systems, but not that the care provided was the same. Rather, the outcomes were the same even though physicians in the fee-for-service system provided 50% more care because half of the additional care was harmful and half beneficial, with the two effects on health outcomes canceling each other out. See *id.*; Newhouse, *supra* note 25. Far from suggesting that financial incentives do not matter, the study suggested that fee-for-service incentives not only induced physicians to order more care but to do so even when it proved harmful to their patients. In any event, my only point in the text is that the attraction of professionalism turns on the “extent to which” professionals overcome their financial interests.

Even if the ethic succeeds in overcoming financial interest, professionalism cannot provide a useful means of limiting unnecessary and harmful care unless there is some scientifically objective means of determining which forms of health care have positive health benefits. The existence of such scientific objectivity is thus crucial to the professional paradigm. However, claims to such objectivity have been undermined by studies showing that in fact medical practice varies widely among physicians and regions,<sup>41</sup> often turns out to be ineffective,<sup>42</sup> and usu-

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<sup>41</sup> See, e.g., Banta & Luce, *supra* note 14, at 47-48; Mark R. Chassin et al., Variations in the Use of Medical and Surgical Services by the Medicare Population, 314 *New Eng. J. Med.* 285, 286-87 (1986); Office of Technology Assessment, *supra* note 9, at 1, 26-28 (noting that "different regions supply very different amounts of medical care, with very different costs, despite apparently similar levels of underlying need"); John E. Wennberg et al., An Assessment of Prostatectomy for Benign Urinary Tract Obstruction: Geographic Variations and the Evaluation of Medical Care Outcomes, 259 *JAMA* 3027 (1988); John E. Wennberg, Dealing with Medical Practice Variations: A Proposal for Action, *Health Aff.*, Summer 1994, at 6, 7-8; John E. Wennberg et al., Hospital Use and Mortality Among Medicare Beneficiaries in Boston and New Haven, 321 *New Eng. J. Med.* 1168 (1989).

<sup>42</sup> See, e.g., Wallace V. Epstein et al., Effect of Parenterally Administered Gold Therapy on the Course of Adult Rheumatoid Arthritis, 114 *Annals Internal Med.* 437, 437-38 (1991) (questioning whether a medical procedure in use for 50 years had significant clinical value); Office of Technology Assessment, *supra* note 9, at 1 (noting that "evidence has been slowly accumulating that suggests that even well-accepted and very common technologies, such as routine chest x-rays, can be ineffective, [and] that a substantial number of medical and surgical procedures are performed for inappropriate reasons"); *id.* at 28-33 (one literature review suggested that "as much as one-fifth to one-quarter of acute hospital services or procedures were felt to be used for equivocal or inappropriate reasons, and two-fifths to one-half of the medications studied were overused in outpatients") (quoting Robert Brook et al., Appropriateness of Acute Medical Care for the Elderly, 14 *Health Pol'y* 225 (1990)); Robert Brook et al., Predicting the Appropriate Use of Carotid Endarterectomy, Upper Gastrointestinal Endoscopy, and Coronary Angiography, 323 *New Eng. J. Med.* 1173, 1173 (1990) (finding that 9% of coronary angiographies performed had no net health benefit and an additional 17% were actually harmful; 11% of endoscopies were not beneficial and another 17% were harmful; and 32% of endarterectomies were unbeneficial and another 32% were harmful); Rolla E. Park et al., Physician Ratings of Appropriate Indications for Three Procedures, 79 *Am. J. Pub. Health* 445, 446-47 & tbl. 3 (1989) (for three specified medical procedures, between 10.5% and 28.5% of those performed were found to be "clearly inappropriate"); see also *infra* note 259 and accompanying text (collecting sources showing widespread medical use of practices later found to be affirmatively harmful, such as universal electronic fetal monitoring, routine episiotomies, radial keratotomy, and DES (diethylstilbestrol) prescriptions).

ally lacks rigorous scientific proof that it works.<sup>43</sup>

The affirmative appeal of professionalism also depends upon the extent to which unnecessary or harmful care would occur in a non-professional system. In preferring professionalism, one must presume that imposing legal standards of conduct and quality on profit-driven physicians or hospitals would to some extent be ineffective. Otherwise, such legal standards could eradicate the problem of unnecessary and harmful care without the need for professionalism. But legal standards fall prey to an inevitable problem: Because the information reaching tribunals is imperfect, no legal regime can perfectly detect and punish undesirable conduct.<sup>44</sup> What gives professionalism its special claim to improving upon legal standards is that self-policing by fellow professionals, coupled with internal monitoring provided by professional ethics, offers the promise of detecting and restraining undesirable medical conduct more successfully than legal standards alone could. More precisely, to be socially desirable, professional ethos and self-regulation must not only be more effective at curbing undesirable medical conduct than the combination of legal standards, market discipline, and the morality of non-professionals, but more effective by a sufficient margin to offset professionalism's allocative inefficiency.

The extent of that allocative inefficiency depends largely on how much care there is that has positive, but marginal, health benefits. If there is little marginally beneficial health care—if most health care falls clearly into the categories of either enor-

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<sup>43</sup> See, e.g., David M. Eddy & John Billings, *The Quality of Medical Evidence*, *Health Aff.*, Spring 1988, at 19, 20 (noting that for some important practices the evidence is so poor that "it is virtually impossible to determine even what effect the practice has on patients, much less whether that effect is preferable to the outcomes that would have occurred with other options"); Institute of Medicine, *Assessing Medical Technologies* 5 (1985) (commenting on the lack of scientific foundation for various aspects of medical practice); Office of Technology Assessment, *supra* note 9, at 21 (noting that a "long-standing estimate" that only 10-20% of medical procedures have ever been formally evaluated for safety and efficacy remains a rule of thumb); The Pepper Comm'n, *U.S. Bipartisan Comm'n on Comprehensive Health Care, A Call for Action: Final Report*, S. Prt. 101-114, at 41 (1990) (only 10 to 20% of medical practices are supported by randomized controlled trials).

<sup>44</sup> See Stephen McG. Bundy & Einer Elhauge, *Knowledge About Legal Sanctions*, 92 *Mich. L. Rev.* 261, 267-79 (1993); Einer Elhauge, *The Triggering Function of Sale of Control Doctrine*, 59 *U. Chi. L. Rev.* 1465, 1494-97 (1992).

mously beneficial or harmful/unnecessary—then there is little reason to worry about the allocative inefficiency of professionally determined outputs. On the other hand, if many medical treatments fall within a marginal “gray area” of care that has health benefits that are small relative to costs, then professional allocation decisions will result in far too many resources being devoted to health care.

When the professional paradigm first became well-established and dominant, the costs of avoidable harmful and unnecessary care were higher, and the costs of additional small marginal benefit care lower.<sup>45</sup> In this time of relatively black or white choices, professionalism was at its height of desirability.<sup>46</sup> But

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<sup>45</sup> As late as 1927, 60% of medical remedies were harmful or ineffective. See Banta & Luce, *supra* note 14, at 15. This put a premium on entrusting care to a profession willing to critically examine medical practice and screen out nonbeneficial care, which the profession in fact did. See *id.*

<sup>46</sup> Much of the critique at the Conference seemed to consist of a defense of professionalism. I do not deny professionalism has attractions, and indeed the beginning part of this Section endeavors to articulate more concretely what those attractions are. Pure professionalism may even remain more attractive than the mishmash of absolutism and cost pressures we now employ. See *infra* Section II.C. And yet, no one seems to deny that professionalism has eroded. The question we need to answer is why it eroded, and was allowed by the political system to erode, if it remained so much more attractive than the alternative.

This question seems especially hard to answer if one believes the proposition advanced at the conference by commentators that my account is flawed because professionalism did include the making of cost/benefit tradeoffs (at least for the uninsured) and rationing at the bedside. See generally Mark A. Hall, *Rationing Health Care at the Bedside*, 69 *N.Y.U. L. Rev.* 693 (1994) (arguing that ethical rules against physician rationing should be lifted). If it was so successful at this, why has society found it necessary to impose additional cost pressures? It seems to me that the reason is that the above proposition was only true, if at all, at the margins. Professionalism has never made cost-benefit tradeoffs to any significant extent nor embodied any coherent norm for making them either systematically or at the bedside. It would be unwise to base policy on the odd exceptions rather than on the main tendency, which is that professionalism has rejected and continues to reject such bedside rationing. See, e.g., Daniel P. Sulmasy, *Physicians, Cost Control, and Ethics*, 116 *Annals Internal Med.* 920, 920 (1992).

In any event, quarrels with my account of professionalism ultimately do not matter to this Article's bottom-line thesis about technology assessment. Whether or not professionalism makes cost-benefit tradeoffs or remains attractive for other reasons, and whether or not we return to it, my thesis remains unaffected. Regulatory technology assessment would still have limited regulatory potential because my arguments for reaching that conclusion apply whether our system adheres to absolutism, tempers it with cost-effectiveness, or allows cost-benefit

the technological revolution has blurred the distinction by dramatically increasing the cost of low-marginal-benefit care. It has produced a host of new treatments, tests, drugs, equipment and devices that are costly but, compared to alternative medical services, do produce a net positive medical benefit. Perhaps by using new technologies, a diagnosis that was once 97 percent certain at a cost of \$100 can now be made 99 percent certain, but at a cost of \$1,000; a drug that had been 80 percent effective at a cost of \$6 is now 82 percent effective, but at a cost of \$60. As a result, there is now a lot more care available with a high cost relative to its benefit. Because professionalism is generally committed to purchasing any care that has net positive health benefits, no matter what the cost, this dramatically increases the social costs of professionally determined resource allocations. And that makes professionalism less socially attractive.

But technology does not simply fall from the sky. It is created and adopted by humans operating under incentives structured by the system in which they live. A system dedicated to purchasing any marginally beneficial health care provides every incentive to create more and more marginally beneficial but costly practices, drugs, tests and technology. Eventually, the cost of this marginal care was bound to overwhelm its benefits. And any net social benefit of a system that avoided harmful care by committing to the purchase of any marginally beneficial care was bound to be eroded and perhaps reversed. However appropriate it might have been at one time, it was *inevitable* that professionalism would eventually lead to its own demise.

After all, most experts believe that we could spend one hundred percent of our gross national product ("GNP") on health care without running out of marginally beneficial care,<sup>47</sup> and no one thinks we should starve ourselves to death to provide health care. Nor do I think that this conclusion depends on the special nature of medical innovations. If our policy were to reimburse individuals for any expenditure on stereo equipment that produced marginally better sound, I expect we could eventually also spend one hundred percent of our GNP on stereo equip-

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tradeoffs.

<sup>47</sup>See Elhauge, *Allocating Health Care Morally*, *supra* note 4, at 1459 n.15 (collecting sources).

ment. No policy of funding all conceivable marginal improvements in any area can be sustained in the long run.

It is the underlying incentive structure, which encourages the production of technology with marginal benefits regardless of costs, that explains the dread with which medical policymakers treat technological innovation.<sup>48</sup> Contrast this to other industries, such as computer manufacturing, where technological innovation is welcomed and often produces enormous cost savings. In medicine, however, there is hardly any incentive to produce innovations that lower costs. Unless the innovations actually produce greater health benefits, professionals will not use them in place of more costly, but more medically effective, practices.<sup>49</sup> But innovations that can offer greater health benefits, regardless of their increased costs, will be readily adopted. No wonder that medical policymakers fear the innovation likely to result—and put the blame on it. But the true culprit is not the innovation itself, but the incentive structure that dictates the use of any new technology with a slightly higher health benefit than the old technology.

### *B. The Not-So-Brave New World of Modern Medicine*

Conventional wisdom says that traditional professionalism is

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<sup>48</sup> See, e.g., Garber, *supra* note 1, at 116-17.

<sup>49</sup> Innovations that produce the same health benefit at lower cost might seem marketable even under this traditional paradigm. But the set of innovations that fall into this category, while important standing alone, are small in relation to all innovations and expenditures. There is almost always some difference in health benefit along some dimension, such as fewer side-effects. Moreover, in practice there was little incentive to adopt such innovations under the traditional paradigm. Even if some new technology did confer the same benefit, the greater certainty of the established technology makes it less risky to use, and thus preferable. And professional norms reflect routinized methods and habits that should not be disrupted unless some gain can be achieved. Professional practice thus appropriately embodies some inertia against change. In addition, considering costs at all distracts somewhat from a single-minded focus on the health of the patient—some part of training and memory devoted to purely medical issues would have to be devoted to knowing relative costs. In any event, in an environment where medical expenditures were fully reimbursed, there was little or no affirmative incentive for physicians or patients to experiment with new treatments offering the same benefit at less cost. In the modern regime, where cost pressures create incentives to cut costs if medical effectiveness is not compromised, there is far more incentive to pursue such innovation. But it has barely slowed down our cost explosion. See *infra* Section II.C.

dead and gone. In the United States, traditional insurance and doctor-patient relationships are being supplanted by HMOs and other intermediaries that combine the insurance and medical provision functions. Such intermediaries receive a fixed annual payment to treat an enrollee and thus have incentives to minimize costs. Medicaid and Medicare are increasingly shifting beneficiaries to HMOs. Non-HMO insurers have had to change in order to compete. Nonprofit hospitals face increasing cost-pressures due to insurer demands for discounts and practice changes, increased competition from for-profit hospitals and outpatient centers, and the sort of fixed payments (e.g., DRGs) now used by Medicare and many other insurers to cover all hospital services associated with a given diagnosis and treatment. Antitrust scrutiny now applies to medical markets and mandates competitive behavior.<sup>50</sup> And regulatory shackles such as prohibitions on advertising and the corporate practice of medicine are increasingly being lifted.

The forecast calls for more of the same. HMO and for-profit market share continues to increase, as do discounting and efforts to give providers incentives to be more cost-conscious. The Clinton Health Plan tried to encourage more competition among private insurers and greater use of HMOs and to impose a global cap on health care expenditures.<sup>51</sup> The Gingrich Medicare Plan tried to do much the same for Medicare coverage.<sup>52</sup> The rest of the world appears to be moving to the same destination. Britain, Sweden, Germany and Canada are all trying to introduce more market pressures and firmer budgetary limits on health care spending.<sup>53</sup>

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<sup>50</sup> Medical markets enjoyed a de facto immunity for the first 85 years of the Sherman Act because professional services were generally understood not to affect interstate commerce. This changed in 1975. See *Goldfarb v. Virginia State Bar*, 421 U.S. 773, 783-93 (1975); *Hospital Bldg. Co. v. Trustees of Rex Hosp.*, 425 U.S. 738 (1976); Clark C. Havighurst, *Health Care Law and Policy* 309-10 (1988). Today, the interstate commerce requirement in health care cases is trivial to meet. See *Summit Health v. Pinhas*, 111 S. Ct. 1842 (1991) (holding interstate commerce requirement satisfied where the defendants allegedly conspired to deny staff privileges in a Los Angeles hospital to a single surgeon).

<sup>51</sup> Proposed Health Security Act, H.R. 3600/S. 1757, 103d Cong., 1st Sess. (1993) [hereinafter Clinton Health Plan].

<sup>52</sup> See Elhauge, *Medi-Choice*, *supra* note 4, at 26-27.

<sup>53</sup> See Her Majesty's Stationery Office, *Working for Patients* 4-9, 48-53 (1989);



This is certainly an important and profound shift. But it does not represent a move to a system designed to encourage the market to make cost-benefit tradeoffs. To the contrary, this Section shows that the current United States regime systematically intervenes to prevent any such tradeoffs from being made and insists on the absolutist imperative that characterized the old regime.<sup>54</sup> The demand for absolutism does not appear only in a few isolated doctrines, or wayward decisions, that can easily be corrected. It is too pervasive, and too imbedded in even the most radical reform proposals, to conclude that it reflects anything other than deliberate national policy. We encourage market participants to minimize costs but simultaneously subject them to the constraint that they not do so by denying any beneficial care. To see how, it is necessary to detail the current legal framework structuring the incentives of each participant in the health care system.

Even under the current regime of cost pressures, HMOs and other insurers do not write insurance contracts that would allow them to make cost-benefit tradeoffs. They write contracts to provide all “medically necessary and appropriate care” within the covered categories of medical services, a term generally understood to mean all beneficial care.<sup>55</sup> Conceivably, pure market factors might dictate this result. Insurers, like everyone else,

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Göran Berleen et al., *The Reform of Health Care in Sweden: National Report to OECD 29-31* (1992); OECD, *The Reform of Health Care: A Comparative Analysis of Seven OECD Countries*, at chs. 1, 10 (1992); Laurene Graig, *Health of Nations*, at chs. 3,4,7 (2d ed. 1993).

<sup>54</sup> I believe one could tell a similar story in other developed nations, which have experienced similar rates of cost-escalation. See *supra* note 26 and accompanying text. Although these nations evidence more explicit discussions by regulators and administrators about making cost-benefit tradeoffs, and some notable examples of doing so, at a macro level each nation remains largely wedded to the near-absolutist imperative that produces the underlying cost escalation problem. However, demonstrating this proposition for each nation is beyond the scope of this Article.

<sup>55</sup> See Hall & Anderson, *supra* note 10, at 1646 n.27 (indicating that courts define “medical necessity” to exclude only care that is “harmful, of no benefit, or nonstandard”). In *Sarchett v. Blue Shield*, 729 P.2d 267, 270-71 (Cal. 1987), the court defined “medically necessary” as any services the insured’s physician reasonably intended for the treatment of illness or injury even though the insurance contract nowhere made the physician the arbiter of this question. As long as the physician had the subjective intent of conferring a health benefit, and it was reasonable for him to think the treatment conferred a health benefit, this standard is satisfied. The reasonableness of the cost does not enter into the picture.

lack intelligible criteria for determining when the monetary costs of care exceed its health benefits.<sup>56</sup> Worse, insurers have a financial incentive to deny care even when the benefits exceed the costs. Consumers would thus discount the value of policies from insurers who promise to weigh benefits against costs before covering medical expenses.

Nor does it seem possible for insurance contracts to specify fully all treatments that would fail a cost-benefit test.<sup>57</sup> Even if full specification were possible, no consumer would have either the time or expertise to read and understand the contract, let alone to decide whether they agree with the insurer's cost-benefit assessments for every treatment for every illness or injury they might suffer. Uniform specifications would also fail to adjust for the individual variations in valuation, priorities, risk-aversion, and health conditions that affect the level of health benefits for different treatments, as well as for variations in regional and provider costs that affect the tradeoff.<sup>58</sup> And any specifications would quickly become out-of-date with changes in costs, demand, information, medical innovation and individual circumstances.<sup>59</sup> Further, any categorical exclusion will likely sweep in some cases where, because of particular circumstances, the benefits do exceed the costs. Given these difficulties, the most efficient market solution under certain circumstances might be to provide insurance that covers all beneficial medical care.

But we have never had a true market test of this proposition because courts effectively do not permit medical insurers to use cost-benefit analysis to make coverage decisions.<sup>60</sup> For example, as a matter of state insurance law, courts have held that an in-

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<sup>56</sup> See *infra* Part V.

<sup>57</sup> See *infra* Parts IV, VI (discussing the technical problems such an effort would face).

<sup>58</sup> See *id.* (discussing this problem as it affects regulatory technology assessment).

<sup>59</sup> *Id.*

<sup>60</sup> See generally Lee N. Newcomer, *Technology Assessment, Benefit Coverage and the Courts in Adopting New Medical Technology* 117 (Annetine C. Gelijns and Holly V. Dawkins eds., ch.10) (1994) (demonstrating tendency of courts to require insurers to cover new technologies); Annotation, *What Services, Equipment, or Supplies Are "Medically Necessary" for Purposes of Coverage under Medical Insurance*, 75 A.L.R. 4th 763 (1990) (collecting legal authorities).

insurance contract cannot define "medically necessary" to exclude beneficial care normally provided by medical providers.<sup>61</sup> Courts have also refused to enforce contract provisions giving insurers the power to decide what procedures are "medically necessary."<sup>62</sup> Instead, such determinations must be made according to medical standards by either the treating physician,<sup>63</sup> an "impartial" peer review committee composed of physicians,<sup>64</sup> or the court upon hearing medical testimony.<sup>65</sup>

Those employers who self-insure can avoid these state insurance rulings and be regulated by somewhat laxer ERISA standards.<sup>66</sup> But unless the self-insurance contract quite explicitly gives a presumption of correctness to the plan administrator's interpretation over the precise matter in issue, ERISA also pro-

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<sup>61</sup> See *Hughes v. Blue Cross*, 263 Cal. Rptr. 850, 857 (Ct. App. 1989) (invalidating "a standard of medical necessity significantly at variance with the medical standards of the community" because such a standard defeats reasonable insured expectations and conflicts with the liberal construction of insurance contract required by insurer's duty of good faith).

<sup>62</sup> See *Ex parte Blue Cross-Blue Shield*, 401 So. 2d 783, 784-86 (Ala. 1981) (finding that the insurer's denial of coverage could be found incorrect and legally invalid even though the insurance contract provided that "medical necessity" was to be determined in the judgment of insurer); *Lopez v. Blue Cross*, 397 So. 2d 1343, 1345 (La. 1981) (finding unreasonable a provision allowing medical necessity to be decided "in the judgment of the Carrier" and awarding plaintiff a double penalty for wrongful denial as provided for by statute).

<sup>63</sup> See, e.g., *Taylor v. Prudential Ins. Co.*, 775 F.2d 1457, 1459 (11th Cir. 1985) (finding that plaintiff approached a "frivolous" argument in asserting that medical experts who examined records after the fact could more accurately assess "medical necessity" than could treating physician, and that to rely on Medicare's judgment as to "medical necessity" was similarly inappropriate because Medicare was "a financially interested party"); *Van Vactor v. Blue Cross Ass'n*, 365 N.E.2d 638, 643 (Ill. App. Ct. 1977) (determination of "medical necessity" up to insured's physician); *Schroeder v. Blue Cross and Blue Shield*, 450 N.W.2d 470 (Wis. Ct. App. 1989) (same); see also *Little v. Blue Cross*, 424 N.Y.S.2d 553, 555-56 (N.Y. App. Div. 1980) (interpreting insurance contract to leave decision about need for services up to insured's physician and unreviewable by the insurer).

<sup>64</sup> See, e.g., *Sarchett v. Blue Shield*, 729 P.2d 267, 274 n.13 (Cal. 1987) (determination of medical necessity need not be made by insured's physician when contract leaves it to impartial medical peer review committee).

<sup>65</sup> See, e.g., *Lockshin v. Blue Cross*, 434 N.E.2d 754, 756-57 (Ohio Ct. App. 1980) (court must make determination, on which judgment of insured's physician is probative but not dispositive); *Siegal v. Health Care Serv. Corp.*, 401 N.E.2d 1037, 1042-43 (Ill. App. Ct. 1980) (medical necessity matter to be decided by jury).

<sup>66</sup> See *Furrow et al.*, *supra* note 10, at 500.

vides for de novo judicial review.<sup>67</sup> Even when the self-insurance contract explicitly vests final interpretation authority in the plan administrator, ERISA courts still find those interpretations subject to judicial review under the arbitrary and capricious standard.<sup>68</sup> And using a plan administrator who is also an insurer (for the employer or others) has been deemed to create a conflict of interest that might itself provide grounds to hold the administrator's interpretation arbitrary and capricious.<sup>69</sup> In any event, under both the de novo and arbitrary and capricious standards, ERISA courts have not hesitated to often overturn denials of care,<sup>70</sup> suggesting that the formal standard of review matters less than the continuing dominance of the professional paradigm. Indeed, one prominent study concluded that the result of the Supreme Court's decision in *Firestone*, announcing

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<sup>67</sup> See *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989); *Pirozzi v. Blue Cross-Blue Shield*, 741 F. Supp. 586, 589 (E.D. Va. 1990) (provision that vested authority in plan administrator to decide what was "medically necessary" was insufficient to avoid de novo review because the plan did not also give administrator authority to decide whether a procedure was "experimental"); *Guisti v. General Elec. Co.*, 733 F. Supp. 141, 146-48 (N.D.N.Y. 1990) (provision giving plan administrator authority to "make all determinations with respect to benefits under this Plan" insufficient to avoid de novo review because it did not expressly state that the administrator had discretion to interpret the terms of the plan or that eligibility determinations made by the administrator were to be given deference). See also *Furrow et al.*, supra note 10, at 523 (noting that "[g]eneral grants of power to administer the plan are probably not enough" to avoid de novo review).

<sup>68</sup> See *Firestone*, 489 U.S. at 115.

<sup>69</sup> See *id.*; *Heasley v. Belden & Blake Corp.*, 2 F.3d 1249, 1260 n.12 (3d Cir. 1993); *Egert v. Connecticut Gen. Life Ins. Co.*, 900 F.2d 1032, 1035 (7th Cir. 1990); *Reilly v. Blue Cross & Blue Shield United*, 846 F.2d 416, 423 (7th Cir. 1988); see also *Doe v. Group Hospitalization & Medical Servs.*, 3 F.3d 80, 85-87 (4th Cir. 1993) (lowering deference); *Furrow et al.*, supra note 10, at 523 & n.37 (collecting cases holding same).

<sup>70</sup> For ERISA cases finding a plan administrator's interpretation denying health benefits arbitrary and capricious, see *Egert*, 900 F.2d at 1038; *Kunin v. Benefit Trust Life Ins. Co.*, 910 F.2d 534, 537-38 (9th Cir. 1990); *White v. Caterpillar, Inc.*, 765 F. Supp. 1418 (W.D. Mo. 1991); see also *DiDomenico v. Employers Coop. Indus. Trust*, 676 F. Supp. 903, 908-09 (N.D. Ind. 1987) (preliminarily enjoining under arbitrary and capricious standard). For ERISA cases invalidating a plan administrator's interpretation under the de novo standard, see *Adams v. Blue Cross/Blue Shield*, 757 F. Supp. 661 (D. Md. 1991); *Pirozzi*, 741 F. Supp. at 588, 594-95; *Stringfield v. Prudential Ins. Co.*, 732 F. Supp. 69, 71-72 (E.D. Tenn. 1989) (denying summary judgment under de novo standard). For an ERISA case rejecting a denial of benefits under a standard between the de novo and arbitrary and capricious standards, see *Doe*, 3 F.3d at 86-89.

the supposedly lax arbitrary and capricious standard of review, was “that almost every ERISA welfare benefit case has since been decided in favor of the participant who has been denied coverage.”<sup>71</sup>

Moreover, courts read any contractual ambiguity against the insurer. This has always been true as a matter of state insurance law.<sup>72</sup> And in this decade it has been established to be true under ERISA as well.<sup>73</sup> This means that any general cost-benefit standard would be interpreted against the insurer, effectively dictating coverage of all beneficial care. Indeed, ERISA courts have held that, “even if an administrator has discretion to construe the terms of a plan, the administrator can abuse its discre-

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<sup>71</sup> See Advisory Council on Social Security, *The Influence of Current Judicial Doctrines on the Cost of Purchasing Health Care* 21-23 (1991).

<sup>72</sup> See, e.g., *Kunin*, 910 F.2d at 538-39 & nn.5-6 (collecting sources); *Sarchett*, 729 P.2d at 273; *Hughes v. Blue Cross*, 263 Cal. Rptr. 850, 857 (Ct. App. 1990); *Little v. Blue Cross*, 424 N.Y.S.2d 553, 556 (N.Y. App. Div. 1980). See generally *Furrow et al.*, supra note 10, § 11-2(a), at 502-03 (noting that “[insurance contracts] are generally construed by the courts against the insurer to protect the reasonable expectations of the insured”).

<sup>73</sup> See *Masella v. Blue Cross & Blue Shield*, 936 F.2d 98, 107 (2d Cir. 1991); *Heasley v. Belden & Blake Corp.*, 2 F.3d 1249, 1257-58 (3d Cir. 1993); *Doe v. Group Hospitalization & Medical Servs.*, 3 F.3d 80, 89 (4th Cir. 1993); *Glocker v. W.R. Grace & Co.*, 974 F.2d 540, 544 (4th Cir. 1992); *Todd v. AIG Life Ins. Co.*, 47 F.3d 1448, 1451-52 (5th Cir. 1995); *Brewer v. Protexall, Inc.*, 50 F.3d 453, 457 & n.8 (7th Cir. 1995); *McNeilly v. Bankers United Life Assurance Co.*, 999 F.2d 1199, 1201 (7th Cir. 1993); *Phillips v. Lincoln Nat'l Life Ins. Co.*, 978 F.2d 302, 311-12 (7th Cir. 1992); *Delk v. Durham Life Ins. Co.*, 959 F.2d 104, 105 (8th Cir. 1992); *McClure v. Life Ins. Co.*, 84 F.3d 1129, 1134 (9th Cir. 1996); *Peterson v. American Life & Health Ins. Co.*, 48 F.3d 404, 411 (9th Cir. 1995); *Kunin v. Benefit Trust Life Ins. Co.*, 910 F.2d 534, 539-41 (9th Cir. 1990); *Lee v. Blue Cross/Blue Shield*, 10 F.3d 1547, 1551 (11th Cir. 1994). See also *Allen v. Adage, Inc.*, 967 F.2d 695, 701 n.6 (1st Cir. 1992) (recognizing rule of construction in insurance cases but declining to extend it to noninsurance ERISA case); *Blair v. Metropolitan Life Ins. Co.*, 974 F.2d 1219, 1222 (10th Cir. 1992) (not deciding whether the rule about construing insurance contracts against insurer applied in ERISA cases but reaching same conclusion that ambiguities should be resolved in insured's favor under basic trust law principles); *Germany v. Operating Eng'rs Trust Fund*, 789 F. Supp. 1165, 1169 (D.D.C. 1992) (applying rule in D.C. district court); *McConocha v. Blue Cross & Blue Shield*, 898 F. Supp. 545, 549 (N.D. Ohio 1995) (district court in Sixth Circuit adopting same rule); *Sprague v. General Motors Corp.*, 843 F. Supp. 266, 307 (E.D. Mich. 1994) (district court in Sixth Circuit concluding that *Edwards v. State Farm Mut. Auto Ins. Co.*, 851 F.2d 134 (6th Cir. 1988), essentially adopted the same rule). Although the Eighth Circuit originally concluded to the contrary, *Brewer v. Lincoln Nat'l Life Ins. Co.*, 921 F.2d 150, 153 (8th Cir. 1990), a subsequent case in that circuit seems to have reversed that conclusion, see *Delk*, 959 F.2d at 105.

tion by failing to apply the rule that ambiguities must be resolved in favor of the insured."<sup>74</sup>

In practice, insurers have not even *tried* to base coverage denials on cost-benefit analysis.<sup>75</sup> The real battleground has been over denials of coverage for "experimental" treatments, and even there insurers often lose even if a treatment has no proven health benefit at all.<sup>76</sup> Such treatments would ordinarily seem to fail not only any plausible social effectiveness (cost-benefit) standard but also a medical effectiveness standard. True, one can sometimes make out a medical effectiveness case for treatments that are experimental in the sense that, while any benefit remains dubious and unproven because not yet tested, a benefit *might* turn out to exist. For terminally ill patients otherwise sure to die, even such an experimental treatment offers some hope of a health benefit.<sup>77</sup> The net expected medical benefit is thus positive even if unknown or vanishingly small, and thus "medically necessary" as that term is generally understood. But courts have gone much further. They have required coverage for experimental treatments that cannot satisfy the standard of being as likely to help as to harm the patients.<sup>78</sup> Courts have even required coverage for so-called "experimental" treatments (such as thermography) that were already tested and found to confer *no* benefit by mainstream medical science.<sup>79</sup> Indeed, courts have

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<sup>74</sup> Brewer v. Protexall, Inc., 50 F.3d 453, 457 n.8 (7th Cir. 1995).

<sup>75</sup> See Hall & Anderson, *supra* note 10, at 1659-61. Insurers have barely begun considering even whether the same medical benefit might be achieved at a lower cost. *Id.*

<sup>76</sup> These cases belie the assertion made by commentators at the conference that we could stamp out care that provides only a small marginal benefit within our current system using technology assessment. If we cannot even effectively stamp out no benefit care, it seems clear we could not stamp out low benefit care without a more fundamental change in the system. In any event, I doubt that eliminating only care with very low benefits can do much about the overall cost trend because of the pressures to keep innovating up to whatever benefit threshold is set.

<sup>77</sup> Hall & Anderson, *supra* note 10, at 1678 & n.155 (collecting cases regarding "experimental" coverage for terminal patients). Insurers' objection to experimental medicine may be based less on its lack of a benefit than on the fact that its very newness and unpredictability makes it difficult to account for actuarially in setting insurance premiums. *Id.* at 1678.

<sup>78</sup> See *id.* at 1655-56.

<sup>79</sup> See John H. Ferguson, Michael Dubinsky & Peter J. Kirsch, Court-Ordered Reimbursement for Unproven Medical Technology: Circumventing Technology

gone to the extreme of interpreting “medically necessary” to cover “experimental” treatments received abroad that, like Laetrile, have actually been *outlawed* as ineffective in the United States.<sup>80</sup> Here the only hope of a benefit is apparently that medical science and government officials will turn out to be wrong. Nor are such decisions limited to interpretations of coverage for “medically necessary” care. Even when insurers insert clauses explicitly excluding “experimental” treatments, they still lose a large proportion of cases,<sup>81</sup> in one case incurring a staggering \$77 million in punitive damages.<sup>82</sup>

Given the above, an insurer could hardly be confident that courts would enforce a far more radical provision excluding care that failed a cost-benefit test.<sup>83</sup> True, the insurer might try to exclude defined types or categories of health services. But in addition to the inherent limits and market problems outlined above, such a strategy faces serious legal obstacles. Some state insurance commissioners effectively prohibit such a strategy by re-

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Assessment, 269 JAMA 2116, 2117 (1993).

<sup>80</sup> See Hall & Anderson, *supra* note 10, at 1646 & n.29 (collecting cases requiring coverage).

<sup>81</sup> See *id.* at 1639-40 & nn. 12-13 (finding that denial of coverage for allegedly experimental autologous bone marrow transplants (ABMT) was upheld in 12 cases and invalidated in 17 cases). ERISA plans have also lost their fair share of cases involving the denial of ABMT. See, e.g., *Farley v. Benefit Trust Life Ins. Co.*, 979 F.2d 653, 661 (8th Cir. 1992); *Adams v. Blue Cross/Blue Shield*, 757 F. Supp. 661 (D. Md. 1991); *Pirozzi v. Blue Cross-Blue Shield*, 741 F. Supp. 586 (E.D. Va. 1990).

<sup>82</sup> See California Jury Orders HMO to Pay \$90 Million to Estate of Cancer Victim, 2 Health Care Policy Report (BNA) 53 (Jan. 10, 1994) (reporting on *Fox v. Health Net*, 3 BNA Health Law Rptr. 18 (Cal. Super. Ct. Dec. 23, 1993) (denial of coverage for bone marrow transplant)).

<sup>83</sup> At a minimum, an insurer would have to conclude that, even if such a provision might conceivably be enforceable, the legal risks of unenforceability are large. This risk probably suffices to discourage any efforts to include such a provision. After all, including such a provision makes the insurance less valuable to buyers. This disadvantage to buyers can be offset only if the provision is enforceable and thus cuts costs in a way that can be passed on to buyers in the form of a lower price. Given legal uncertainty, the insurer would have to be willing to incur a certain loss of business from having a less valuable product in return for an uncertain gain in business from cost-cutting that would allow a lower price. Such a tradeoff is unlikely to be profitable even if a clearly enforceable provision would on balance be attractive to consumers. Of course, further complicating matters is the fact that enrollees do not bear the full cost of their choices because of government payment or tax subsidies. These subsidies may make a price-for-quality tradeoff unattractive that would have been attractive if consumers had to bear the full price of all beneficial care coverage.

quiring language making such exclusions inapplicable when the treatment is "medically necessary."<sup>84</sup> Even if allowed by the state commissioner, courts strain to interpret any ambiguity in the exclusion against the insurer, often with unexpected results.<sup>85</sup> When an insurer responds by making the exclusion more specific and detailed, courts have still denied enforcement on the grounds that the detail makes the exclusion too complex and technical for insureds to understand. For example, courts have prohibited denials of treatment for temporomandibular joint syndrome ("TMJ"), a condition caused by jaw misalignment, ruling in some cases that an exclusion of "dentistry" was too ambiguous, and in other cases that a specific exclusion of TMJ was too complex to be understandable.<sup>86</sup> Further, the amount of detail that can fit in a brochure is limited, and exclusions omitted from such brochures are unenforceable even if included in a complete policy known to the employer.<sup>87</sup> In any event, such a strategy does nothing to stem open-ended expansion of expenditures on the categories of services that do remain covered.<sup>88</sup>

Despite modern changes, Medicare continues to follow the same model. It continues to reimburse providers for all treatments within covered categories that are "reasonable and medically necessary,"<sup>89</sup> or "reasonable and necessary for the diagnosis or treatment of illness or injury."<sup>90</sup> Although the term "reasonable" might be read to refer to reasonable in cost, in practice the term has been interpreted to include all care reasonably considered medically appropriate.<sup>91</sup> Further, although the position of Medicare administrators is that the medical opinion of

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<sup>84</sup> Hall & Anderson, *supra* note 10, at 1684 & n.175. The need for regulatory approval also imposes a delay that exacerbates the problem of updating specified exclusions. *Id.* at 1684-85 & n.176.

<sup>85</sup> See *supra* note 72 and accompanying text; Havighurst, *supra* note 50, at 1210 (collecting cases).

<sup>86</sup> See Hall & Anderson, *supra* note 10, at 1648 n.35.

<sup>87</sup> See Furrow et al., *supra* note 10, § 11-2(a), at 502-03 (collecting cases showing this is true under both ERISA and state insurance law); Hall & Anderson, *supra* note 10, at 1685 & n.177 (collecting cases where courts declined to enforce exclusions contained in the master contract, but not in brochures).

<sup>88</sup> See Elhauge, *Allocating Health Care Morally*, *supra* note 4, at 1470-71.

<sup>89</sup> 42 U.S.C. § 1320c-3(a)(1)(A) (1994).

<sup>90</sup> 42 U.S.C. § 1395y(a)(1) (1994).

<sup>91</sup> See Havighurst, *supra* note 9, at 780 & n.10.



the treating physician is not conclusive,<sup>92</sup> some cases have held either that it provides presumptive evidence of medical necessity<sup>93</sup> or more broadly that determinations of medical necessity rest “with the individual recipient’s physician and not with clerical personnel or government officials.”<sup>94</sup>

Likewise, Medicaid has been interpreted to cover all “necessary medical services.”<sup>95</sup> Although the federal government sometimes grants states waivers from Medicaid regulations, this has been severely constrained recently. Agencies under the Bush and Clinton Administrations have denied waivers, ruling that it constitutes illegal discrimination against the disabled to take into account any differing capacity to benefit from health care other than a different probability of avoiding death.<sup>96</sup> This makes it impossible as a practical matter to make rational cost-benefit tradeoffs in Medicaid, or (if followed by the courts<sup>97</sup>) in any governmental health plan or regulation.<sup>98</sup>

But surely, you must be thinking, Medicare DRGs, insurer mandated discounts, and capitated payments have changed all this in practice, if not in form. Whether public and private insurers admit they are doing it or not, doesn’t the cost containment they impose on hospitals and physicians have to force providers into making implicit cost-benefit tradeoffs? The perhaps surprising answer is probably not under the current regime, at least not legally.

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<sup>92</sup> See Furrow et al., *supra* note 10, § 13-7, at 569.

<sup>93</sup> See, e.g., *Weaver v. Reagen*, 886 F.2d 194, 200 (8th Cir. 1989).

<sup>94</sup> See *Pinneke v. Preisser*, 623 F.2d 546, 550 (8th Cir. 1980).

<sup>95</sup> *Beal v. Doe*, 432 U.S. 438, 444 (1977). See also *Hall & Anderson*, *supra* note 10, at 1680 n.161 (collecting cases holding that Medicaid must cover unapproved uses of AZT, a sex change operation, and a pancreas transplant considered experimental under Medicare).

<sup>96</sup> See *infra* notes 276-286 and accompanying text (discussing Oregon plan and noting that costs were ultimately only used as a tie-breaker in cases of equal probability of avoiding death).

<sup>97</sup> Courts seem more willing to conclude that distinctions based on the capacity to benefit from treatment do not constitute discrimination against the disabled. See *Johnson v. Thompson*, 971 F.2d 1487, 1493-94 (10th Cir. 1992); *United States v. University Hosp.*, 729 F.2d 144, 156-57 (2d Cir. 1984).

<sup>98</sup> An exemption for private insurance plans gives them greater flexibility to consider disabilities under the Americans with Disabilities Act. See 42 U.S.C. § 12201(c) (1994).

Let's take Medicare DRGs to start. The idea is to impose a fixed payment on the inpatient hospital services offered in connection with a given diagnosis and treatment.<sup>99</sup> The commonly noted problems are that DRGs can be evaded by recoding patients, unbundling diagnoses, or shifting treatment to outpatient settings not subject to fixed payments.<sup>100</sup> But the underlying problem is deeper. Each payment amount is set to equal the costs of providing all the services physicians typically order for that diagnosis and treatment. This does not encourage cost-benefit tradeoffs, for as long as costs can be covered by an efficient provider, the services will be provided no matter how low their benefit.<sup>101</sup> If Medicare administrators instead tried to set DRG payments lower than the cost with which the services could efficiently be provided, they would likely be found to be in violation of the statute's directive to provide all reasonable and necessary care.<sup>102</sup> Such an approach would in addition be perverse, since it would result in denial of those services no matter how high their benefit. The only way to force cost-benefit tradeoffs would be to set prices equal to the *benefit* of the services, and no Medicare administrator has tried to do that. On the contrary, the Medicare statute polices hospitals' incentives to deny beneficial care by mandating oversight by peer review organizations.<sup>103</sup> Such review organizations must be composed of physicians and must have the power to review the completeness of

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<sup>99</sup> As of 1989, seventeen states were also using a DRG approach under Medicaid. See Furrow et al., *supra* note 10, § 14-9(a), at 625.

<sup>100</sup> See, e.g., Havighurst, *supra* note 50, at 91-92 (Supp. 1992) (citing Prospective Payment Commission, Report and Recommendation to the Congress 89-93 (1991)) (over ten year period, "[i]npatient surgical operations declined 30 percent, while outpatient surgical operations increased 304 percent").

<sup>101</sup> DRGs can, on the other hand, encourage productive efficiency and curb medical inflation. See *infra* Section III.C.1.

<sup>102</sup> See *supra* notes 89-94 and accompanying text. Likewise, Medicaid payment rates must be sufficient to make medical services as available to beneficiaries as they are to the general public. See Furrow et al., *supra* note 10, § 14-10, at 628. Rates cannot be set according to budgetary constraints, but must reflect the costs of provision by identifiable efficient providers. *Id.* § 14-9, at 626-28.

<sup>103</sup> 42 U.S.C. § 1395cc(a)(1)(F) (1994). See also *American Hosp. Ass'n v. Bowen*, 640 F. Supp. 453, 457 (D.D.C. 1986) (citing 42 U.S.C. § 1395cc(a)(1)(F)), *rev'd* on other grounds, 834 F.2d 1037 (D.C. Cir. 1987).

the hospital's care and its admissions decisions.<sup>104</sup> The professional norm of providing all beneficial care thus remains enforced by statute. Small wonder that Medicare expenditures have continued to increase, recently at rates of over ten percent per year.<sup>105</sup>

Moreover, the treating physician remains the one who largely dictates which services the hospital must provide. Physicians have the power to admit and discharge patients, to order tests and make diagnoses, and to prescribe and perform treatments. The hospital's legal duty is to provide the services the physician orders or the support the physician needs to perform the services herself.<sup>106</sup> No matter what cost pressures they might be under, hospitals have little legal power to interfere with the judgment of treating physicians. The standards of the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") require that overall responsibility for professional services be vested in a self-governing medical staff composed of professionals who have independent authority to act within the scope of their hospital privileges.<sup>107</sup> Few hospitals can do without such accreditation, and only one percent try.<sup>108</sup> Accreditation is relied upon for most state licenses, is required for automatic participation in Medicare and some Blue Cross plans, and is necessary for residency programs and specialty certification.<sup>109</sup> Even if a hospital tried to do without such accreditation, those standards would remain in hospital staff bylaws, which some courts have found constitute a contract between the hospital and its medical staff that the hospital cannot change without the

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<sup>104</sup> See 42 U.S.C. § 1320c-1 (1994) (physician composition); 42 U.S.C. § 1395cc(a)(1)(F) (1994) (power to review).

<sup>105</sup> See Elhauge, *Medi-Choice*, *supra* note 4, at 24.

<sup>106</sup> See *Burns v. Forsyth County Hosp. Auth.*, 81 N.C. App. 556, 563 (Ct. App. 1986) (stating that hospital has duty to obey the physician's instructions unless they are obviously negligent or dangerous).

<sup>107</sup> See Joint Commission on Accreditation of Healthcare Organizations, 1996 Comprehensive Accreditation Manual for Hospitals MS. 1 to MS. 2, at 484-85 (1995) [hereinafter JCAHO].

<sup>108</sup> See Timothy S. Jost, *The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care and the Public Interest*, 24 B.C. L. Rev. 835, 842 (1983).

<sup>109</sup> See *id.* at 843-45.

medical staff's consent.<sup>110</sup> The hospital might try to control physicians through the denial or revocation of hospital staff privileges. But such decisions are judicially reviewable and receive deference only to the extent they are made on professional grounds upon the medical staff recommendation, and hospitals may be prohibited from making such decisions based on the physician's propensity for excessively costly practices.<sup>111</sup> As a result studies find, not just legally but in actual practice, that "hospitals must cater to physicians' desire for new technology."<sup>112</sup>

Nor is there much difference when physicians are hired as employees. In many states, the corporate practice of medicine doctrine still prohibits charging for medical services provided by physician-employees absent an exception or statutory exemption.<sup>113</sup> The reasoning behind the default prohibition is that physicians should not be subject to lay control that might undermine professional standards.<sup>114</sup> To be sure, this doctrine is on the wane and often unenforced. But the reason for this decline, and the primary rationale cited for allowing such arrangements, is that the corporation is not "practicing" medicine; this implicitly requires a lack of corporate involvement in medical decisions.<sup>115</sup> Indeed, at least one state allows employed physicians to provide medical care only on the express condition that the cor-

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<sup>110</sup> See *St. John's Hosp. Med. Staff v. St. John Reg'l Med. Ctr.*, 245 N.W.2d 472, 474-75 (S.D. 1976). See also *JCAHO*, *supra* note 107, MS. 2.1, at 485 (requiring approval of medical staff to amend medical staff bylaws).

<sup>111</sup> See *Furrow et al.*, *supra* note 10, §§ 4-6 to 4-7, at 99-101. On the other hand, hospitals have been able to cite cost considerations in deciding to provide certain medical services through an exclusive contract with some physicians. *Id.* § 4-10, at 105.

<sup>112</sup> *Banta & Luce*, *supra* note 14, at 42 (collecting studies). Doctors also continue to dominate the use of medical technology in Europe despite more extensive state involvement there. *Id.* at 49.

<sup>113</sup> See *Furrow et al.*, *supra* note 10, § 5-10(a)-(b), at 183-87.

<sup>114</sup> *Id.* § 5-10(a), at 184.

<sup>115</sup> See *id.* § 5-10(a), at 184 & n.4; *id.* § 5-10(b), at 187 & n.34. See also *id.* § 5-10(b), at 186 & n.25 (noting cases immunizing hospitals and HMOs from liability for actions of their doctors on grounds that they "cannot practice medicine or direct the practice of physicians in their employ"). The exceptions and statutory exemptions for non-profit hospitals and HMOs seem to be provided on the same understanding and the sometimes explicit condition that the treating physicians' medical judgment not be interfered with. See *id.* § 5-10(c), at 187-88.

poration exercise no "lay control of medical judgment."<sup>116</sup> A corporate policy requiring physician-employees to make cost-benefit tradeoffs would probably still be considered the illegal practice of medicine in every state.

Moreover, whether the physician is an employee or independent contractor, a hospital that tries to induce a physician to order fewer medical services runs the risk of severe malpractice penalties. In *Muse v. Charter Hospital*,<sup>117</sup> for example, a North Carolina court found that a hospital policy of discharging patients when their insurance expired influenced a treating physician's decision to discharge a patient who seventeen days later committed suicide.<sup>118</sup> The court concluded that this violated the hospital's "duty not to institute policies or practices which interfere with the doctor's medical judgment."<sup>119</sup> Not only was the hospital held liable in malpractice, it was initially found liable for \$6 million in punitive damages as well.<sup>120</sup> In truth, the applicable duty is not a general duty not to interfere but rather a duty not to interfere in ways that produce a lower health benefit. For other cases make clear that hospitals will be liable in malpractice if they *fail* to interfere to make sure the treating physician provides the full health benefit of customary professional care.<sup>121</sup>

And what are the physician's incentives? Under Medicare, the physician continues to be paid on a fee-for-service basis and thus has few incentives to avoid care that is not cost-beneficial.

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<sup>116</sup> See Op. Att'y Gen. N.M. 87-39, at 1 (July 30, 1987).

<sup>117</sup> 452 S.E.2d 589 (N.C. Ct. App.), aff'd per curiam, 464 S.E.2d 44 (N.C. 1995).

<sup>118</sup> *Muse*, 452 S.E.2d at 593-96.

<sup>119</sup> *Id.* at 594. See also *Wickline v. State*, 192 Cal. App. 3d 1630, 1647 (Ct. App. 1986) (stating that "it is essential that cost limitation programs not be permitted to corrupt medical judgment").

<sup>120</sup> The finding of punitive damages is currently on remand due to a flawed jury instruction. *Muse*, 452 S.E.2d at 594, 599.

<sup>121</sup> See *id.* at 594 (stating that hospital also has a "duty to make a reasonable effort to monitor and oversee the treatment prescribed and administered by doctors practicing at the hospital") (citing *Bost v. Riley*, 262 S.E.2d 391, 396 (N.C. Ct. App. 1980)); *Darling v. Charleston Community Memorial Hosp.*, 211 N.E.2d 253 (Ill. 1965) (duty to supervise even physicians who are independent contractors), cert. denied, 388 U.S. 946 (1966); *Furrow et al.*, supra note 10, § 7-4, at 301-03 (same); *id.* § 7-2, at 292-97 (discussing courts' extension of the vicarious liability doctrine to hospitals, making all medical personnel who used the hospital part of the enterprise whether staff employees or independent contractors).

Indeed, efforts to give physicians financial incentives to order less care are explicitly illegal. Under federal statute, a hospital cannot make "a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided" to Medicare or Medicaid beneficiaries.<sup>122</sup> Further, physicians must comply with their own malpractice standards. Those standards do not incorporate the "B < PL" negligence formula, which would allow cost-benefit tradeoffs.<sup>123</sup> Rather, they require following the customary practice of physicians, which generally does not allow such tradeoffs and is determined by the profession itself.<sup>124</sup> Nor do courts generally allow physicians to contract with patients for a release from customary malpractice standards.<sup>125</sup>

To be sure, one can try to change *patients'* incentives with deductibles and copayments. But patients do not have the expertise to second-guess their physicians' recommendations. And physicians as a group retain a legal monopoly on prescribing drugs, ordering tests and admitting patients for hospital treatment. This means a patient may have to follow the physician's

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<sup>122</sup> 42 U.S.C. § 1320a-7a(b)(1) (1994). It is also illegal for a physician to accept such a payment. 42 U.S.C. § 1320a-7a(b)(2) (1994).

<sup>123</sup> As famously articulated by Judge Learned Hand, a defendant's conduct is ordinarily negligent only if the burden of the safety protection (B) is less than the probability of injury (P) times the magnitude of the liability (L); as expressed in algebraic terms, where  $B < PL$ . See *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947). Even if the courts did adopt B < PL analysis in malpractice cases, it probably would not undermine professional absolutism because, unlike in ordinary negligence cases, the actor bears the risk of PL but not the B, which is paid by the insurer and patient. The professional can thus be expected to minimize PL, which again means maximizing the expected health benefit. But B < PL analysis might make a difference in cases where the provider was the insurer, such as an HMO, and thus had incentives to take both sides of the formula into account.

<sup>124</sup> See, e.g., *Furrow et al.*, *supra* note 10, § 6-2, at 238-39. Occasionally, but rarely, courts have allowed plaintiffs to argue that even though the defendant's conduct was customary, it was nonetheless negligent because it failed a B < PL inquiry. See *id.* (noting that *Helling v. Carey*, 519 P.2d 981 (Wash. 1974), followed such an approach but making clear that the Washington court is in the minority). No court yet seems to have allowed a defendant to avoid liability by showing that, although he offered less than customary professional practice, it was cost-justified.

<sup>125</sup> See 225 Ill. Comp. Stat. Ann. 60/29 (1993); *Tatham v. Hoke*, 469 F. Supp. 914, 919 (W.D.N.C. 1979); *Tunkl v. Regents of the Univ. of California*, 383 P.2d 441, 441-42 (Cal. 1963); *Emory Univ. v. Porubiansky*, 282 S.E.2d 903, 905 (Ga. 1981); *Meiman v. Rehabilitation Ctr., Inc.*, 444 S.W.2d 78, 80 (Ky. 1969); *Olson v. Molzen*, 558 S.W.2d 429, 432 (Tenn. 1977).

recommendation if he wants any kind of drug, test, or hospitalization at all. Nor do patients have much incentive to demand only cost-beneficial care since Medicare still covers the bulk of treatment costs and Medigap insurance usually covers the rest.<sup>126</sup>

One can say much the same about cost pressures put on hospitals by private insurers. They do not try to set prices equal to the benefit of services, probably would not know how to do so, and would likely run afoul of the sort of insurance law rulings described above if they did.<sup>127</sup> In any event, any cost constraints are unlikely to be effective in forcing cost-benefit tradeoffs as long as the hospitals are legally unable to control attending physicians. Efforts to change physicians' incentives run up against the obstacle of malpractice liability, as well as laws prohibiting fee-splitting and other payments that create conflicts of interest between physicians and their patients.<sup>128</sup> Efforts to select which physicians the insurer will deal with often run afoul of "all willing provider" statutes.<sup>129</sup> Even when the statutes explicitly authorize preferred provider arrangements, they seem to require the insurer to deal with any quality physician that will accept the insurer's terms and fees, thus precluding selection based on whether the physician avoids providing care that is not cost beneficial.<sup>130</sup> These laws also often require the insurer to pay the preferred rate for any "medically necessary" care unavailable with a preferred provider.<sup>131</sup> Finally, deductibles and copayments can have only a limited effect: Medical costs must mainly be covered if the insurance is to provide the financial protection that insurers are selling.

Well, what about HMOs? Surely they have greater ability to get away with making implicit cost-benefit tradeoffs. They need not do so by setting prices, have more control over their physicians, and can deny care without creating the sort of insurer-provider dispute that alerts patients as to what is happen-

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<sup>126</sup> See Elhauge, *Medi-Choice*, *supra* note 4, at 26.

<sup>127</sup> See *supra* notes 60-88 and accompanying text.

<sup>128</sup> See generally Havighurst, *supra* note 50, at 257-64 & 1992 Supp., at 32-34 (discussing physician conflicts of interest and fee-splitting).

<sup>129</sup> See Furrow et al., *supra* note 10, § 11-12, at 533.

<sup>130</sup> *Id.*

<sup>131</sup> *Id.* § 11-12, at 534.

ing. However, HMOs are generally allowed to operate only under statutory exemptions (to the prohibition on the corporate practice of medicine) that forbid them to interfere with the professional judgment of their physicians<sup>132</sup> and require them to provide all beneficial care.<sup>133</sup> HMOs that treat Medicare or Medicaid beneficiaries are not allowed to deny coverage for any "medically necessary" services those programs traditionally provide.<sup>134</sup> Malpractice liability for interfering with a physician's medical judgment still applies. HMOs also by statute cannot make any payment "directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services" to Medicare or Medicaid beneficiaries.<sup>135</sup> Any such financial incentives might in addition be deemed to make the HMO liable for its physicians' malpractice, even if those physicians are independent contractors.<sup>136</sup> And of course those physicians remain under their own malpractice liability threat. As for patients, their incentives to demand marginally beneficial new technology are not weaker but stronger under HMOs because HMOs impose lower deductibles and copayments.

In addition, HMOs that employ and control their physicians can be directly subject to malpractice standards that would be violated by making cost-benefit tradeoffs.<sup>137</sup> True, such malpractice claims are difficult to discover and bring because HMOs are more likely to avoid or hide insurer-physician splits about the proper medical practice. If a traditional insurer denies reimbursement for a drug prescribed by an independent physician, the patient is alerted to the possible deviation from the absolutist standard. If an HMO instructs its physicians to stop pre-

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<sup>132</sup> See, e.g., *id.* § 5-10, at 187-88.

<sup>133</sup> See *id.* § 11-11(a), at 529 (to qualify under federal law, HMOs must provide "comprehensive benefits" that are "medically necessary" at all times).

<sup>134</sup> See 42 U.S.C. §§ 1395mm(c)(2), 1395mm(c)(2)(4), 1396b(m)(1)(A)(i)-(ii), 1396b(m)(5)(A)(i) (1994).

<sup>135</sup> 42 U.S.C. §§ 1395mm(i)(8)(A)(i), 1396b(m)(2)(A)(x) (1994). HMOs can, however, put physicians at financial risk for services provided by other physicians as long as there is stop-loss protection deemed adequate by the Secretary of Health and Human Services. 42 U.S.C. § 1395mm(i)(8)(A)(ii) (1994).

<sup>136</sup> See Furrow et al., *supra* note 10, § 8.2(c), at 314.

<sup>137</sup> See *id.* § 8.2(b), at 312-14 (collecting cases).



scribing that same drug and prescribe a cheaper one instead, the patient who goes home with the cheaper drug is unlikely to know another drug might have been a better option. But the difficulty of enforcement goes only to the possibility of evading the absolutist standard,<sup>138</sup> not to the existence of such a standard itself. Indeed, traditional malpractice standards have sometimes been extended even to insurers and utilization review organizations who perform no medical services if they deny coverage prospectively.<sup>139</sup> Many states also require by statute that utilization review performed for insurers be carried out only by physicians applying traditional medical standards.<sup>140</sup>

Thus, HMOs legally remain subject to the same absolutist constraint on cost-minimization as other insurers. And that absolutism produces the same "Field of Dreams" technology problem that plagues other insurers.<sup>141</sup> Consistent with this, HMOs and fee-for-service insurers have experienced no significant difference in the rate of premium growth, and the growing market share of HMOs has not slowed national health care cost escalation.<sup>142</sup>

One might be tempted to dismiss all of the above as remnants of an old paradigm that remains in the law only because the law is backwards-looking. But the same phenomenon repeats itself in modern health care proposals. Take the Clinton Health Plan and the Gingrich Medicare Plan. The Clinton Plan, although it attempted to foster managed competition among plans and threatened to impose a global cap on premiums if managed competition failed to constrain costs, would not have permitted plans to make cost-benefit tradeoffs. It would have required them to provide all "medically necessary" and "appropriate" care within broadly defined categories of services.<sup>143</sup> And those

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<sup>138</sup> This possibility is discussed *infra* at Section II.C.

<sup>139</sup> See *Wilson v. Blue Cross*, 222 Cal. App. 3d 660, 671-75 (Ct. App. 1990); Nathan Hershey, *Fourth-Party Audit Organizations*, 14 *Law, Med. & Health Care* 54, 62-63 (1986).

<sup>140</sup> See Furrow et al., *supra* note 10, § 11-10, at 527-28.

<sup>141</sup> See discussion *supra* Part I & Section II.B.

<sup>142</sup> See *supra* notes 20-26 and accompanying text.

<sup>143</sup> Clinton Health Plan, *supra* note 51, at § 1141. A National Health Board would have been authorized to issue regulations defining what this term included and excluded. *Id.* §§ 1141, 1151, 1154. But the term would likely have been interpreted

categories would have been as generous as the best corporate health plans.<sup>144</sup> Further, administrative review would have been available to appeal any denial of care that could not be justified on purely medical grounds.<sup>145</sup> Likewise, the Gingrich Medicare Plan would have tried to encourage managed competition among health plans by allowing beneficiaries to use their share of the Medicare budget to buy private insurance.<sup>146</sup> And it would have imposed a global budgetary cap in case such competition did not restrain costs. But the Gingrich Plan would not have allowed those plans to make cost-benefit tradeoffs. Rather, it would have required plans to cover at least all of the types of services Medicare does, and within those covered services compelled them to provide all “medically necessary” care.<sup>147</sup> It would also have made this obligation enforceable by administrative review for any denied care costing over \$100 and by judicial review if over \$1,000.<sup>148</sup>

Given that each has condemned the other’s plan, the irony is fairly delicious: They are basically the same plan.<sup>149</sup> But for present purposes I want to emphasize a different lesson. Even in the most far-reaching health care reforms proposed in the last thirty years, which the Clinton and Gingrich plans surely were, no one even *suggests* deviating from medical absolutism. Rather, the political advantage clearly lies with the party that opposes cost containment reform on the grounds that it *might* lead to a hidden deviation from absolutism. If politicians ranging from Clinton to Gingrich can agree that any cost containment must be coupled with a prohibition on making cost-benefit tradeoffs, one has to conclude this combination has deep reso-

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to conform to the general understanding in insurance law. See *supra* notes 60-88 and accompanying text.

<sup>144</sup> *Id.* §§ 1101-28 (detailing what would be covered under the Clinton plan).

<sup>145</sup> *Id.* at §§ 5202-06.

<sup>146</sup> See Elhauge, *Medi-Choice*, *supra* note 4, at 26.

<sup>147</sup> See *id.* at 27.

<sup>148</sup> See The Medicare Preservation Act: “A BETTER MEDICARE,” at 16 (Sept. 1996) (House Republican Memorandum) (on file with the Virginia Law Review Association).

<sup>149</sup> They even both involved the same strategies of countering risk selection through regulation and risk-adjusted premium payments, strategies which each side has condemned as insufficient when proposed by the other side. See Elhauge, *Medi-Choice*, *supra* note 4, at 27.

nance in our society.

*C. Why Impose Cost Pressures and Ban Cost-Benefit Tradeoffs?*

Why do we put cost pressures on institutions when we prohibit them from making cost-benefit tradeoffs? There are a number of possibilities.

*1. Medical and Cost Effectiveness without Allocative or Social Effectiveness*

Perhaps we are simply trying to squeeze out pure waste; that is, eliminate harmful and unnecessary care, curb medical inflation and excessive profits, and increase productive efficiency to provide the same health benefit at lower cost. If so, this is a coherent strategy. It pursues admirable and important goals that could save tens of billions of dollars. Moreover, we can in theory achieve those goals without decreasing the quality of care provided.

Unfortunately, it seems plain that, even if completely successful, such a strategy might slow down the cost escalation problem but could not cure it. As Section II.A discussed, it is the commitment to funding all beneficial care that produces the unending cost escalation. If we could spend one hundred percent of our GNP without running out of care with a positive marginal benefit, then eliminating all care that has no benefit (or produces the maximum benefit at higher cost) will not solve the problem.

One can reach this same conclusion by examining the possible cost-savings from eliminating waste and productive inefficiencies. In 1994, for example, William Schwartz and Daniel Mendelson carefully analyzed each source of potential savings in reducing unnecessary care, administrative costs, and excess profits.<sup>150</sup> They then adopted highly optimistic assumptions about the magnitude of the savings by ignoring various obstacles and assuming the efforts to achieve those savings are themselves costless. Their conclusion: Even on those optimistic assumptions, the best we can hope to achieve is to decrease the annual

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<sup>150</sup> Schwartz & Mendelson, *supra* note 24, at 224, 225-32.

rate of increase in health care costs from 6.5 percent to 5 percent.<sup>151</sup> The estimated savings—\$72 billion—are certainly well worth seeking. But the cost spiral would remain because its fundamental cause would remain: medical absolutism.

Indeed, to my mind the Schwartz-Mendelson estimate is overly optimistic; not just because they expressly used overly optimistic assumptions but because they implicitly—and quite wrongly—assume that growth in various sectors is static. That is, they assume that if growth in some sectors can be reduced, growth overall will be reduced by that amount. It seems far more likely that reducing some forms of growth will induce higher rates of growth elsewhere unless the basic incentives that create the expansionary pressures in health care are altered.<sup>152</sup>

In any event, however one reaches it, the conclusion that eliminating cost-ineffective medicine cannot stop our cost-spiral is hardly new. Indeed, one of those authors had presciently reached the same conclusion in 1978:

We doubt, after a rather close look at the available evidence, whether pure production inefficiency and care that yields no medical benefit account for more than a small fraction of the rising cost of health care. The largest proportion of expenditures, we believe, will prove to be of the type that buys at least some medical benefits.<sup>153</sup>

He has been proven right, of course. The period from 1978 to 1994 saw an explosion in efforts to make health care more cost effective, including an explosion in technology assessment. Yet the cost spiral continued unabated. Not surprisingly, earlier confident statements that technology assessment could produce significant cost-savings have faded. Today, the administrator of the Agency for Health Care Policy and Research (“AHCPR”) himself states that “outcomes research is not a cost cutting exercise.”<sup>154</sup> And the Office of Technology Assessment (“OTA”) concedes that “reducing inappropriate and ineffective care. . .

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<sup>151</sup> *Id.* at 234.

<sup>152</sup> See *infra* Part VII.

<sup>153</sup> William B. Schwartz & Paul L. Joskow, *Medical Efficacy Versus Economic Efficiency: A Conflict in Values*, 299 *New Eng. J. Med.* 1462, 1464 (1978).

<sup>154</sup> Office of Technology Assessment, *supra* note 9, at 34.

cannot be expected to lower health care costs substantially.”<sup>155</sup>

Some anecdotal evidence may help. Consider the cost of treating heart attacks. It increased 32 percent per heart attack (using constant dollars over a seven year period) even though the price of the various treatments actually *decreased* by 0.2 percent annually over that period.<sup>156</sup> This cost increase did not reflect an increase in medical inflation or a decrease in productive efficiency. Nor did it reflect the use of a technology that was medically ineffective or cost ineffective in the sense of producing the same health benefit at a higher cost. Rather, it reflected the increased use of catheterization, angioplasty and bypass surgery—technologies that offer some benefits over traditional medical management of the problem, but at higher cost.

## 2. *Hypocrisy: Hoping for Hidden Cost-Benefit Tradeoffs*

Another possibility is that we *do* want institutions to make cost-benefit tradeoffs. We just do not want to *know* about them. That is why we put cost pressures on institutions to force such tradeoffs and yet prohibit the tradeoffs: to keep them from being done openly. The polite way of phrasing this argument is that we gain the symbolism of affirming the priceless value of human life and health but also recognize the practical necessity of efficiency. The less polite way is to say we are cowards and hypocrites.

In any event, it is plain that this tragic failure to make choices results in the worst of both worlds. We do not assure the provision of all beneficial care, because we allow tradeoffs to be made. Nor, on the other hand, do we actually encourage real cost-benefit tradeoffs. Under such a regime, insurers and providers have incentives to deny care not to those who benefit less from it than it costs but to those unlikely to complain or be noticed. An institution will deny care when it can get away with it, not when the same resources could produce a greater health benefit elsewhere.

Patients on the verge of dying are unlikely to be denied care under such a regime, even if they are the ones medicine can help

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<sup>155</sup> See *id.* at 5.

<sup>156</sup> See Cutler, *supra* note 2, at 10 & tbl. 3.

least, because they are identifiable and they and their families are focused intensely on the care they do or do not receive. The existing patients who will be denied care are those who may never notice: the patient who suffers from sinus allergies she does not know could be treated; the psychologically disturbed (but not suicidal) patient who does not realize she could be better adjusted; the new mother who has no inkling of the child care advice she no longer receives. Or, rather than denying care outright, institutions will substitute cheaper but less effective care where patients are unlikely to know or appreciate the substitution being made. Whether the denied or replaced care would confer benefits on the patients exceeding any additional costs is irrelevant under such a regime. The insurers and providers must minimize costs without *being caught* denying beneficial care. They thus have incentives to choose those patients who will either never know they were denied more beneficial care or who—even if they do notice—have ailments too minor or too easy to pay out of pocket to make it worth their while to litigate or otherwise make a stink about the denial of care.<sup>157</sup>

Even more likely to suffer are the nameless patients who are never treated. It is harder to avoid blame for identifiable patients under your care; it is easier when you never let them in the door to begin treatment. We can expect market actors under such a regime to slight preventive care whose benefits may be large but are merely statistical. We can also expect them to seek to avoid patients likely to have complex, costly-to-treat ailments. For example, what can we predict as the main prospective effect of *Muse v. Charter Hospital*,<sup>158</sup> which effectively prohibited hospitals from discharging patients who had exceeded the hospital days their insurer would cover but did not prohibit the insurers from limiting payment to that number of days? The main behavioral change we can predict is that hospitals are going to become more leery of admitting patients whose insurance coverage might end or who seem likely to require long periods of hospitalization. How much those prospective

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<sup>157</sup> That the ailments are minor does not mean their treatment would not be cost beneficial because the costs of treatment may proportionally be even lower.

<sup>158</sup> 452 S.E.2d 589 (N.C. Ct. App.), *aff'd per curiam*, 464 S.E.2d 44 (N.C. 1995).

patients would have benefited from the admission does not affect hospital incentives under such a system.

Not surprisingly, under the current regime, insurers have devoted most of their cost-cutting efforts to risk selection, not to making optimal cost-benefit tradeoffs.<sup>159</sup> Denying coverage based on cost-benefit assessments conflicts with the absolutist imperative, creating serious risks of legal liability and bad publicity. Selecting enrollees who are relatively healthy (and thus cheaper to treat) is less directly in conflict and easier to get away with. It also involves far less insurer effort and requires no consumer knowledge. With rudimentary screening techniques, insurers can lower the costs of treating their most expensive patients by seventy percent or more.<sup>160</sup> Such screening can take the form of seeking out healthy enrollees or selectively disenrolling unhealthy existing enrollees. The means of risk selection are probably too subtle to regulate. Insurers might advertise sports medicine or baby care to attract young subscribers.<sup>161</sup> They might locate application pick-up spots and services where the sick and elderly are unlikely to go. Or they might give accurate advice to enrollees about better treatments available elsewhere.

Indeed, it is often hard to distinguish between devices for risk selection and efforts to increase efficiency. Consider utilization review. To all outward appearances it is a strategy to increase efficiency by screening out unnecessary and perhaps cost-ineffective care. But it has another effect: It imposes delay. This delay will not be noticed much by those who rarely use the health services, but it can frustrate frequent users and encourage them to switch to other care plans. We cannot tell for sure whether any resulting reduction in plan expenditures is the product of more efficient care or more effective risk selection. But the percentage of coverage requests actually denied is so

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<sup>159</sup> James C. Robinson and Laura B. Gardner, *Adverse Selection Among Multiple Competing Health Maintenance Organizations*, 33 *Med. Care* 1161 (1995) (noting that HMOs have historically held premiums down primarily through risk selection).

<sup>160</sup> See Wynan Van de Ven & René Van Vliet, *How can we prevent cream skimming in a competitive health insurance market?*, in *Health Economics Worldwide* 23, 29 (P. Zweifel & H.E. Frech, III eds., 1992).

<sup>161</sup> See Harold S. Luft & Robert H. Miller, *Patient Selection in a Competitive Health Care System*, *Health Aff.*, Summer 1988, at 97, 99 (discussing various methods of selection).

small—one to two percent in one recent study<sup>162</sup>—that (even though a larger proportion results in some modification of treatment) it seems unlikely to explain expenditure reductions of eight to eleven percent,<sup>163</sup> let alone likely to achieve real cost savings sufficient to outweigh the administrative costs to insurers<sup>164</sup> and the disvalue of delay to patients.

Even when it does reduce health care expenditures, it is uncertain that utilization review does so by making sound medical or economic decisions. It may reduce expenditures by simply creating a barrier so onerous that patients or providers give up. For example, MediCal adopted a policy of requiring that a seven-page Treatment Authorization Review form be filled out before it would reimburse patients for “off-formulary” or restricted drugs. Such a large amount of paperwork hardly seemed cost efficient. But that was apparently not the motive. As California Assemblyman Bruce Bronzan explained with remarkable candor: “[Do we do this] because we are concerned about quality of care? No. We do it in order not to have prescriptions filled.”<sup>165</sup> Whether the prescription *should* be filled on medical or cost-benefit grounds remains unaddressed by such an approach. But an open conflict with medical effectiveness is avoided because the patient or provider who really wants the drug would find it easier to fill out the form than to bring a lawsuit.<sup>166</sup>

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<sup>162</sup> Institute of Medicine, *Controlling Costs and Changing Patient Care?: The Role of Utilization Management* 77 (Bradford H. Gray & Marilyn J. Field eds., 1989); Office of Technology Assessment, *supra* note 9, at 180 (“Little evidence exists to suggest that long-term patterns of expenditure growth are altered by adoption of UR [utilization review] methods.”). This 1-2% is not only smaller than the proportion of treatments that are not cost beneficial but far smaller than the proportion of treatments that are not medically beneficial. See *supra* notes 42-43 and accompanying text.

<sup>163</sup> See Furrow et al., *supra* note 10, § 8-7(a), at 323 (noting one study finding 8.3% reduction in expenditures and another finding 11.9% reduction in expenditures).

<sup>164</sup> See Garber, *supra* note 1, at 122-23 (finding utilization review responsible for a substantial share of the growth in administrative expenses).

<sup>165</sup> Bryan L. Walser, *Pharmaceutical Cost Containment and Quality Assurance: Trends in Outpatient Utilization Review Programs and Pharmaceutical Benefits Management* 70-71 (1994) (on file with the Virginia Law Review Association).

<sup>166</sup> A rough cutoff might be thought to be reached: Only those who benefit by more than the time cost of filling out the forms are likely to pursue the drug. But the cutoff is crude because the costs of filling out the form need bear no relation to the cost of



Worse, while such a strategy can lower the costs of individual insurers, it does so only by displacing the unhealthy onto other insurers and thus cannot lower the costs to society or to insurers as a group. Indeed, risk selection efforts would seem to pose a collective action problem for insurers. They each have an individual incentive to do it, since refraining from doing so will increase their costs no matter what other insurers do.<sup>167</sup> But risk selection does not benefit insurers collectively since it involves effort and cannot lower total insurer costs. The result is not only an absence of true cost-benefit tradeoffs, but inefficiency and a lack of true cost containment as well.

### 3. *The Pathology of Health Care Policy*

A third possibility strikes me as the most plausible. Namely, that we have made no conscious decision at all. Not a decision to achieve cost effectiveness without social effectiveness. Nor a decision to affirm symbolic values while allowing hidden cost-benefit tradeoffs. Rather, we have simply, in different areas of health law, simultaneously pursued conflicting paradigms for allocating health care resources without any meaningful thought about how to coordinate them.<sup>168</sup> The result is not only incoherence but, as discussed in Section II.C.2, outcomes worse than if we had pursued either paradigm consistently and certainly far worse than if we had coordinated them intelligently. Technology assessment, I submit, is yet another reflection of this fundamental pathology of health care policy. It aims to fur-

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the drug. The policy will thus deter the use of some drugs with lower costs even if their benefits exceed their costs, and it will fail to deter the use of other drugs with much higher costs even if their costs exceed their benefits. And whenever the cost of the form *is* incurred, it is a sheer societal waste, for the cost of the drug is still incurred. Most important, the ones who actually fill out the forms are the providers; since they do not benefit from the drug, they will likely take the path of least resistance and order another drug that does not require a form even if it is far less medically *or* socially effective.

<sup>167</sup> If all insurers risk select equally, they will end up with similar risk pools. An insurer who abstains from risk selection will end up with a worse risk pool and higher costs. And if no insurer risk selects, each forfeits an opportunity to lower costs by obtaining a better risk pool than the others.

<sup>168</sup> See Elhauge, *Allocating Health Care Morally*, *supra* note 4, at 1452. This is the central theme of a book-in-progress that I have tentatively entitled "The Pathology of Health Care Policy."

ther goals that make sense in isolation. But it cannot achieve them because it operates at cross-purposes with other health care policies.

### III. PURELY INFORMATIONAL TECHNOLOGY ASSESSMENT

#### A. *The Public Good Argument for Informational Assessments*

Technology assessment might abjure regulation, seeking only to provide reliable information on the actual effects and costs of technology. The Agency for Health Care Policy and Research ("AHCPR") was, for example, set up by Congress to conduct and commission technology assessment research, and any guidelines it produces have, so far, only advisory status.<sup>169</sup> This goal seems undeniably positive.<sup>170</sup> One might, however, wonder why public funding is necessary. Why will the private market not provide this information if it is so valuable? There is a ready answer. Reliable information is a public good. It is costly to create, but once created is costless for others to use, and it is hard to exclude them from doing so.<sup>171</sup> We can thus predict the market will underprovide such information.

Nor would we want to solve the private market problem by giving intellectual property rights akin to patent rights to those who create the information.<sup>172</sup> Doing so would give some persons a monopoly over information about the effects of technologies they themselves did not own and cannot produce and

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<sup>169</sup> See Havighurst, *supra* note 8, at 90-91.

<sup>170</sup> I thus do not claim that informational technology assessment is unhelpful. My point is that *regulatory* technology assessment is unlikely to be helpful. Informational technology assessment is generally helpful, and likely to be increasingly so if we move to a system that allows cost-benefit tradeoffs. See *infra* Part VIII. The question that remains to be addressed, however, is why the actual production of informational technology assessment has been disappointing as described in this Part.

<sup>171</sup> That is, it fits the two technical criteria of a public good: it is (1) nonrival, in that the costs of providing it do not increase the more persons who use it, and (2) nonexcludable, in that others cannot readily be prevented from using it.

<sup>172</sup> Intellectual property rights often solve the public good problem for information by allowing rights holders to exclude others from using the information without paying a fee, thus providing an incentive to create the information in the first place. Neither patent nor copyright law seem applicable here, but the question is whether we would ever want to recognize intellectual property rights for this type of information.

sell. And the first firm to discover the information would have this monopoly even though the creation of the information is fairly straightforward and easily duplicated by others. Such a rule would also be unadministrable, since it would be all but impossible to detect if others have used information about the effects and costs of technology. Unlike making a patented widget, no physical evidence may be left, and any particular use of technology need not mean the user took the patented information. The only administrable form of intellectual property protection would appear to be allowing the firm that created the information to treat it as a trade secret. Indeed, utilization review firms apparently do precisely that with their medical data, selling their proprietary data on condition of confidentiality to many insurance companies, thus ameliorating the public good problem by spreading the cost among those insurers.<sup>173</sup> But such confidentiality inherently limits dissemination of the information, though it is likely to be revealed in any event if the insurer has to defend a suit over coverage denial.<sup>174</sup>

This public good problem means the government can fill a market void by funding the creation and dissemination of reliable assessments of technology. This role may become increasingly important because increased cost-containment and market pressures tend to reduce private research that does not return a profit. Moreover, unlike making cost-benefit tradeoffs, determining what precisely are the effects and costs of various medical technologies on various persons is a purely scientific question that technical personnel can answer.<sup>175</sup>

### *B. The Actual Paucity of Information*

Still, the types of technology assessment we have actually conducted are limited in various ways. First, it has involved less the creation of new information than the processing of existing information.<sup>176</sup> The focus has been on collecting, synthesizing

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<sup>173</sup> Hall & Anderson, *supra* note 10, at 1686 n.180.

<sup>174</sup> See also Furrow et al., *supra* note 10, § 11-10, at 528 (noting that several states require disclosure in certain instances).

<sup>175</sup> Cf. discussion *infra* Part V.

<sup>176</sup> See Susan B. Foote, *Assessing Medical Technology Assessment*, 65 *Milbank Q.*

and distributing existing studies and data, not on conducting new studies to generate new information. In 1982, the Office of Health Technology Assessment ("OHTA") conducted twenty-six full-scale assessments but had actual evidence from randomized clinical trials for only two of them.<sup>177</sup> Likewise, "[a]lthough the FDA reviews evidence accumulated in assessments directed by product sponsors, the agency does not conduct clinical trials of medical products."<sup>178</sup> Nor is the focus on reviewing previously-published work, rather than newly-generated data, limited to the United States. For example, of twenty-one reports currently being prepared by the Swedish Council on Technology Assessment in Healthcare ("SBU"), *none* of them rely primarily upon newly generated evidence from randomized clinical trials ("RCTs").<sup>179</sup> To be sure, an assessment with "meta-analysis" of existing studies is highly useful.<sup>180</sup> It permits the aggregation of data into more statistically significant forms,<sup>181</sup> and it is much less expensive than conducting large-scale clinical trials.<sup>182</sup> Indeed, the focus on such meta-analysis is partly the product of legislative design. Congress explicitly wanted the AHCPR to make existing data more accessible and to use it as a quick and relatively inexpensive approach to filling in gaps in technology assessment.<sup>183</sup>

Nonetheless, the failure of government and research universities to exert more effort to create new technology assessment information rather than processing existing information is disappointing and odd. Private firms have ample incentives to

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59, 60 (1987) (citing David Blumenthal, *Federal Policy Toward Health Care Technology: The Case of the National Center*, 61 *Milbank Memorial Fund Q.* 584, 589-90 (1983) (distinguishing between knowledge processing and knowledge development)).

<sup>177</sup> Institute of Medicine, *supra* note 43, at 5.

<sup>178</sup> Institute of Medicine, *supra* note 43, at 41. See generally Office of Technology Assessment, *supra* note 9, at 132-35 (describing the relatively limited scope of federal technology assessment activities from the 1970s to the present).

<sup>179</sup> See SBU Projects (visited on Nov. 3, 1996), <<http://www.sbu.se/projects.html>>.

<sup>180</sup> Office of Technology Assessment, *supra* note 9, at 59-62.

<sup>181</sup> *Id.* at 60.

<sup>182</sup> See Joseph Lau, Christopher H. Schmid & Thomas C. Chalmers, *Cumulative Meta-Analysis of Clinical Trials Builds Evidence for Exemplary Medical Care*, 48 *J. Clinical Epidemiology* 45 (1995).

<sup>183</sup> See Banta & Luce, *supra* note 14, at vii; Tunis & Gelband, *supra* note 9, at 357.

disseminate valuable information on their own. What they need is a publicly funded actor to create it. Without someone creating the primary information, meta-analysis cannot be done. And meta-analysis is clearly a less reliable way of assessing technologies and treatments than randomized clinical trials.<sup>184</sup> Indeed, the aggregation of primary studies that are often of poor quality can not only make meta-analysis inaccurate but also tends to systematically *overstate* any benefits of the technology or treatment.<sup>185</sup> For example, because studies with positive or statistically significant results are more likely to be written up and published, this bias will turn up in the meta-analysis that aggregates those published studies.<sup>186</sup> Further, if the meta-analysis incorporates nonrandomized studies, it becomes infected with the known bias such studies have of finding a beneficial effect.<sup>187</sup> Such a bias towards finding a positive benefit means technology assessment can make it *more*, rather than less, difficult to make accurate technology management decisions.

In addition, almost no assessments of any kind are done of existing technologies and practices. "Only a small minority of existing technologies have been formally assessed. The emphasis of most agencies until the present has been on newer, capital-intensive technologies . . ."<sup>188</sup> In the United States, the principal regulator of technology is the Food and Drug Administration ("FDA"). It assesses new drugs and novel medical devices before they can be approved for marketing, but conducts and requires few studies once a product is on the market.<sup>189</sup> New medical procedures and treatments require no regulatory ap-

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<sup>184</sup> See Michael J. Domanski & Lawrence M. Friedman, Relative Role of Meta-Analysis and Randomized Controlled Trials in the Assessment of Medical Therapies, 74 Am. J. Cardiology 395 (1994).

<sup>185</sup> Khalid S. Khan, Salim Daya & Alejandro R. Jadad, The Importance of Quality of Primary Studies in Producing Unbiased Systematic Reviews, 156 Archives of Internal Med. 661, 665 (1996).

<sup>186</sup> Office of Technology Assessment, *supra* note 9, at 63.

<sup>187</sup> *Id.* at 44.

<sup>188</sup> Office of Technology Assessment, Health Care Technology and Its Assessment in Eight Countries 343 (1995).

<sup>189</sup> See, e.g., Institute of Medicine, *supra* note 43, at 3, 41, 48; Office of Technology Assessment, *supra* note 9, at 21. In Europe, few devices are regulated at all. See Banta & Luce, *supra* note 14, at 31.

proval at all.<sup>190</sup> The result:

The bulk of all resources allocated for technology assessment is in premarketing tests of drugs for safety and efficacy. . . . [I]nsufficient attention is given to postmarketing studies. Even less attention is paid to evaluating medical and surgical procedures for safety and effectiveness. Among all technologies, existing assessment activities are concentrated on the new technologies and not on those that are widely accepted and possibly outmoded.<sup>191</sup>

This remains largely true today despite AHCPR's focus on evaluating existing technologies and medical practice<sup>192</sup> and a serious increase in outcomes research and practice guidelines.<sup>193</sup> As the Office of Technology Assessment itself recognized recently, "[m]uch, if not most, of existing medical technology and practice has been inadequately evaluated, even with regard to its effectiveness in improving people's health."<sup>194</sup> The problem exists for new technologies, because "a high proportion of newly introduced technologies, even today, are not required to show rigorous evidence of efficacy before they are adopted."<sup>195</sup> And it exists for old technologies because, as of 1995, "[o]nly a small minority of existing technologies have been formally assessed. . . ."<sup>196</sup> Indeed, only ten to twenty percent of current

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<sup>190</sup> See Office of Technology Assessment, *supra* note 9, at 21-22, 130; Banta & Luce, *supra* note 14, at 21 (same true internationally).

<sup>191</sup> Institute of Medicine, *supra* note 43, at 3.

<sup>192</sup> Office of Technology Assessment, *supra* note 9, at 33; see also Banta & Luce, *supra* note 14, at 21 (drawing similar conclusion internationally).

<sup>193</sup> See 42 U.S.C. § 299 (1994) (statute authorizing the creation of the Agency for Health Care Policy and Research to conduct and commission research on the actual outcomes and effectiveness of medical treatments). See generally Furrow et al., *supra* note 10, § 6-2(a), at 240 (noting the development of "clinical practice protocols"); Havighurst, *supra* note 8, at 87-94 (noting the professional and regulatory pressure which has resulted in the rise of the practice guidelines movement during the past ten years); Havighurst, *supra* note 9, at 777-83 (discussing the "movement to specify better standards for medical practice"); William L. Roper et al., Effectiveness in Health Care, 319 *New Eng. J. Med.* 1197 (1988) (describing an HCFA "effectiveness initiative" that includes establishing a Medicare data resource center and developing mechanisms to encourage more effective procedures).

<sup>194</sup> Office of Technology Assessment, *supra* note 9, at 37.

<sup>195</sup> *Id.* at 21. "Many—probably most—new medical technologies need not undergo rigorous review of their effectiveness before being adopted." *Id.* at 90.

<sup>196</sup> Office of Technology Assessment, *supra* note 188, at 343; see also Banta & Luce,

medical practices are substantiated by randomized clinical trials.<sup>197</sup>

Like the relative lack of new information, the paucity of assessments of existing technologies or of either old or new medical procedures is disappointing and odd. The firms that create new drugs and technologies are highly motivated to conduct studies proving the merit of their products, to gain both regulatory approval and market acceptance for the products they sell. It is existing technologies and old and new medical procedures for which information gathering poses the largest public good problem, since there are few private incentives for creating it.<sup>198</sup> It would thus seem that it is there that the government and research universities should focus their technology assessment energies.

Finally, any assessments done on either new or old technologies rarely consider whether their costs exceed their benefits.<sup>199</sup> The FDA assesses only the safety and medical efficacy of new products, not their cost or any cost-benefit tradeoffs.<sup>200</sup> Nor do other agencies do many cost-benefit studies.<sup>201</sup> Even the level of

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supra note 14, at 43 (observing that “relatively little information is available on efficacy and safety, and even less on cost and cost-effectiveness”).

<sup>197</sup> See supra note 43 and accompanying text.

<sup>198</sup> Until recently, it was understood that new medical procedures could not be patented, and Congress has just responded to recent decisions recognizing a process patent for medical procedures by enacting a statute making such patents unenforceable against medical practitioners performing medical activities. See 35 U.S.C. § 287(c) (1996) (added by § 616 of last year’s Omnibus Budget Reconciliation Act). Thus, the owner of a patent on a medical procedure cannot hope to increase patent royalties by disseminating information that increases the use of his unenforceable process patent.

<sup>199</sup> See Office of Technology Assessment, supra note 9, at 108 (“Cost-benefit analysis is not the primary focus of this chapter [titled “The State of Cost-Effectiveness Analysis”], because its need to place dollar values on lives has resulted in disfavor among medical analysts, and it is relatively little used for the direct comparison of particular medical technologies.”); *id.* at 109 (“[V]aluing health and life in dollars—necessary for cost-benefit analysis—was controversial and, some maintained, unethical. As a result, the subsequent emphasis in health care tended to be on cost-effectiveness analysis, . . . rather than on cost-benefit analysis.”).

<sup>200</sup> See Institute of Medicine, supra note 43, at 41, 48.

<sup>201</sup> See *id.* at 3 (“[a]ssessments of cost-effectiveness and cost-benefit are few”); Office of Technology Assessment, supra note 9, at 108-09. See also Agency for Health Care Policy and Research (visited on Nov. 3, 1996), <<http://text.nlm.nih.gov/ftrs>> (clinical practice guidelines); Agency for Health Care Policy and Research (visited on Nov. 3, 1996), <<http://text.nlm.nih.gov/ftrs/tocview/>>

cost-effectiveness analysis (which avoids making cost-benefit tradeoffs) performed by federal agencies “is surprisingly small.”<sup>202</sup> The practice guidelines promulgated by the AHCPR sometimes informally discuss costs, but none has apparently ever been based on formal cost-effectiveness analysis.<sup>203</sup> The Health Care Financing Administration (“HCFA”) once dared to propose regulations allowing it to consider whether a technology is “cost-effective” in deciding whether Medicare should cover it.<sup>204</sup> But it never actually implemented them because of fears about the political reaction.<sup>205</sup> And the research HCFA has funded has tended to focus on the relative cost-effectiveness of preventive care not now covered by the Medicare statute, with the aim of *expanding*, not contracting, the provision of medical services.<sup>206</sup> In other countries, governmental cost-effectiveness analysis has been more serious. For example, in Australia and France, agencies now evaluate the cost-effectiveness of new drugs before permitting government reimbursement.<sup>207</sup> Like

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(independent technology assessment). None of the published reports engages in any formal cost-benefit analysis. The closest they come is stating the average cost of the technology or treatment being assessed, and occasionally (and more recently) pointing out the costs of alternative treatment modalities. Likewise, the Technology Assessment Statements of the NIH tend to stop with a statement of their costs, although in some areas of large apparent benefit the NIH has published figures estimating the savings potential of *adopting* a new technology. See, e.g., NIH Consensus Development Panel on the Effect of Corticosteroids for Fetal Maturation on Perinatal Outcomes, Effect of Corticosteroids for Fetal Maturation on Perinatal Outcomes, 273 JAMA 413, 416 (1995) (noting that the new procedure “yields substantial cost savings in addition to improving health” and detailing the dollar costs). One exception to the above is the Centers for Disease Control (“CDC”), which has done some cost-benefit studies, but the extent of its activity is relatively small. Office of Technology Assessment, *supra* note 9, at 123-24. This may be because CDC activities are more likely to involve “statistical” lives than the “identifiable” lives implicated by acute care, thus posing less of a conflict with the absolutist imperative. *Id.* at 124. See *infra* Part IV.

<sup>202</sup> Office of Technology Assessment, *supra* note 9, at 122, 130; see *supra* introduction to Part II (clarifying distinction between cost-benefit analysis and cost-effectiveness analysis). This may change because of 1992 laws requiring the AHCPR to include cost effectiveness analysis in technology assessments and practice guidelines. Office of Technology Assessment, *supra* note 9, at 2, 122.

<sup>203</sup> See Office of Technology Assessment, *supra* note 9, at 153.

<sup>204</sup> *Id.* at 124.

<sup>205</sup> *Id.* at 124-25.

<sup>206</sup> See *id.* at 124.

<sup>207</sup> See David Hailey, Health Care Technology in Australia, 30 Health Pol’y 23, 31-



their American counterparts, however, they do not delve into ultimate questions of cost-benefit analysis.

Private firms, especially pharmaceutical companies, do now produce more studies than ever before on the cost-effectiveness of new products.<sup>208</sup> But they too have shied away from actually offering cost-benefit tradeoff analysis,<sup>209</sup> and they tend to focus on new products they are trying to market. The result: Even internationally, “relatively little information is available on efficacy and safety, and even less on cost and cost-effectiveness.”<sup>210</sup> Accordingly, “surprisingly little is known about the cost-effectiveness of even well-established health care technologies,”<sup>211</sup> let alone whether they are cost-beneficial. Indeed, some observers believe that “[n]o class of technologies is adequately evaluated for either cost-effectiveness or social and ethical implications.”<sup>212</sup>

### C. The Disincentives to Public Information Creation

Why don't public agencies and research universities do a bet-

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32 (1994); Chris S. Smith, David Hailey & Michael Drummond, *The Role of Economic Appraisal in Health Technology Assessment: The Australian Case*, 38 Soc. Sci. & Med. 1653 (1994); J.P. Moatti, C. Chanut & J.M. Benech, *Researcher-Driven Versus Policy-Driven Economic Appraisal of Health Technologies: The Case of France*, 38 Soc. Sci. & Med. 1625 (1994).

<sup>208</sup> Office of Technology Assessment, *supra* note 9, at 125.

<sup>209</sup> See Institute of Medicine, *supra* note 43, at 5, 41, 48; Office of Technology Assessment, *supra* note 9, at 108-09. For example, technology assessment by the Blue Cross and Blue Shield Association for its member plans considers “only whether the technology improves net health outcomes equal to the alternatives,” not “whether equally effective alternatives are less costly or whether the incremental increase in net health outcomes is justified by the additional costs.” Hall & Anderson, *supra* note 10, at 1660 n.83. See also Office of Technology Assessment, *supra* note 9, at 139 (concluding that Blue Cross/Blue Shield Medical Necessity Program looked only at whether procedures contributed to cost without contributing to quality and that various physician organizations also focused solely on procedures without proven benefits); Furrow et al., *supra* note 10, § 11-10, at 525 (utilization review normally limited to eliminating unnecessary and harmful care). The new Technology Evaluation and Coverage Program of Blue Cross/Blue Shield is more explicitly concerned with cost, see Office of Technology Assessment, *supra* note 9, at 139, but it remains to be seen whether this will be limited to cost-effectiveness rather than true cost-benefit analysis.

<sup>210</sup> Banta & Luce, *supra* note 14, at 43.

<sup>211</sup> See Garber, *supra* note 1, at 123.

<sup>212</sup> Office of Technology Assessment, *supra* note 9, at 21 (emphasis added).

ter job of filling the public good void by creating new data and assessing old technologies and old and new medical procedures? One possible explanation is that politically accountable bodies, because they must run for re-election frequently, are excessively short-term oriented.<sup>213</sup> Governments might thus systematically underinvest in informational studies that take years to complete and whose benefits are garnered over an even longer period of time. Congress did, after all, explicitly direct that the technology assessment it funded use existing data because it offered a relatively quick and cheap way of creating medical information.<sup>214</sup> Legislatures in other nations might have similar incentives to focus on cheap short-term results. Governmental agencies and research universities that rely on public funding might thus not receive it if they undertook the costly and time-consuming creation of new information.

Still, it is not clear why voters would not discount the future appropriately rather than excessively. Moreover, surely public agencies and research universities have some discretionary funds they could devote to this cause. Why don't they? It is a puzzle, but perhaps part of the answer is that even they face a quasi-public goods problem. There is not just one relevant public agency and research university but many, each of which has a limited budget that it is loathe to spend on the costly creation of new information. In the United States, for example, without a dedicated national agency for medical technology assessment, "activities have grownup [sic] into many, probably hundreds, of different public and private organizations."<sup>215</sup> And even nations that do have a dedicated national agency recognize that many agencies in other nations are creating technology as-

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<sup>213</sup> See Linda R. Cohen & Roger G. Noll, *The Technology Pork Barrel* 61 (1991) (observing that research gains more electoral support the earlier the benefits are realized); Morris P. Fiorina, *Retrospective Voting in American National Elections* 20-43 (1981) (noting that voters vote based on already delivered governmental benefits, not those that will be received in the future due to the operation of current governmental programs).

<sup>214</sup> See *supra* note 183 and accompanying text.

<sup>215</sup> Office of Technology Assessment, *supra* note 188, at 343. See also Office of Technology Assessment, *supra* note 9, at 136-38 (listing the seven governmental and thirty nongovernmental organizations that produced technology assessment in the United States in 1988 and noting that over 200 did so by 1995).

assessment information as well. Suppose that the credit each agency or university receives from the public or from politically accountable representatives is the same whether they process existing information or create new information. If so, agencies and universities may try to free-ride off of the technology assessment efforts of each other rather than create new information whose cost would come out of their own budgets.<sup>216</sup>

Of course, while such theories might explain *why* the agencies do not create more useful technology assessment information, they do not justify that failure. The normative lesson remains that they should. But such theories might offer useful lessons for how best to structure public agencies to get them to conduct the right studies. For example, the public goods explanation suggests that perhaps research funds for a particular medical issue should be concentrated in one governmental agency—perhaps even one international agency—so that the option of free-riding on others is not available and so everyone knows who to hold responsible if no new data is created.

Even more interesting is the rarity of studies that simply process and disseminate *cost-benefit* analysis of new technologies. The lack of such publicly funded studies could possibly be explained by the above factors. But it also seems traceable, as Part V discusses, to political problems with medical cost-benefit tradeoffs and the lack of any medical or scientific standards for making such tradeoffs.

#### *D. The Disincentives to the Private Creation of Reliable Information*

Whatever the cause, the lack of much publicly funded cost-benefit assessment is problematic because reliable information of this kind remains underprovided by private industry. Granted, there has recently been an explosion of pharma-

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<sup>216</sup> This may also explain why the most extensive government-directed technology assessment we do see, the one directed by the FDA, takes the form of forcing private firms to conduct the studies out of the firms' budgets before their product can gain regulatory approval. See Institute of Medicine, *supra* note 43, at 2-5, 47-48. The expenditure of FDA budgetary funds on technology assessments is comparatively minimal. *Id.* at 3.

coeconomic studies by major drug manufacturers.<sup>217</sup> This is not surprising since such firms have the most incentives to conduct studies that help them to market or get regulatory approval for new drugs. But there are a number of problems with such studies.

First, they are focused on new drugs that need to be marketed. They thus do not provide the necessary cost-benefit information for old drugs, let alone old or new procedures, treatments, or other technologies.

Second, while these studies often stress the cost-effectiveness of the new drug (spurred by government agencies and purchasers demanding such evidence), they do not generally engage in rigorous cost-benefit analysis. Rather, the usual effort is to show that under some plausible measure (perhaps one that excludes side effects, for example), the health benefits of the new drug are no worse than existing drugs but the cost is much less. These are efforts in salesmanship indicative of a regime that has merely added cost-effectiveness to traditional medical effectiveness criteria, not an effort to provide information about social effectiveness.<sup>218</sup>

The salesmanship aspect of these studies brings us to the third major problem with them. They are widely feared to be unreliable because of the biases of those who produce them. Even without falsifying any data, there is such a wide range of possible ways of reporting and analyzing the health effects and costs of new drugs that the incentives of those who write the studies can matter greatly.<sup>219</sup> Indeed, the concerns became so great that the FDA has established draft guidelines regulating the dissemination of such studies.<sup>220</sup> And the *New England Journal of Medicine* now refuses even to consider a pharmacoeconomic

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<sup>217</sup> See Daniel Green, *Survey of Pharmaceuticals*, *Fin. Times*, Mar. 25, 1996, at 3; Office of Technology Assessment, *supra* note 9, at 125.

<sup>218</sup> See *infra* Part II (noting difference between cost-effectiveness and social effectiveness).

<sup>219</sup> Alan L. Hillman et al., *Avoiding Bias in the Conduct and Reporting of Cost-Effectiveness Research Sponsored by Pharmaceutical Companies*, 324 *New Eng. J. Med.* 1362 (1991).

<sup>220</sup> See Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, *Principles for the Review of Pharmacoeconomics Promotions* (1995).

study for publication if it was infected by such a conflict of interest.<sup>221</sup> The explosion of private studies, in other words, does not mean an explosion in *reliable* information about the costs and benefits of drugs.

Fourth, under health care systems that decline to make cost-benefit tradeoffs, as Part II argues we still have, the overall effect of such studies is to *exacerbate*, not ameliorate, the tendency of new technologies to escalate health care costs. Consider, for example, the case of coronary artery clot-dissolvers.<sup>222</sup> The traditional one used was streptokinase. Genetech then genetically-engineered a new clot-dissolver called tPA. However, initial sales were inhibited by tPA's high cost: \$2,200 per dose compared to \$76-\$300 for streptokinase. In response, Genetech embarked in the late 1980s on a series of clinical trials aimed at quantifying some clinical benefit for tPA. It produced and then disseminated a study showing a mortality benefit of one percent. This was deemed by some a statistically insignificant difference that meant the drugs were equally effective. There was much brave talk of physicians not being willing to order a drug that cost so much more but conferred so little additional benefit. And in 1990 HCFA refused to pay extra for tPA on the grounds that the lower cost clotting agents worked just as well.<sup>223</sup> But notwithstanding a benefit that was dubious and at best low, an enormous cost, the opposition of Medicare, and the difficulties of overcoming the inertia of medical practice, the one percent benefit won out. Sales of tPA rose significantly and came to account for more than three-quarters of the market.

The victory of tPA over streptokinase helps confirm the conclusion of Part II—that despite new cost pressures we have not yet moved to a health care system that encourages cost/benefit tradeoffs. For if we have, why did the profession order tPA when the benefit was understood to be so low? And as long as we live in a system that rejects cost/benefit tradeoffs, the other

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<sup>221</sup> Jerome P. Kassirer & Marcia Angell, *The Journal's Policy on Cost-Effectiveness Analyses*, 331 *New Eng. J. Med.* 669 (1994).

<sup>222</sup> The rest of this paragraph draws on Andrew Pollack, *The Battle of the Heart Drugs*, *N.Y. Times*, June 30, 1991, § 1, at 1, and Genentech Inc.: *When Put Comes to Call*, *Bioventure View*, Mar. 1, 1996, available in LEXIS, News Library, Curnws file.

<sup>223</sup> See Baker, *supra* note 26, at 8.

lesson of the tPA saga will remain true. Even informational technology assessment will have more potential to exacerbate health care cost escalation than to lessen it. Nor is this effect limited to tPA or to studies by pharmacology firms. The General Accounting Office has noted that many congressionally-funded practice guidelines might increase health care spending by increasing the provision of beneficial services not now provided.<sup>224</sup> And the history of medical innovation is replete with examples of technologies that became widely used despite extensive technology assessment confirming their relatively low benefit and high additional cost.<sup>225</sup> Unless the underlying incentive structure creating the problem is reformed, informational technology assessment will often exacerbate cost problems by establishing that some new costly technology has some minor benefit.

This brings us finally to insurers and utilization review firms that provide services to insurers. They now conduct or purchase far more technology assessment than they did as recently as the 1980s.<sup>226</sup> But why don't they conduct or purchase more cost-benefit studies?<sup>227</sup> Their interest would not be limited to new drugs being marketed. And those with large market share would seem to have considerable incentives to collect or disseminate cost-benefit information to make and justify decisions limiting coverage. True, insurers might be biased toward underestimating the benefits of treatments and overestimating their costs, since that would justify more denials of care. But this would not seem much of an obstacle to information development, when the information is being developed by, or sold to, insurers who share that bias. And one might suppose it would

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<sup>224</sup> See Havighurst, *supra* note 9, at 781 n.13.

<sup>225</sup> See, e.g., H. David Banta and Hindrik Vondeling, *Strategies for Successful Evaluation and Policy-Making Toward Health Care Technology on the Move: The Case of Medical Lasers*, 38 *Soc. Sci. & Med.* 1663 (extensive technology assessment of use of lasers for coronary angiography did not slow down their concurrent adoption in clinical practice). See also Office of Technology Assessment, *supra* note 188, at 343 (observing that despite the volume of technology assessment activity in the United States, there is little actual implementation of technology assessment findings).

<sup>226</sup> See Office of Technology Assessment, *supra* note 9, at 135, 141-42.

<sup>227</sup> See *supra* note 209 and accompanying text.

prove important to insurers and utilization review companies to develop market reputations for accuracy. Finally, the problem of new cost-benefit information exacerbating cost escalation where purchasers of care do not trade off benefits and costs would seem less of a problem because the insurers themselves are the purchasers and could make the cost-benefit tradeoffs themselves.

The most likely explanation, reinforcing Part II, is that cost-benefit information has little use in a regime still committed to rejecting cost-benefit tradeoffs. Private firms will only invest in information they can use, and any decision to deny coverage or medical care based on a cost-benefit tradeoff will most likely be found illegal.<sup>228</sup> Such information will not help an insurer trying to defend itself in court or a drug company trying to sell its product. Indeed, the mere possession and consideration of such cost-benefit information might itself be grounds for condemnation, *à la* the famous Pinto case where Ford Motor was held not just negligent but liable for \$3.5 million in punitive damages for consciously weighing the health benefits of a safer fuel tank design against its monetary costs.<sup>229</sup> A regime that permits at best only hidden cost-benefit assessments is unlikely to encourage much information flow on the topic. Thus it is not surprising that, while HMOs and other insurers have technology assessment committees, they explicitly “report that cost and cost-effectiveness are not criteria for acceptance.”<sup>230</sup>

This suggests another lesson. If the government and medical researchers *did* create more information on the cost-benefit tradeoffs of various drugs, that would still do nothing to change the incentives of market participants to use the information. This may be the most powerful explanation for why neither has produced much cost-benefit analysis in their technology assessment. Why produce something no one has incentives to use? Indeed, even cost-effectiveness technology assessment (which has been increasingly produced) has turned out to have little ef-

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<sup>228</sup> See discussion *supra* Part II.

<sup>229</sup> *Grimshaw v. Ford Motor Co.*, 119 Cal. App. 3d 757 (Ct. App. 1981).

<sup>230</sup> Banta & Luce, *supra* note 14, at 43. The closest they come to considering costs is that their selection of which technologies to assess for medical effectiveness tends to focus on those that are highly expensive. *Id.*

fect on actual policy or medical practice.<sup>231</sup> If assessment with this relatively modest deviation from pure medical effectiveness standards goes unused, the prospects for cost-benefit technology assessment are slim indeed.

In short, the potential for even purely informational cost-benefit assessments of technology is dim unless we change the basic incentives that guide the medical industry. We would be far more likely to get the private market to systematically collect and use reliable outcomes data if they had real incentives to trade off benefits and costs. Public goods problems would remain with the creation of such information, which counsels for funding government and medical researchers. But even such entities are unlikely to get fully involved without a more fundamental shift in industry incentives. It is hard to get motivated about publishing papers no one will read.

#### IV. EXCLUDING INNOVATIONS WITH NO NET POSITIVE HEALTH BENEFIT

Regulatory technology assessment need not be aimed at making cost-benefit tradeoffs. A more modest policy aim (modest in terms of regulatory power, not technological difficulty) is to screen out technology that is affirmatively harmful to patients. Somewhat more ambitious is the goal of screening out medically ineffective technology, that is, technological innovations that confer no net benefit on patients even though they do not harm them either.<sup>232</sup> The FDA, for example, judges new drugs and medical devices for both their safety and efficacy even though it does not make cost-benefit tradeoffs.<sup>233</sup> Likewise, HCFA approves a medical innovation for Medicare reimburse-

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<sup>231</sup> See *id.* at 21. Even the most prestigious academic medical centers tend to make technology purchase decisions based on “‘political,’ ‘informal,’ or ‘ad hoc’” criteria rather than systematic technology assessment information. See Saul N. Weingart, *Acquiring Advanced Technology: Decision-Making Strategies at Twelve Medical Centers*, 9 *Int'l J. Tech. Assessment in Health Care* 530, 530 (1993).

<sup>232</sup> Banta & Luce, *supra* note 14, at 1 (explaining that although one purpose of technology assessment is figuring out whether the benefits of a technology are worth its cost, the main purpose is to assure that the technology is safe and has a health benefit).

<sup>233</sup> 21 U.S.C. § 355(d) (1994); 21 U.S.C. § 360d(a) (1994); Institute of Medicine, *supra* note 43, at 41.



ment only upon "authoritative evidence . . . that it is safe and effective."<sup>234</sup> On both safety and efficacy, there is some claim to medical and scientific expertise that makes the venture hopeful. But even here there is reason to doubt any governmental agency can make such decisions effectively.

*A. The Difficulty of Determining When Given Effects Constitute a Net Health Benefit*

When an innovation confers no medical benefit at all on anyone, the matter is relatively easy. However, most medical innovations produce a mixture of beneficial and harmful effects, or at least the risk of harmful effects.<sup>235</sup> The innovation might relieve pain, but have the side effect of producing drowsiness; it might remove a disability, but have the side effect of creating pain; it might lower the risk of death, but have the side effect of increasing disability. Weighing one against the other is not really a scientific question, and different patients will vary in how they value different effects. The patient who is an avid athlete, for example, may be willing to take greater risks to repair a torn rotator cuff than a non-athlete. Similarly, the risk of death may be less important to a ninety-year-old than to a thirty-year-old. Such valuations do not submit to objective scientific determination. Moreover, such medical benefits and adverse effects usually come not with certainty but with differing uncertain probabilities. And different patients might rationally have different aversions to risk. These difficulties help explain

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<sup>234</sup> Gordon B. Schatz, Medicare Coverage of Technology, HealthSpan, July 1987, at 9 (citing Part A Intermediary Letter 77-4 and Part B Intermediary Letter 77-5), reprinted in Havighurst, supra note 50, at 1277-78 (1988). Unlike FDA review, this standard applies to new medical techniques as well as to new drugs and devices. Some scholars believe that, like the FDA, HCFA lacks statutory authority to make cost-benefit tradeoffs, see Schatz, supra, at 9. However, one might try to locate such authority in the statute authorizing reimbursement only for services that are both "reasonable and necessary." 42 U.S.C. § 1395y(a)(1) (1994). See supra notes 89-95 and accompanying text.

<sup>235</sup> See, e.g., Schwartz & Joskow, supra note 153, at 1462 ("some innovations offer the patient nothing of value. . . . [but] as is more usually the case, technology does produce benefits but also carries with it noteworthy risks"); Office of Technology Assessment, supra note 9, at 20 (noting that definition of efficacy and safety is "whether, under at least some conditions, the technology provides a health benefit that outweighs any attendant risks").

why technology assessment often limits itself to the question of whether the new device does what its maker claims rather than examining whether those effects are, on balance, beneficial.<sup>236</sup>

Granted, there are various techniques for surveying patients to assess which outcomes have an expected positive net health benefit. One might, for example, determine whether the treatment increases or decreases net Quality Adjusted Life Years ("QALYs"). Such QALY figures can be arrived at by asking patients questions such as: "How much shorter a life would you be willing to live if, in exchange, you would no longer have your current condition?" Similar questions might be posed to persons about choices between two conditions they do not have, or by observing the risks they are actually willing to undergo in daily life. But using QALYs is controversial, and there are many other possible metrics for assessing the importance of positive and negative health effects.<sup>237</sup> Indeed, even if one is committed to using QALYs, there is considerable controversy about how to calculate them and different methods produce significantly different conclusions.<sup>238</sup> Even if we could collectively resolve these disagreements, using one measure "implicitly assumes that it is average group values, and not individual values, that are important."<sup>239</sup> What right do we have to impose any one measure, based on an aggregated study, on every individual when each person might reach a different conclusion?<sup>240</sup>

An additional problem is that, even assuming we could agree on a common metric, individual responses under that metric could be aggregated in many possible ways. The choice among

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<sup>236</sup> See Michael Jastremski et al., *A Model for Technology Assessment as Applied to Closed Loop Infusion Systems*, 23 *Critical Care Med.* 1745 (1995); William J. Sibbald & Kevin J. Inman, *Problems in Assessing the Technology of Critical Care Medicine*, 8 *Int'l J. Tech. Assessment in Health Care* 419 (1992).

<sup>237</sup> See Elhauge, *Allocating Health Care Morally*, *supra* note 4, at 1493-1526.

<sup>238</sup> See Office of Technology Assessment, *supra* note 9, at 115, 119.

<sup>239</sup> *Id.* at 120.

<sup>240</sup> See Elhauge, *Allocating Health Care Morally*, *supra* note 4, at 1524-26 (arguing that such centralized medical rationing is hard to justify morally). See also Office of Technology Assessment, *supra* note 9, at 120-21 (collecting studies showing that average patient preferences often differ from those of nonpatients and that an individual's preferences can differ enormously from those of other individuals and the average response of the group).

methods of aggregating votes is not obvious, yet each generally produces a different conclusion.<sup>241</sup> Even the choice between using a mean and a median can have a profound effect. And since every measure seeks to aggregate preferences collectively, each is subject to the problem that it necessarily violates the rationality conditions set forth in Arrow's Impossibility Theorem.<sup>242</sup> The result is that aggregation produces not one collective view but many possible ones. The choice of any one of the possible aggregations reflects the imposition of the chooser's normative views on the set of individual preferences we seek to aggregate.

Further, the accuracy of survey data seems dubious. Can patients accurately gauge how much they would value or disvalue conditions they do not have? Do they have incentives to accurately reveal their assessment of the value or disvalue of conditions they do have? While this undermines technical surveys, it may help bolster the claim for medical expertise. Medical practitioners can plausibly claim that, having seen many patients suffer through various conditions and have varying degrees of satisfaction and regret with the treatment decisions made, the practitioner can make a sound judgment about when a net medical benefit has been conferred. There is something to this claim. Perhaps the art of medicine can confer answers where pure science cannot.

The claim of medical expertise is undermined, however, by evidence that assessments of medical benefit differ widely across physicians and may simply reflect values different than those patients hold.<sup>243</sup> And some of the particular measures used by the

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<sup>241</sup> See Elhauge, *Allocating Health Care Morally*, supra note 4, at 1524-25.

<sup>242</sup> See Kenneth J. Arrow, *Social Choice and Individual Values* (2d ed. 1963); see also Einer R. Elhauge, *Does Interest Group Theory Justify More Intrusive Judicial Review?*, 101 *Yale L.J.* 31, 101, 108-09 (1991) (summarizing Arrow's Theorem and stressing its applicability to *any* system for collectively aggregating preferences).

<sup>243</sup> See Office of Technology Assessment, supra note 9, at 120; Nick Black et al., *Do Doctors and Patients Disagree? Views of the Outcome of Transurethral Resection of the Prostate*, 7 *Int'l J. Tech. Assessment in Health Care* 533 (1991); see also Elhauge, *Allocating Health Care Morally*, supra note 4, at 1509 n.185 (collecting studies that have found physicians' assessments differ widely in their assessments of the quality of life for the same patients, and from those of the patients themselves); supra note 41 (noting widespread variations in actual medical practice). Even more worrisome, there is some evidence that physician convenience affects the use of technology in a way unjustified by the benefits to the patients. See Sarah Bouchard et al.,

medical profession seem positively wrong-headed. For example, treatments are often judged effective or ineffective based on whether the percentage of patients who go on to live five years meets a certain threshold. When this measure is actually used, it implicitly makes the following five dubious value judgments: (1) living less than five years has no value; (2) life beyond the five-year threshold confers no additional value; (3) quality of life has no relevance; (4) the lives of patients below the threshold percentage have no value; and (5) the lives of patients beyond the threshold percentage confer no additional value.<sup>244</sup> Of course, the most reflective physicians recognize this problem, and know both that any such metric leaves a lot out and that one must at least examine the whole survival curve rather than such single-figure metrics.<sup>245</sup> Heated debates often ensue about which figure is most relevant given the full survival curve. But at the end of such debate, one single-figure metric or another is usually chosen despite its flaws because it is easier to use than a full curve. Even full survival curves have their limits. Unless one lies completely within the other, there are no scientific grounds for concluding one is "better" than the other even if survival is the only goal. And even if such grounds did exist, the survival curves would still leave out all quality of life considerations. There remains no scientific standard for judging that.

*B. Variations in Effect between Drugs, across Patients and Uses, and over Time*

Even if we knew how to find a net health benefit, difficulties would remain. What regulators should really be looking at in assessing the safety and efficacy of a new medical product is

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Technology Assessment in Laparoscopic General Surgery and Gastrointestinal Endoscopy: Science or Convenience?, 110 *Gastroenterology* 915, 922 (1996) (noting that when a change in gallbladder surgery method made doing the associated cholangiograms more difficult, many doctors stopped doing them routinely despite the lack of any medical evidence to suggest cholangiograms had become any less medically beneficial).

<sup>244</sup> I expand here on Elhauge, *Allocating Health Care Morally*, *supra* note 4, at 1495 (citing Alan Williams, *Cost-Effectiveness Analysis: Is It Ethical?*, 18 *J. Med. Ethics* 7, 10 (1992)).

<sup>245</sup> A full survival curve plots the percentage of patients living month by month after the treatment in question.

whether it is *relatively* safe and effective compared to the alternatives. A drug may look safe when viewed in isolation but would nonetheless be unsafe if another drug can confer precisely the same medical benefit at the same cost with fewer or less serious side effects. And a medical device considered effective compared to nothing is actually ineffective if another device can confer a greater medical benefit without any difference in cost or side effect. But in fact the FDA generally approves medical products without considering relative safety and efficacy.<sup>246</sup> Perhaps the reason is that, unless it were willing to preclude the entry of all *cheaper* medical drugs and devices with worse side effects or lower efficacy, the FDA would have to engage in cost-benefit tradeoffs it lacks any capacity to make.<sup>247</sup>

Further, no technology is safe and efficacious for all patients and uses. It is particular applications that either are or are not safe and effective. The same medicine or treatment can have different effects among patients depending on their severity of illness and what other illnesses they have.<sup>248</sup> A technology may be safe and effective when used by a highly skilled specialist but not by a general practitioner. But although *use* regulation is sometimes stated as a goal of technology assessment, in fact there is little of it. For example, although the FDA regulates the entry of new drugs and medical devices, it does not effectively regulate their post-entry clinical use.<sup>249</sup> Once it approves a medical product, it does not disapprove particular uses. Nor is it easy to imagine the FDA or any agency effectively regulating all uses of medical care. That would call for detailed, case-specific

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<sup>246</sup> See Institute of Medicine, *supra* note 43, at 41 (“sponsors . . . are not required to show safety and efficacy relative to similar products”); Office of Technology Assessment, *supra* note 9, at 90 (of those new technologies “reviewed for their effectiveness, most need not prove that they are actually more effective than other alternative technologies already on the market”); see also David Henry & Suzanne Hill, *Comparing Treatments: Comparison Should Be Against Active Treatments Rather Than Placebos*, 310 *Brit. Med. J.* 1279 (1995) (British regulators also do not judge effectiveness relative to existing products).

<sup>247</sup> See *infra* Part V.

<sup>248</sup> See, e.g., Schwartz & Joskow, *supra* note 153.

<sup>249</sup> See Institute of Medicine, *supra* note 43, at 48, 50. See also Office of Technology Assessment, *supra* note 9, at 21 (“a technology, once introduced, is frequently used in circumstances that are quite different from those in which it was first shown to be efficacious”).

information that no centralized government agency could ever hope to process, let alone process quickly enough to make timely medical decisions.<sup>250</sup>

Nor, for that matter, does the FDA conduct or require much testing of any new drug once it is allowed in the market.<sup>251</sup> This is problematic. Further testing after the product's widespread marketing might discover new data that could change conclusions about the technology's safety or efficacy. This is particularly likely, since premarketing studies are: (1) relatively short-term, thus missing long-term effects; (2) carried out by top specialists who are likely to enjoy more success than the average practitioner who will use the technology once it becomes widely available; and (3) limited to small patient groups that exclude many of the kinds of patients who ultimately receive the drug.<sup>252</sup> The drug might also come to be used in ways not contemplated when initially approved. Moreover, even if the data on the approved technology has not changed, the introduction of *other* new technologies may change our conclusions. The drug considered safe and effective today should be considered unsafe and ineffective if a new drug with the same cost can confer a higher medical benefit with lower side effects. Unfortunately, the administrative problems of continuing to update information about the relative safety and efficacy of all medical products are likely to prove insuperable.<sup>253</sup> Controlling initial entry may thus rationally seem the most feasible means of regulation. But it falls far short of what would truly be necessary to achieve even this minimal regulatory goal.<sup>254</sup>

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<sup>250</sup> Cf. *infra* Part VI.

<sup>251</sup> See Institute of Medicine, *supra* note 43, at 48.

<sup>252</sup> *Id.* at 47-48.

<sup>253</sup> The FDA does do a few postmarketing studies but far less than the large number of premarketing studies. *Id.* at 48.

<sup>254</sup> See Banta & Luce, *supra* note 14, at 4-5 (noting that the informational demands of collecting information on the relative effectiveness of alternative technologies at each stage in its life-cycle makes a complete system of technology assessment impossible).

*C. The Incentives of Regulators*

Finally, it is not clear the FDA or any other government agency has the right incentives in evaluating the safety and efficacy of medical innovations.<sup>255</sup> Injuries that result from an approved medical product are politically salient and easy to trace to the approver. They affect identifiable individuals who know they used the medical product and know whom to blame. Injuries that result from the nonuse of unapproved medical products are far less salient and much harder to trace back to the responsible agency. They affect statistical individuals who may not even know the medical product existed. And injuries that result during delays in the approval process are even harder to blame on regulators because they can always plausibly say that further investigation was necessary. But such injuries from the inability to use new medical products (even just during some delay period) are nonetheless equally real and worth taking into account, especially when the delay period stretches out (as it has) to seven to ten years.<sup>256</sup> And the costs of such extensive FDA review—some \$287-500 million per drug<sup>257</sup>—not only raises their prices but discourages the entry of drugs for uncommon diseases. Again, these costs and deterred entry are something an agency has little incentive to take into account.

Unfortunately, even if the forgone benefits of the new drug or device likely exceed the expected harm, the above factors mean that any agency would have incentives to disapprove them or delay their approval until they can conduct enough studies to eliminate the risk of getting blamed for adverse effects. This same analysis helps explain why agencies do few post-marketing studies. Such studies may further the goals of safety and effectiveness. But politically they can only reveal that the agency made a mistake in allowing the medical product to enter the

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<sup>255</sup> See, e.g., Henry G. Grabowski & John M. Vernon, *The Regulation of Pharmaceuticals: Balancing the Benefits and Risks* (1983).

<sup>256</sup> See Banta & Luce, *supra* note 14, at 29.

<sup>257</sup> See Joseph A. DiMasi, *Trends in Drug Development Costs, Times, and Risks*, 29 *Drug Info. J.* 375, 377 (1995) (\$287 million); letter from Peter Hutt, former Chief Counsel, FDA (1971-75), to Professor Einer Elhauge (Apr. 22, 1996) (on file with the Virginia Law Review Association) (upcoming industry study likely to put figure at near \$500 million).

market initially.

Given the enormous difficulties in deciding when new technologies have a net health benefit as well as agencies' distorted incentives in deciding the matter, it is worth asking why we want a governmental agency making such determinations at all. The answer under the old regime of fee-for-service medicine seems clear. Providers had an incentive to use expensive new technologies whether they were safe and effective or not. To be sure, professionalism should have led to the voluntary refusal to use such technologies no matter how much they increased profits.<sup>258</sup> But in fact medical practice has often experienced the widespread adoption of innovations later shown to carry net negative impacts on health outcomes, such as universal electronic fetal monitoring, routine episiotomies, radial keratotomy, DES (diethylstilbestrol), and many others.<sup>259</sup> This should not be so surprising even if we assume the best intentioned of professionals. Scientific and professional judgment is not perfect. There is an excitement to new technology. Consumers often irrationally demand new technologies that have no demonstrable benefit.<sup>260</sup> And it is easier for a professional's judgment to be affected (even if subconsciously) by novelty, consumer demand and the manufacturer's claims about the new product's effectiveness if using the new product also increases the professional's income. Moreover, professional self-regulation often involves enforcement of professional norms against wayward or simply mistaken providers. Thus, for most of its history, the regulatory screening of unsafe and ineffective medical products could best be understood as an important means of enforcing

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<sup>258</sup> See *supra* Section II.A.

<sup>259</sup> See Banta & Luce, *supra* note 14, at 3; David A. Grimes, *Technology Follies: The Uncritical Acceptance of Medical Innovation*, 269 *JAMA* 3030 (1993); Office of Technology Assessment, *supra* note 9, at 20 (noting that DES not only was found to be harmful but turned out to be ineffective at its supposed function, preventing miscarriages); see also *id.* at 1, 28-33 ("evidence has been slowly accumulating that suggests that even well-accepted and very common technologies, such as routine chest x-rays, can be ineffective").

<sup>260</sup> See A. Mark Fendrick & J. Sanford Schwartz, *Physicians' Decisions Regarding the Acquisition of Technology*, in *Adopting New Medical Technology* 76-78 (Annetine C. Gelijns & Holly V. Dawkins eds., ch. 5, 1994); Banta & Luce, *supra* note 14, at 55-56.



professional norms under a fee-for-service regime.

But what are we to make of such regulatory review under the new regime of prepaid medicine and cost containment? Even under the interpretation given in Section II.B, medical providers have full incentives to minimize costs to the extent they can do so without denying beneficial care. Such a system thus creates little incentive for providers to use costly technologies that are harmful or ineffective. To be sure, providers might be duped by disreputable drug and device makers making false claims. But these are knowledgeable purchasers who have incentives to demand real proof of effectiveness before they spend money on any medical product.

The shift to a cost-minimizing medical regime thus suggests that the goal of eliminating unsafe and ineffective medical technology will be far less important in the future. The main remaining purpose might simply be certification and convenience: having a single skilled body to which manufacturers can turn for verification of their product's safety and effectiveness, thus avoiding duplicative and costly efforts to prove it to each buyer. But this in turn suggests the regulatory approval should be optional, rather than mandatory. It also suggests that manufacturers should be able to market their medical products to knowledgeable buyers pending a regulatory decision.

#### V. NO REGULATORY EXPERTISE OR INCENTIVES TO TRADE OFF BENEFITS AND COSTS

Since merely keeping unsafe and ineffective medical technology off the market does little to curb health care cost escalation,<sup>261</sup> it is not surprising that a hot issue is whether medical technology assessment should try to exclude new products that are not cost beneficial. Making such cost-benefit tradeoffs conflicts with the absolutist medical imperative.<sup>262</sup> Nonetheless, because the increase in costly new technologies with small marginal benefits has helped undermine professionalism by increasing its societal cost,<sup>263</sup> curbing new technologies can also

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<sup>261</sup> See discussion *supra* Section II.C.

<sup>262</sup> See *supra* Part II for a description of the absolutist paradigm.

<sup>263</sup> See discussion *supra* Section II.A.

be understood as a last ditch effort to save professionalism as a viable process of decisionmaking. The hope is that professionals could continue to comply with professional norms by getting the maximum health benefit out of the technology available to them, while bureaucrats achieve the necessary cost containment by limiting the new technology available to the professionals.<sup>264</sup>

*A. The Theoretical Problems with Cost-Benefit Regulation of Medical Innovation*

The first problem with this strategy is that technology regulators are unlikely to actually weigh health benefits against monetary costs. To see why, let's break down the possible regulatory strategies. The first strategy would be to vest the regulatory decision with relatively politically-insulated technical experts. Regulators with medical expertise would seem a logical place to begin. But are they likely to be capable of making cost-benefit tradeoffs? They may have some expertise in gauging likely health effects, but nothing in their education prepares physicians for putting a value on health improvements that allows those improvements to be compared on a common metric with monetary costs. Worse, cost-benefit tradeoffs run against everything physicians have been taught and are contrary to the professional ethics in which they have been steeped.<sup>265</sup>

A second strategy, then, would be to staff our regulatory boards with nonmedical scientists. They might lack some expertise about the likely real world effects of various technologies in practice, such as patients who do not always follow directions and physicians who are not always experts. But nonphysician

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<sup>264</sup> See Charles Fried, *Rights and Health Care—Beyond Equity and Efficiency*, 293 *New Eng. J. Med.* 241, 243-44 (1975) (arguing that bureaucrats and physicians have different ethical duties: Bureaucrats can ethically limit the resources available to physicians but medical ethics forbids a physician to deny any beneficial care he can provide to his patients with whatever resources the bureaucrats make available).

<sup>265</sup> See *supra* Section II.A; Henry D. Royal, *Technology Assessment: Scientific Challenges*, 163 *Am. J. Roentgenology* 503, 506 (1994) (“In the future, clinical excellence will be defined as doing more to give patients ‘better value.’ . . . [But] [h]ow are we to measure value?”); Schwartz & Joskow, *supra* note 153, at 1463 (“Asking doctors to make [technology assessment] decisions by balancing dollars against improved quality or length of life introduces a demand totally alien to [physicians’] current training and philosophy.”).

scientists have the advantage of not having been indoctrinated into the belief that all beneficial care should be provided. Still, they would face an insuperable barrier. They, too, have no scientific basis for weighing monetary costs against health benefits. The reason is simple: None exists. Deciding whether the health benefits of some technology are worth the monetary costs requires putting a subjective valuation on both that in no way derives from any scientific method.<sup>266</sup>

For that matter, deciding whether the benefits of *any* product are worth the money, that is, the opportunity cost of giving up other products we could buy with that money, does not rest on scientific judgment. For ordinary economic products, it rests on the preferences revealed by the decentralized decisions of consumers. For products bought by the government, it rests on tradeoffs made in our political process. Those processes are capable of making open-ended tradeoffs of benefits and costs. The scientific method is not.

The results can sometimes be comical. Consider certificate of need ("CON") regulation, a form of technology assessment that required regulatory approval not of a technology's entry into the market in general, but of its purchase by a particular provider. The motivation for such regulation was also cost containment, coupled with the rationale, sometimes called Roemer's Law, that physicians and hospitals could induce their own demand to utilize fully any technology they bought.<sup>267</sup> But the regulators had a problem. By what scientific standard can one decide whether a technology is "needed"? Lacking any realistic alternative, the regulators largely looked to whether the present or projected utilization of the technology required the additional equipment.<sup>268</sup> But basing such decisions on utilization conflicted with the whole Roemer's Law rationale for the review in the first place!

One might accordingly adopt a third regulatory strategy in-

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<sup>266</sup> See Banta & Luce, *supra* note 14, at 2 (technology assessment can provide information to help make technology decisions but cannot "determine the decision made").

<sup>267</sup> See Havighurst, *supra* note 50, at 930-32.

<sup>268</sup> See, e.g., *Sinai Hosp. v. Maryland Health Resources Planning Comm'n*, 509 A.2d 1202, 1204-05 (Md. 1986).

stead: Make the regulators politically responsive. This has already happened to some extent. For example, Congress has tried to make AHCPR more politically representative by appointing members representing a variety of interests to the panels that adopt practice guidelines.<sup>269</sup> Likewise, some commentators have complained about the lack of public participation in HCFA coverage decisions and have proposed procedures to require more extensive consultation with interested parties.<sup>270</sup>

Will such a strategy work? Not likely. To begin with, interest group theory allows us to predict that small groups with concentrated interests are far more likely to participate in any political process than large groups whose members are only diffusely interested.<sup>271</sup> Three groups are likely to lobby on behalf of new technologies even if their benefit is less than their cost: (1) product manufacturers who want to make the new technology; (2) physicians and hospitals who want to use it; and (3) patients who want to receive it. All are relatively small groups whose members have relatively high individual stakes in the issue. On the other side are the persons who will ultimately pay for the excessively costly technology: (1) taxpayers and (2) insured persons.<sup>272</sup> They are exactly the sort of large diffuse group one never sees represented at agency hearings.

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<sup>269</sup> See Havighurst, *supra* note 8, at 90-91; Havighurst, *supra* note 9, at 786-87; Office of Technology Assessment, *supra* note 9, at 145.

<sup>270</sup> See, e.g., Eleanor D. Kinney, National Coverage Policy Under the Medicare Program: Problems and Proposals for Change 833, 894-95 *in* 2 Administrative Conference of the United States: Recommendations and Reports (1987); Schatz, *supra* note 234, at 1277.

<sup>271</sup> See Elhauge, *supra* note 242, at 35-44.

<sup>272</sup> One might think insurance companies would lobby against overly expensive new technology, but as long as it applies to all insurers equally they have little incentive to do so. They can pass on the cost, and the new technology effectively increases the amount of their business. There are also probably enough different insurers that they would not form nearly as cohesive a group as their opponents.

Employers who pay health insurance costs would seem to be another possible lobbying group, and indeed they have been the most active. But they remain a large and diffuse group that is much harder to mobilize than their opposition on this issue. Nor are employers as highly motivated, because they can pass the cost of health insurance on to their employees in the form of lower wages. Their motive is thus more marginal: a desire not to suffer the inefficiency cost of underutilizing labor relative to capital. And even this may be offset by the government tax subsidy for wages that are paid in the form of health insurance.

Exacerbating this tendency is the fact that denials of beneficial technology are likely to be much more politically salient than the costs of allowing it.<sup>273</sup> Denials will often produce identifiable individuals who provide the news media with a good dramatic story as they go on television to complain about the medical injury they are suffering because a stingy public official will not approve the technology they need. The costs of allowing such technology, on the other hand, are merely statistical, too dull for television and too obscure to be readily understood. The combined effect is that politically responsive regulators—or the legislators who supervise them—will see all the political gain in voting to allow new technology with net health benefits and none in denying it. They thus have political incentives to approve any beneficial new technology even if its benefits do not exceed its costs, especially when the technology assists the sort of acute care that creates identifiable patients.

*B. The Actual Paucity of Cost-Benefit Regulation of Medical Technology, and the Real Lesson of the Oregon Experiment*

I was unable to find any instance where a federal agency deliberately rejected a more beneficial medical treatment because it cost more than a less beneficial treatment. Occasionally agencies like the Department of Defense engage in cost-effectiveness analysis, choosing a cheaper medical product if it is just as beneficial.<sup>274</sup> Decision-makers at more politically vulnerable agencies, like Medicare administrators, shrink even from making such pure cost-effectiveness decisions.<sup>275</sup>

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<sup>273</sup> Political saliency may also distort decisions to allocate health care resources. In particular, politicians are likely to divert resources towards matters that are relatively easy to measure and report and away from others that are harder to measure but may offer a greater health benefit. For example, the media attention to hip replacement waiting periods in the British National Health Service, which are relatively easy to measure, seems to have led the government to devote far more resources there. But it may come at the expense of a general degradation on the quality of other care that is more difficult to measure and discern.

<sup>274</sup> See Pharmacoeconomic Analysis of Typhoid Vaccines, PEC Update, Jan. 19, 1996 (also available at PEC Update (visited Nov. 19, 1996) <[http://www.ha.osd.mil/pec/pec\\_upda.html](http://www.ha.osd.mil/pec/pec_upda.html)>) (switching to a cheaper vaccine with the exact same typhoid prevention rate).

<sup>275</sup> See *supra* text accompanying notes 204-05.

Nor is this general tendency rebutted by the much-ballyhooed Oregon Medicaid program. After making an initial decision to fund maternity care instead of organ transplants, Oregon embarked on a more systematic effort to expand the number of persons covered by Medicaid by limiting the categories of services covered.<sup>276</sup> A state commission considered cost-effectiveness data, surveyed public valuations of different health outcomes, held public hearings, and then proposed a priority list of the services the state would cover.<sup>277</sup> It then estimated how much it would cost to provide each service and kept including services until it reached the point on the list when the budget ran out. Every service below that point on the priority list was excluded. Does this prove the government can effectively make the cost-benefit tradeoffs necessary to contain our health care costs?

I think not. First, we must remember that the Oregon plan is famous precisely because it is so anomalous. Its willingness to consider costs and cut off beneficial care does not in any way typify the mainstream even of state Medicaid decision-making, let alone government health policymaking in general.

Second, the situation was the sort that maximizes the government's willingness to consider costs and deny beneficial care. It involved: (1) government funding for a health care program that had a budgetary shortfall; (2) the denial of health care to what from the perspective of the majority of voters were *other* persons, namely those poor enough to be on Medicaid; and (3) the *addition* of health care for other (probably more politically active) voters. The willingness to consider costs and cut beneficial care here thus cannot be extended to government programs that benefit a majority of voters, let alone to regulatory efforts to bar the private provision of overly expensive beneficial care.

Third, the larger political lesson was that, in the end, cost-benefit tradeoffs were stymied in Oregon. Bold initial proposals to prioritize based on the cost-benefit ratios of various treat-

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<sup>276</sup> James F. Blumstein, *The Oregon Experiment: The Role of Cost-Benefit Analysis in the Allocation of Medicaid Funds 1-2* (unpublished manuscript) (on file with the Virginia Law Review Association).

<sup>277</sup> See *id.* at 4-8; Office of Technology Assessment, *Evaluation of the Oregon Medicaid Proposal 4* (1992).

ments were rejected after political opposition arose, and the commission proposal that ultimately resulted ranked services by their net benefit rather than their cost-benefit ratio.<sup>278</sup> The costs of the services did not figure into the presumptive ranking, though costs were considered in an ad hoc fashion when services were moved up and down the ranking.<sup>279</sup> Obviously, one cannot make rational cost-benefit tradeoffs if one focuses on benefits divorced from costs. Instead, such prioritization exacerbates the tendency of the system to focus on providing the highly expensive end-of-life care (such as organ transplants) that Oregon initially wanted to curb. Not surprisingly, then, the Office of Technology Assessment found that the Oregon plan ended up putting a high ranking on last-minute lifesaving measures for terminally ill patients.<sup>280</sup> Worse, because the commission kept moving services up and down the priority list as it received political input, even the "net benefit" of the service had "surprisingly little effect on the final ranking."<sup>281</sup>

Ultimately, even the watered-down proposal that came out of Oregon was struck down by the federal government on the ground that considering the varying capacity of individuals to benefit from health care illegally discriminated against the disabled.<sup>282</sup> As I have shown elsewhere, this effectively smuggles in absolutism under the guise of antidiscrimination law.<sup>283</sup> If the government cannot consider the different capacities of persons

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<sup>278</sup> Blumstein, *supra* note 276, at 4-8; Office of Technology Assessment, *supra* note 277, at 4.

<sup>279</sup> See David C. Hadorn, *Setting Health Care Priorities in Oregon: Cost-Effectiveness Meets the Rule of Rescue*, 265 JAMA 2218, 2220 (1991).

<sup>280</sup> Office of Technology Assessment, *supra* note 277, at 19.

<sup>281</sup> *Id.* at 5.

<sup>282</sup> Blumstein, *supra* note 276, at 9.

<sup>283</sup> See Elhauge, *Allocating Health Care Morally*, *supra* note 4, at 1511-16. I argue there that there is a difference between taking into account (1) conditions that reduce the capacity to improve the health problem under treatment, and (2) conditions unrelated to the capacity to improve the health problem under treatment (but relevant to a general quality of life). The former should not count as discrimination against the disabled, but the latter should. Thus, it should not be considered discrimination against the disabled to allocate scarce surgical resources to a person whose limp can be completely cured over another whose limp can only be partially cured, but it should be considered discrimination to allocate life-saving care to a person without a limp over another with a partial limp.

to have their health problems improved by treatment, then it cannot consider the varying benefits of care in a way necessary to make rational cost-benefit tradeoffs. After all the federal reviews were done, the *only* capacity to benefit that the Oregon plan was allowed to consider was the probability of avoiding death.<sup>284</sup> Thus, the final prioritization was by the ability of the treatment to prevent death, with cost used only as a tie-breaker.<sup>285</sup> This obviously ignores much that is relevant to evaluating the benefits of care. It also makes no cost-benefit tradeoff since services that produce a lower probability of life for much lower cost (and thus potentially for more persons) end up lower on the priority list than much more costly services with a higher probability. And by categorically ranking life-saving above all other goals, the prioritization further exacerbated the focus on last-minute lifesaving efforts for terminally ill patients.

Fourth, even as originally conceived, the Oregon plan did not truly involve the making of cost-benefit tradeoffs. Granted, the very initial plan would have considered the costs and benefits of care in formulating the priority list. Once the list was set, however, benefits and costs became irrelevant. No matter how much a particular patient benefited from a service below the dividing line on the priority list, it would be denied regardless of cost.<sup>286</sup> No matter how little a particular patient benefited from a service above the dividing line on the priority list, it would be provided regardless of cost. The latter means that such a list provides *no effective cost-containment within the covered categories*. This relocates the "Field of Dreams" problem, but does not eliminate it. The open-ended expansion will simply occur within the categories of service above the line on the priority list. In each succeeding year the government will be faced with the following choice: (1) increase the budget to maintain the services covered, which allows the cost spiral to continue; or (2) shrink the list of services covered, which means providing less and less services for the same money.

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<sup>284</sup> Blumstein, *supra* note 276, at 8-9.

<sup>285</sup> *Id.* at 9.

<sup>286</sup> Office of Technology Assessment, *supra* note 277, at 78 (noting that one problem with approach was care would be denied to patients who would receive a higher benefit than other patients whose category of service was ranked higher).



The above sorts of problems apply even when the government seeks to do no more than decide which research projects to fund. Where government funds are scarce, it makes perfect sense to allocate them to technologies that seem likely to provide the biggest spread between likely benefits and costs. Indeed, the government might be expected to provide an important source of funding for cost-cutting research.<sup>287</sup> Unfortunately, there is little evidence that the government does so. In keeping with the dominant absolutist paradigm, the government tends to fund medically beneficial innovation without much regard for its costs.

None of this should be too surprising since it fits perfectly with what Part II shows is the medical effectiveness norm that generally dominates lawmaking in health care. What is surprising is the expectation that things would be any different for regulatory technology assessment. Despite much talk of cost-benefit analysis, in fact such regulatory assessments do little more than try to screen out new machines, medicines or procedures that have dubious health benefits.<sup>288</sup> This allows the regulators to focus on something important while avoiding the hard issue of cost-benefit tradeoffs. It also confirms the pervasive legal framework described in Part II. But it does little to stop our health care cost spiral.

### *C. The Limits of Cost-Effectiveness Regulation*

In reaching the above conclusion about cost-benefit regulation, we must be careful to distinguish what regulators or reform proposals mean when they call for disapproving technologies that are "cost ineffective."<sup>289</sup> This term generally refers not to technologies whose costs exceed their benefits but rather to technologies that produce no greater health benefit at higher cost.<sup>290</sup> The aim of such regulation is not making sure we do not spend more than the care is worth, but rather productive inefficiency: making sure that whatever care we provide costs as little

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<sup>287</sup> See Cutler, *supra* note 2, at 31.

<sup>288</sup> See *supra* Part IV.

<sup>289</sup> See *supra* note 15 and accompanying text.

<sup>290</sup> See Office of Technology Assessment, *supra* note 9, at 108.

as possible. Such a strategy has limited potential since productive inefficiency probably accounts for only a small share of rising health care costs.<sup>291</sup> And even it has proven politically controversial enough to dissuade most federal agencies from engaging in it.<sup>292</sup>

Moreover, there is reason to doubt such regulation can achieve the goal of productive efficiency. The analysis in Part IV can easily be extended to show that there are enormous problems with figuring out what "no greater" benefit might mean, given the likely mix of beneficial and harmful effects and the variation among individuals both in the effects they experience and in their valuation of those effects. Further, how is an agency supposed to predict likely future costs for a product that has not yet been marketed? Those costs would vary with output, demand, labor costs, supply costs, and the method of production the manufacturers ultimately employ. The weight of such costs would, moreover, vary with the discount rate used and the predicted future costs of substitute products. The difficulties are such that, in practice, cost-effectiveness analysis is rarely done correctly. One review found that out of seventy-seven published articles, only three followed six basic analytical principles of cost-effectiveness analysis while most followed no more than three of those principles.<sup>293</sup> And although these principles were long-established, the quality of the studies did not improve over time.

Even if we could get over these technical problems, it is unlikely many new technologies would fit the description of producing no greater benefit at greater cost.<sup>294</sup> And if they did, no one would have much incentive to use them. Even under a traditional absolutist regime, doctors do not change accepted practice for no good reason. They require proof of an actual health

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<sup>291</sup> See *supra* Section II.C.1.

<sup>292</sup> See *supra* Part IV.

<sup>293</sup> See I. Steven Udvarhelyi et al., *Cost-Effectiveness and Cost-Benefit Analyses in the Medical Literature: Are the Methods Being Used Correctly?*, 116 *Annals of Internal Med.* 238 (1992). See also Office of Technology Assessment, *supra* note 9, at 114-15 (discussing this study).

<sup>294</sup> See *supra* note 49.

improvement before changing what has worked before.<sup>295</sup> Physician incentives to refrain from using cost-ineffective technology are even greater if we have moved, as Section II.B argues, to a regime that encourages cost minimization subject to an absolutist constraint. Patients generally have some deductible or co-payment that would discourage them from paying more for the same health benefit. And insurers have strong incentives to monitor and prevent the ordering of expensive technologies that do nothing other than increase costs.<sup>296</sup> Indeed, there is some evidence that makers of drugs and medical devices are starting to shift research toward cost-reducing innovations.<sup>297</sup> But then excluding “cost-ineffective” products through regulation seems unnecessary. It may even be harmful to consumer welfare if it precludes the entry of a new competitor who might ultimately have driven prices down.

#### VI. TECHNICAL PROBLEMS WITH REGULATING THROUGH TECHNOLOGY CONTROLS

Suppose we are able to overcome all the obstacles described in Part V. Pretend that despite the apparent political disincentives and the conflict with pervasive legal norms, the political will exists to allow cost-benefit tradeoffs in health care. Further, assume the physicians and scientists who know most about the effects of medical technology are somehow able, perhaps by bringing in some health economists, to adopt a methodology that yields a common metric for trading off health benefits and monetary costs. Notwithstanding these heroic assumptions, insuperable technical obstacles remain. We can divide these difficulties into various categories.

##### *A. The Difficulty of Assessing Benefits or Costs*

Measuring health benefits is monstrously difficult. Recall all the problems already discussed in Part IV about the difficulty of

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<sup>295</sup> See *id.*

<sup>296</sup> See *supra* Section II.B (describing how insurance companies can minimize costs, subject to the constraint of having to allow the provision of all necessary care).

<sup>297</sup> See Annetine Gelijns & Nathan Rosenberg, *The Dynamics of Technological Change in Medicine*, *Health Aff.*, Summer 1994, at 29, 36-37.

determining whether there even *is* a net health benefit. Those problems continue to apply. But they are multiplied several times over by the need to assess the *magnitude* of the net health benefit at issue. In deciding whether any net health benefit exists, many individual variations (in health condition, valuation of health outcomes, risk aversion, physician skill) can safely be ignored because they are unlikely to alter the bottom line conclusion that some health benefit exists. But *all* such variations must be considered here because they affect the size of the net health benefit. Knee surgery may be beneficial for all persons with a broken kneecap, but much more important to an athlete than to a dedicated couch potato. And while we might be able to reach collective agreement on some measure (such as QALYs) for determining whether any net benefit exists, collectively agreeing on the means of measuring the precise *magnitude* of that net benefit is vastly more disputable and complicated.

Indeed, quite apart from the difficulties of reaching *agreement* on a method for measuring the magnitude of health benefits, the sheer practical problems of collecting the necessary data and analyzing it have meant that technology assessment generally uses life expectancy instead of QALYs.<sup>298</sup> By leaving out quality of life altogether, however, life expectancy obviously ignores much information relevant to measuring health benefits.

Even leaving aside quality of life, life expectancy remains a normatively controversial way of measuring health benefits.<sup>299</sup> If all lives are equally valuable no matter how long they last, then total lives saved might be a better measure than total life-years added.<sup>300</sup> Or if maximizing the number of persons who reach a minimum age is the ultimate goal, then life years added to an older person would be less beneficial than life years added to a younger person.<sup>301</sup> Indeed, these alternative measures provide strong grounds for rejecting QALYs as a “scientific” measure of health benefit even if we could feasibly collect and analyze the

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<sup>298</sup> See Garber, *supra* note 1, at 118-19.

<sup>299</sup> In addition to the problems that follow, we might reasonably care about the shape of the survival curve, see *supra* note 245 and accompanying text, and not just one figure (life expectancy) that tells us the total area under that curve.

<sup>300</sup> See Elhauge, *Allocating Health Care Morally*, *supra* note 4, at 1505-07.

<sup>301</sup> See *id.* at 1512-13.

necessary life-quality information. The choice of any one measure of health benefit is a moral question on which reasonable persons might differ (and have differed).<sup>302</sup>

Costs are also variable and difficult to measure. Economies of scale may mean that the cost of the technology depends critically on a firm's sales and output. Costs will vary depending on the patient, the provider, the price of labor, and the prices of other inputs needed to make or use the technology. The level of monetary costs will be different for each region in which the technology might be used. Further, the present value we attach to any costs incurred in the future will turn on the discount rate used, and there are no normatively uncontroversial grounds for choosing the "correct" discount rate. Worse, assessing the disvalue of any given monetary cost requires an assessment of the opportunity cost of all the other goods that could be bought with the same money. A full understanding would thus require complete information about costs and relative consumer demand for all other goods and services in the marketplace.

#### *B. Variations between Products and over Time*

To achieve true efficiency the regulators would need to know not only whether the technology survives some cost-benefit tradeoff, but whether it offers a better spread between benefit and cost than other possible technologies. *Relative* efficiency is what matters. Thus, we need to multiply all of the above problems by the difficulty of getting the same data for all the alternative technologies that might be used for the same purpose.<sup>303</sup>

Even if regulators can get the initial cost-benefit assessment right, it may quickly change with the passage of time. Any conclusions reached about the magnitude of benefits would have to be continually updated—a mind-bogglingly difficult task.<sup>304</sup> The

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<sup>302</sup> See *id.* at 1508-10, 1524-26.

<sup>303</sup> Such difficulties no doubt have been at least one reason why the AHCPR's practice guidelines have not included assessments of the relative cost-effectiveness of alternative interventions. See Office of Technology Assessment, *supra* note 9, at 154. And that question, while enormously complicated in its own right, is much easier than trying to assess relative social effectiveness.

<sup>304</sup> See Office of Technology Assessment, *supra* note 9, at 21 (noting that "[n]either providers nor patients can be certain that a treatment used for a new population or in

net benefits of the technology may change. It might be employed for uses different than originally foreseen. The attitudes or health condition of the population may change. Physician or hospital skill in using the product may change for the better or worse. And further technological innovation can quickly change the accuracy of any past decision.

Technological costs change with shifts in demand, changes in input prices, and regional spread. They may also decrease over time as output increases or as technology changes. In the early 1970s, my grandfather bought one of the first calculators marketed to consumers. He paid over \$2,000. It performed the same functions a \$10 calculator does today. But the calculator technology was worth pursuing even though the initial calculators were hardly worth their cost for many persons.<sup>305</sup> And regulators would have to keep up with changes not only in the costs of the technology in question, but of all alternative technologies as well. Worse, they would have to keep up with all changes in other markets that affect the opportunity cost forgone by a monetary cost expenditure.

### *C. The Inevitable Imprecision of Entry or Use Regulation*

The sort of entry controls normally used by technology assessment pose an all-or-nothing problem. Suppose, for example, that regulators approved the entry of new technology whenever its cost was exceeded by the *biggest* benefit it could produce. Such an approach does nothing to restrain the use of such technology for other lower benefit uses. If *some* uses of a device are more valuable than its cost, it will get approved under this test even if most of its uses are not cost beneficial.<sup>306</sup> This does little to slow the health care cost spiral.

We might try to eliminate this problem by allowing the entry

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a new setting will actually have the same risks and benefits as those shown in the initial efficacy studies").

<sup>305</sup> Of course, it might not have been worth pursuing in a system that reimbursed for any beneficial purchase of calculating power. But that merely reinforces my point: The problem is the underlying incentive structure, not the free entry of technology.

<sup>306</sup> Indeed, it will be approved even if many uses confer no net benefit at all. See Banta & Luce, *supra* note 14, at 3 (CT scanners were undeniably beneficial for some problems but came to be used where little benefit resulted, such as for a chronic headache).

of new technology only if *all* its uses conferred benefits exceeding its costs (problems identified in Sections VI.A and VI.B would of course still remain). But such draconian regulation would deprive us of new technologies that *normally* are highly beneficial. For example, cardiac catheterization on average produces substantial decreases in mortality; yet the marginal person receiving it gains no health benefit at all.<sup>307</sup> Entry controls can eliminate the latter effect only by denying cardiac catheterization to everyone.

Surely there must be a happy medium, you say. Suppose regulators made decisions based on whether the *average* benefit of the technology exceeded its average cost. This sounds good in the abstract, assuming we can get over the enormous practical problems of predicting what the average use, effect and cost will be. But the deeper conceptual problem is that such a rule would preclude new technology even when *some* of its uses do confer benefits in excess of costs on a subset of patients.<sup>308</sup> Why would we want to do that? Cost increases *per se* are not bad—only cost increases that exceed benefits.

Moreover, suppose a new technology passed an average cost-benefit test. Once approved, nothing would stop physicians from using it even in cases where the benefit was below average—and thus less than its cost. Such uses will almost always be tempting for a large category of patients, since any technology that confers a benefit in excess of costs for half the patients almost certainly confers a somewhat smaller benefit on others. The result would be that such technologies would be used to the point where their marginal benefit is zero, as in the cardiac catheterization example just noted. The bottom-line effect: a shift in open-ended cost escalation from some technologies to a smaller subset that satisfies the average cost-benefit test. Like limiting absolutism to certain categories of services, such a strat-

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<sup>307</sup> Mark McClellan, Barbara J. McNeil & Joseph P. Newhouse, Does More Intensive Treatment of Acute Myocardial Infarction in the Elderly Reduce Mortality?, 272 JAMA 859 (1994). See also Cutler, *supra* note 2, at 28 & Fig. 6 (discussing this study).

<sup>308</sup> See C. David Naylor et al., Technology Assessment and Cost-Effectiveness Analysis: Misguided Guidelines? 148 Can. Med. Assoc. J. 921, 923 (1993) (observing that cost-effectiveness guidelines provide “rough justice at best”).

egy would do little to stop cost escalation in the system as a whole.<sup>309</sup>

Of course, we might try to avoid the all-or-nothing problem by moving away from entry controls and instead approving technology only for specific uses. The specificity might vary. Regulators might approve uses for certain classes of patients. For example, kidney dialysis could be approved only for patients below the age of sixty-five. Alternatively, regulators might, as with certificate of need regulation, approve the use by certain providers. Or, in the extreme, they might seek to approve each use case by case.

But the less case-specific, and more rule-like, the use regulation got, the more vulnerable the approach would be to all-or-nothing problems. Perhaps in some cases the particular sixty-six-year-old is sufficiently healthier than normal that the benefits of providing the dialysis would be worth the costs. In other cases, a particular sixty-four-year-old might be sufficiently unhealthy that dialysis would be less beneficial than for an average person over sixty-five. More generally, any such rule fails to adjust for all the factors identified in Sections A and B, which also affect costs and benefits. Nor does the rule do anything to stop open-ended expansion of costs for caring for persons under sixty-five. A complete set of rules covering all the possible uses of technology for medical care would also probably be too complex for any regulator to write, let alone administer and continually update as circumstances changed.<sup>310</sup>

The more case-specific our use regulation became, the more it would magnify the tremendous informational needs identified in Sections VI.A and VI.B. No centralized regulator seems remotely capable of processing and considering all the information necessary to make case-by-case cost-benefit tradeoffs about the use of technology in millions of cases. Even if regulators were capable of this, regulatory proceedings are surely too slow

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<sup>309</sup> See *supra* note 286 and accompanying text (discussing similar aspect of the Oregon plan).

<sup>310</sup> See Office of Technology Assessment, *supra* note 277, at 64-68, 77-78 (noting that, if the Oregon plan were to be rewritten to try to eliminate over- and under-inclusion, the categories of service would have to be defined so specifically as to make them unworkable for any practical program purpose).



and costly to permit operational case-by-case decisions. Because of the far greater ease of controlling the entry (i.e., initial adoption) of new technology, “[f]ormal government policies have . . . [internationally] dealt much more with adoption than with use.”<sup>311</sup>

Regulators could try to articulate general standards and guidelines and enforce them with penalties after the fact. But such standards would necessarily be vague. This means that even physicians who earnestly endeavor to conform treatment decisions to the standard are likely to make mistakes. So are tribunals adjudicating them, which may produce errors as great as the over- and under-inclusion of a more rule-like approach.<sup>312</sup>

One could imagine rules that are flexible, yet seemingly definite. Suppose, for example, that the government decreed that a technology could be used whenever the QALYs per dollar spent exceeded some set value.<sup>313</sup> Such a rule seems flexible enough to cover every case, yet clear enough to give a definite answer in each case that corresponds to a government policy decision about the proper tradeoff between health care costs and benefits. It would, of course, remain vulnerable to the problems identified in Sections VI.A and VI.B. But perhaps the combination of flexibility and clarity such a rule provides could at least eliminate the all-or-nothing problem.

This seeming combination of flexibility and clarity is, however, illusory. We must ask this important question: Where do the QALY values for a particular treatment come from? Suppose they come from a system-wide schedule of QALY values for each treatment, presumably adjusted for patient characteristics and the illness being treated. Then the rule might well provide clarity, but only because the schedule is over- and under-inclusive. Such schedules, after all, must come from statistical reviews of average medical outcomes and patient evaluations of those outcomes. But some patients having given characteristics will have more capacity than others to benefit from a given treatment for a given illnesses, and some patients will value

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<sup>311</sup> See Banta & Luce, *supra* note 14, at 36.

<sup>312</sup> See Bundy & Elhauge, *supra* note 44, at 267-79.

<sup>313</sup> See Garber, *supra* note 1, at 119.

similar outcomes differently than others. Because a QALY schedule would not adjust for these case-specific variations, it would inevitably be over- and under-inclusive.

If, in order to avoid this over- and under-inclusion, the QALY value is uniquely determined for each case, then the rule is flexible but loses any clarity. Whether the prohibition on providing care below a certain QALY per dollar level was breached could not be determined by simply ascertaining the cost and the category of treatment, patient and illness. Instead, it would depend on the treating physician's assessment of what health benefits the particular patient would enjoy from the treatment, and the patient's assessment of how to "quality adjust" the expected medical outcome. Since these assessments are often debatable or subjective, substantial uncertainty would result even if everyone sincerely endeavored to comply with the guidelines.

In fact, of course, not everyone would try to comply with guidelines. Indeed, this problem is inherent in the regulatory objective: The rationale for regulation is that patients and physicians have inappropriate incentives to use technology. This incentive to resist is important because guidelines are not self-enforcing. They must be enforced through some system for detecting and adjudicating whether or not the guideline was breached. Such enforcement and adjudication is inevitably imperfect. The information necessary to detect a guideline violation may not be available, or it may simply be too expensive to collect.<sup>314</sup> The cost, for example, of determining the QALY values for each medical treatment are so high that any enforcement body will likely review only some cases. Moreover, since patients and physicians have superior or privileged access to most of the relevant information, they would often be able to slant the information reaching the adjudicator.<sup>315</sup> Under the QALY rule, for example, patients may exaggerate their symptoms to

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<sup>314</sup> See Richard A. Posner, *An Economic Approach to Legal Procedure and Judicial Administration*, 2 *J. Legal Stud.* 399, 401 (1973) (arguing that at some point the costs of collecting information will outweigh the benefits of increased accuracy).

<sup>315</sup> See Stephen McG. Bundy & Einer R. Elhauge, *Do Lawyers Improve the Adversary System? A General Theory of Litigation Advice and Its Regulation*, 79 *Cal. L. Rev.* 313, 324, 338-39 (1991).

get treatment, and physicians may shade their diagnosis or their assessment of how beneficial the treatment will be. Or they may be perfectly accurate in what they report but nevertheless withhold or suppress information that might suggest a lower QALY value. Benefit assessments are particularly subject to manipulation to the extent they turn on the patient's subjective assessment of how much she values a given health improvement.

#### VII. A REGULATORY DAM CANNOT STOP AN INCENTIVE FLOW

When I was a kid, I used to go down to a marsh near my house and build mini-dams out of mud to stop little rivulets from running. When the water started to go over or around my dam, I added more mud. Eventually I learned that no matter how much mud I added, the water kept rising or going wider. I could not stop the water from flowing. The best I could hope for was to direct it in a certain direction.

The history of medical cost containment efforts is a history of repeated efforts to set up regulatory dams against the expansionary pressures created by our absolutist system. And what that history shows is that such regulatory dams inevitably fail. Regulatory efforts to reduce hospital days and inpatient costs succeeded in doing so temporarily; but eventually increases in outpatient costs offset any savings from lowered inpatient costs.<sup>316</sup> Price controls on patient visits result in shorter visits and higher volume.<sup>317</sup> When Medicaid limited reimbursement for prescription drugs, Medicaid hospital admissions increased.<sup>318</sup> Efforts to favor cheaper HMOs increased their market share without any decrease in the rate of national growth because sicker patients shifted to other insurers.<sup>319</sup> None of this should

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<sup>316</sup> See Mark V. Pauly & Peter Wilson, *Hospital Output Forecasts and the Cost of Empty Hospital Beds*, 21 *Health Servs. Res.* 403 (1986); Thomas M. Wickizer, John R.C. Wheeler & Paul J. Feldstein, *Have Hospital Inpatient Cost Containment Programs Contributed to the Growth in Outpatient Expenditures?*, 29 *Med. Care* 442 (1991); Havighurst, *supra* note 50, at 91-92 (Supp. 1992) (citing Prospective Payment Commission, *Report and Recommendation to the Congress 89-93* (1991)) (noting that while inpatient surgeries declined 30%, outpatient surgeries increased 304%); Office of Technology Assessment, *supra* note 9, at 180.

<sup>317</sup> See Schwartz & Mendelson, *supra* note 24, at 233.

<sup>318</sup> See Office of Technology Assessment, *supra* note 9, at 180-81.

<sup>319</sup> See *supra* notes 20-25, 159-161 and accompanying text.

surprise us. The only way to stop expansionary pressures is to alter the incentives that create them. Pressures that are merely checked in one place are bound to build up and pop out somewhere else, where the regulatory dam is weakest. But having failed to learn this lesson of history, we seem determined to repeat it, over and over again.

Efforts to stop cost escalation by regulating expensive new technologies pose the same problem. No matter how carefully we construct them, they are inevitably incomplete and do not stop the drive for expansion created by an incentive structure that encourages the provision of all beneficial care. The result is simply to displace efforts to improve health outcomes at any cost to other unregulated areas. If not permitted to purchase a certain costly new technology, for example, that incentive structure will encourage market actors to buy other unregulated technologies. The flow of expansion created by those incentives can be displaced, but it cannot be stopped unless the incentives are changed.

Consider certificate of need regulation, an early form of case-specific technology assessment that prohibited the purchase of technology costing over a certain amount unless the provider got a certificate that the technology was "needed."<sup>320</sup> Regulators expected this to reduce cost escalation in the 1970s since then, as now, the leading cause of cost increases was said to be expensive new technology. There is no evidence, however, that certificate of need regulation slowed the growth in medical costs.<sup>321</sup> Why? Because it just displaced spending to non-controlled areas such as labor, leases, and smaller-scale capital investments. Indeed, one study showed that CON regulation *raised* overall costs.<sup>322</sup> It created barriers to entry, which were only exacerbated by the regulators' tendency to conclude that overcapacity (a classic symptom of reduced output by oligopolists) was a reason to deny a certificate of need to new entrants.

Similar problems plague efforts to prevent overly expensive

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<sup>320</sup> See *supra* notes 268-270 and accompanying text.

<sup>321</sup> See Havighurst, *supra* note 50, at 934.

<sup>322</sup> See Joyce A. Lanning, Michael A. Morrisey & Robert L. Ohsfeldt, Endogenous Hospital Regulation and Its Effects on Hospital and Non-hospital Expenditures, 3 J. Reg. Econ. 137, 144 (1991).

new technology from entering the market at all. To begin with, such efforts do nothing to curb the increasingly intensive use of *existing* technologies. Recall the example of treatment costs per heart attack, which increased thirty-two percent in constant dollars from 1984 to 1991.<sup>323</sup> This increase did not reflect the introduction of any new technology. Rather it reflected the increasing use of some technologies already existing in 1984: catheterization, angioplasty and bypass surgery.<sup>324</sup>

Nor does regulation of the entry of devices and drugs do anything to curb innovations like new surgical procedures. Researchers foiled by restrictions on physical forms of innovation have incentives to devote increasing energy to deriving marginal health benefits through non-physical innovations, like new procedures or treatments. And efforts to extend regulatory review to these non-physical innovations would be far harder to administer since they need not involve the creation of a physical product that must be mass produced and marketed.

Additional problems plague governmental restrictions on the technology used in the health care the government itself provides or reimburses. Such restrictions do not have the bad effects of barring innovation outright. But they are also far less effective. The reason is that any marginally beneficial technology produced in the private sector quickly becomes demanded in the public sector. Consider the Italian health system. It tried to curb cost escalation by limiting the technology used by its public system.<sup>325</sup> But it also guaranteed reimbursement for the purchase of any prescribed health care that was unavailable through the public system.<sup>326</sup> The effect? It spurred private innovation of expensive technology to create something "unavailable" in the public sector that could be marketed as reimbursable by the government.<sup>327</sup> It also regressively skewed

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<sup>323</sup> See *supra* note 156 and accompanying text.

<sup>324</sup> *Id.*

<sup>325</sup> See George France, *Emerging Policies for Controlling Medical Technology in Italy*, 4 *Int'l J. Tech. Assessment in Health Care* 207 (1988).

<sup>326</sup> See Elhauge, *Allocating Health Care Morally*, *supra* note 4, at 1466 & n.38.

<sup>327</sup> See George France, *Centralised Versus Decentralised Funding of Evaluative Research: Impact on Medical Technology Policy in Italy*, 38 *Soc. Sci. & Med.* 1635, 1639 (1994) (noting that the unintended result of Italian policy has been to make competition in the Italian health care system increasingly technology-based, and

the distribution of public resources to the wealthy, who could better afford to pay for their health care and await government reimbursement.

Likewise, the government can stop providing research funding for medical technologies that are not cost beneficial. But that will do nothing to stop private research into such technologies, and such research can be expected to continue as long as the system eventually pays for all marginally beneficial care. Researchers research what people will use. Unless we change the incentives to use overly costly medical technology, it is unlikely that we can stop it from being discovered.

#### VIII. THE POTENTIAL IS EVEN LOWER IF COST-BENEFIT TRADEOFFS ARE ALLOWED

Suppose I was wrong in Section II.B. Suppose we are shifting to an incentive structure that encourages insurers or providers to perform cost-benefit tradeoffs. If so, the potential for regulatory technology assessment is even lower.<sup>328</sup>

The reason is straightforward. Under any regime that encourages cost-minimization, medical providers have no incentive to use costly technologies that are harmful or ineffective.<sup>329</sup> Nor do they have any incentive to use cost-ineffective technologies.<sup>330</sup> And if the regime not only encourages cost-minimization but also allows cost-benefit tradeoffs, then providers would also refrain from using technology that was not cost beneficial. Researchers would thus not create overly expensive technology. Even if they did, it would have little effect on expenditures since no one would use it. The rationale for curbing the entry of expensive new technologies would thus evaporate.

Concern would instead shift to whether providers would *underuse* the technology available. After all, if we give providers incentives to minimize costs, they may well—assuming they can

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“medical technologies prevented by planners from entering the NHS [National Health Service] in an unlimited way through the public front door slip in via the private side window”).

<sup>328</sup> The potential for informational technology assessment, on the other hand, increases. See discussion *supra* Part III.

<sup>329</sup> *Id.*

<sup>330</sup> See *supra* notes 296-297 and accompanying text.

avoid undue legal and reputational costs—not use technologies even in cases where their benefits exceed their costs.<sup>331</sup> For example, a provider might decline to prescribe a new drug for treating sinus allergies, recommending instead an over-the-counter medication that causes far more drowsiness. That the benefits of avoiding this drowsiness far exceed the additional cost of the medication may not matter to the provider. The patient may not notice the denial, and even if she did, she would hardly be likely to sue or go to the newspapers over it.

Perhaps then the wave of the future in technology assessment will be assessing when technologies must be used by reluctant HMOs. Perhaps, but unlikely. The problems I identify in Parts V and VI would, after all, still apply. Regulators would still have no idea how to trade off health benefits against monetary costs, and little incentive to do so. Moreover, the technical problems would remain enormous. Indeed, they would be far worse, because the option of regulating the point of entry would no longer be available. Regulation would have to focus on *non-*uses of technology. This poses all the problems of regulating technology uses and more: For nonuses create no event that might signal the regulator to pay attention.

#### IX. CONCLUDING REMARKS

The potential for regulatory technology assessment is limited under professional fee-for-service systems, and even more so under the systems of prepaid medicine to which we are rapidly switching. Regulatory assessments that do not make cost-benefit tradeoffs cannot seriously affect health care cost escalation. Governmental expertise and incentives to make cost-benefit tradeoffs are low. The technical problems in centrally making cost-benefit tradeoffs are insuperable. And the incentives that fuel cost escalation are likely to simply displace expansion to unregulated areas. None of this should be surprising. A well-functioning market is a marvel, impounding an enormous amount of information quickly into prices that allow decentralized market participants to make cost-benefit tradeoffs with surprising ease. However, we don't have anything close to such

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<sup>331</sup> See *supra* Section II.C.2.

a market in health care.

What would a well-functioning market in health care look like? Given the inherent market defects unavoidably posed by health care, the best we can do is to minimize problems. But the most promising alternative is a publicly restructured market that creates new entities with both the knowledge and incentives to trade off a treatment's benefits against its costs. My own plan would involve the creation of care-allocating plans that would (1) receive a budget fixed by the number and condition of their enrollees, and (2) be obligated to allocate that budget among treatments according to a health maximization goal those enrollees consented to in advance.<sup>332</sup> The incentive to over-treat (in fee-for-service systems) would be eliminated by the fixed nature of the budget, while the incentive to under-treat (in modern capitated systems) would be eliminated by the plans' inability to retain profits from that budget. The main incentive would be for plans to do the best job possible at allocating their budgets in order to attract more enrollees next year.<sup>333</sup> The various doctrines prohibiting or penalizing deviations from the absolutist imperative would also have to be relaxed to allow plans to make explicit tradeoffs.

In this system, the conflict with moral norms would be minimized in various ways. Everyone would have free access to a plan. Plans could not personally profit from denying care. Tradeoffs would be framed as allowing the denial of beneficial treatments only to provide more beneficial treatments to others. Finally, individuals would have a choice of plans and thus consent to the particular allocation system their plan uses.<sup>334</sup> The last point is crucial. Prior moral analyses tended to be preoccupied with finding one morally most justifiable method of rationing health care, perhaps on the assumption that rationing

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<sup>332</sup> See Elhauge, *Allocating Health Care Morally*, supra note 4, at 1453-54.

<sup>333</sup> Risk selection would be minimized by (1) risk adjusting the payment made per enrollee, (2) banning risk selection and forcing plans to take all comers, and (3) minimizing the incentive to risk select by disallowing the retention of profits. The latter is important because risk-adjustments and risk-selection regulation are both inevitably imperfect and unlikely to be successful if insurers/plans have strong incentives to profit by selecting relatively healthy enrollees in any risk category.

<sup>334</sup> Elhauge, *Allocating Health Care Morally*, supra note 4, at 1453-56.



would have to be executed in some centralized bureaucratic or political manner. But a central thesis of my prior work is to reject any such centralized imposition of one allocation scheme as morally unjustifiable.<sup>335</sup> Instead, my plan finds its moral legitimacy on a respect for a diversity of moral views about the best rationing method and on allowing individuals to choose (and thus to consent to) the method of rationing they find most morally justifiable.

The strengths of professionalism would be maintained under such a system in two ways. Most physicians would remain independent suppliers whose interests coincide with the patients' interests in providing as much care as the plan can be persuaded to buy. And each plan would have both professional expertise and a professional duty of loyalty to the group of patients as a whole.

The political process would be left to make the tradeoff between costs and benefits that requires an open-ended normative judgment that neither lends itself to scientific and moral analysis, nor can be made by market processes given pervasive market defects. But the government would make the implicit cost-benefit tradeoff by making one general decision about what share of Gross Domestic Product to devote to health care, not by trying to make detailed decisions about which types of health care to provide to which types of persons. Limiting the political process to this general question leaves it sensitive to both the benefits and costs of care (both of which the polity experiences), but less susceptible to interest group pressures (because the issue involves relatively low information costs) and collective choice problems (because the global issue is more likely to provoke single-peaked preferences).<sup>336</sup> In this publicly restructured market, the decisions about where the general budget goes would first follow individual decisions about which plan each person wants to receive her share of the global budget, and, second, follow the decisions of those plans about which treatments each plan wants to fund out of its fixed budget.

If the market were restructured in this fashion, technology as-

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<sup>335</sup> *Id.* at 1451, 1456, 1524-26.

<sup>336</sup> See *id.* at 1543-44 & n.296.

assessment would then be done or used the way it normally is in our economy: by decentralized market actors with incentives to trade off benefits and costs in their purchase decisions. Being closer to the case-specific situations, these plans would have a much easier time collecting or using the information necessary to make the tradeoffs, in part because a huge amount of the relevant information would be impounded into constantly fluctuating input prices. They would also have more incentive to do so.

Moreover, whether plans prove more knowledgeable or not, market discipline will punish those who turn out to make poor decisions. Plans that use excessively costly technologies will find themselves unable to provide as great a health benefit to their enrollees as other plans. Enrollees will switch to the plan that turns out to be using its scarce resources to purchase the technology that provides the best care per resource spent.

With knowledgeable plans all buying the most cost-beneficial services and technology they can, and plans that succeed expanding at the expense of those that do not, suppliers would have an incentive to compete by providing cost-beneficial services and technology. Sellers of technology would have incentives to purchase reliable, independent assessments of the cost-beneficial nature of their technology to certify it to buyers and users. And researchers would, finally, have some real incentives to focus their innovation efforts on technology that provides the best benefit to cost ratio.

But we do not yet have a well-functioning market in health care. And no amount of technology assessment can substitute for it.