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FUNDING FAIRNESS: PUBLIC INVESTMENT, PROPRIETARY RIGHTS AND ACCESS TO HEALTH CARE TECHNOLOGY

*William M. Sage**

INTRODUCTION

In her accompanying Article, "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research,"¹ Professor Rebecca Eisenberg suggests that federal technology transfer policies should be reexamined in light of actual experience with patented technologies. Indeed, the relationship among federal research funding, patent law, and medical innovation has become more complicated in the years since the passage of the Bayh-Dole Act.² Rising health care spending despite slowing overall economic growth has fostered the development of private sector managed care, has led to cutbacks in government support for both research and clinical services, and has increased the percentage of uninsured Americans with marginal access to health care.

In response to cost concerns in the private sector, dramatic changes are occurring in the way that health care is financed and delivered. Managed care is forcing the industry to integrate, consolidate, and otherwise restructure services to improve efficiency. Managed care health plans and the employers and individuals who pay their premiums are increasingly resistant to research and service expenditures that do not immediately and directly benefit them. Moreover, because expensive technology is a perceived barrier to sustained savings, these companies are beginning to insist on evidence of effectiveness proportionate to cost as a condition of offering particular services.

At the same time, government resources seem in short supply. Public contempt for bureaucracy limits revenues (particularly in a fragile econ-

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¹ Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 *Va. L. Rev.* 1663 (1996).

² Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015, 3028 (codified as amended at 35 U.S.C. §§ 200-211, 301-307 (1994)) (commonly known as the Bayh-Dole Act). As Professor Eisenberg relates, the Bayh-Dole Act allowed small businesses and nonprofit organizations to retain patent ownership of government-sponsored research, a privilege which was later extended by executive memorandum to large businesses.

omy) while deficit politics restricts borrowing. Demographics alone portend poorly for long-term cost containment. As most clearly illustrated by projections for the Medicare "trust fund," the aging of America means increasing demand for expensive health care services supported by a shrinking pool of younger, working individuals.

As a result of these trends, our nation finds itself in a highly unstable climate for biomedical research and the applied technologies it generates. If the cost of the United States health care system continues to increase, a consensus may emerge that national resources available for health care are limited—and that those resources should be distributed fairly. In that case, the conventional wisdom underlying the Bayh-Dole Act—that the proliferation of new technology developed at public expense is an unqualified good³—must be reassessed as well.⁴

I. MEDICAL INNOVATION AND HEALTH CARE SPENDING

Conventional economic analysis argues that investments in the production of useful knowledge will not be made if the benefits cannot be appropriated by the investor. Two strategies are commonly used to overcome the public goods aspect of information. Applied research is usually promoted through the award of patent monopolies for novel, useful and non-obvious inventions, in effect substituting one form of market failure for another. On the other hand, basic research tends to be funded directly by government because it is unlikely to yield patentable results.

As Professor Eisenberg observes, the Bayh-Dole Act reflects this paradigm.⁵ The space program and similar experiences suggested that, although the United States government was a highly effective generator of knowledge, it was not as well equipped to develop commercial applications of funded technologies.⁶ The architects of Bayh-Dole theorized that lack of patent protection inhibited private industry from making the additional investment necessary to bring products to market.⁷ By ad-

³ See *id.* at § 200, 94 Stat. at 3019.

⁴ That self-interest, consumer demand, and government policy can have ambiguous consequences for public welfare would be unsurprising but for American medicine's recent "golden age" of professional hegemony, scientific supremacy, and limitless funding. The distant past is in some ways more revealing. See, e.g., Howard W. Haggard, *Devils, Drugs, and Doctors* 44-65 (1929) (telling the tale of the Chamberlen family of physicians, who kept their invention of the obstetrical forceps secret for four generations); James H. Young, *The Toadstool Millionaires* 16-30 (1961) (relating the story of Elisha Perkins, a Colonial doctor who received the first medical device patent for his galvanic tractors, metal pins intended to draw off "noxious electrical fluid").

⁵ Eisenberg, *supra* note 1, at 1665.

⁶ See Thomas A. Massaro, *Innovation, Technology Transfer, and Patent Policy: The University Contribution*, 82 Va. L. Rev. 1729, 1731 (1996).

⁷ Recent amendments to the Stevenson-Wydler Technology Innovation Act of 1980,

justing the balance between the two tools—patentability and government sponsorship—available to overcome market failures in the production of useful knowledge, the legislation's sponsors hoped to maximize the development of marketable technologies.⁸

Things are not so straightforward today. Patent rights for medical innovations developed at public expense must be considered in the context of an informed debate over the appropriate level of health care services and the way in which those services are distributed. Resources devoted to health care have increased sharply over the last two decades, with new technology one of the principal culprits. Annual expenditures are approaching one trillion dollars, nearly fourteen percent of gross domestic product.⁹ The macroeconomic effects of increased health care spending, such as the potential impairment of American competitiveness in international markets, are debatable. Nonetheless, a financial commitment to health care of this magnitude necessarily implies sacrificing other uses of money. Because basic health care is generally considered a necessity, this trade-off extends beyond the economic choices of individuals to the social choices of the citizenry as a whole. In particular, the political appeal of publicly subsidized health care for the indigent diminishes as its cost rises.

As health care costs increase, two related questions arise. First, are we spending too much on health care? Second, are we getting 'value' for the money we spend? The second question is particularly important given that, whereas most other industrialized nations have universal medical insurance programs, more than fifteen percent of Americans are uninsured and receive substantially fewer health care services than individuals with health coverage.¹⁰

Health policy optimists often hope to avoid the first question by focusing on the second. According to various theories, eliminating "waste, fraud and inefficiency" in the current system could allow a significant ex-

Pub. L. No. 96-480, 94 Stat. 2311, a statute cut from the same cloth as the Bayh-Dole Act, confirm the government's continued intention to encourage private sector development of publicly funded technologies. See, e.g., National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, § 4, 110 Stat. 775, 775-77 (1996) (amending subsection 12(b) of the Stevenson-Wydler Technology Innovation Act of 1980) (authorizing federal laboratories to give their private sector partners patent rights to any inventions created in collaborative research, presumably including Cooperative Research and Development Agreements).

⁸ For a detailed discussion of the incentives created by patent policy, see Yusing Ko, Note, An Economic Analysis of Biotechnology Patent Protection, 102 *Yale L.J.* 777 (1992).

⁹ Katharine R. Levit, Helen C. Lazenby & Lekha Sivarajan, Health Care Spending in 1994: Slowest in Decades, *Health Aff.*, Summer 1996, at 130, 132.

¹⁰ Janice Somerville, Census: Almost 40 Million Uninsured Americans, *Am. Med. News*, Nov. 7, 1994.

pansion of coverage while restraining costs. Unfortunately, there is little agreement on what constitutes waste and how it should be reduced. Reformers frequently offer contradictory remedies: some advocate improved management and market competition,¹¹ while others criticize administrative spending and profit-seeking behavior.¹²

Still more problematic is the strong likelihood that even the most efficient health care system will absorb a large and increasing share of production. There is evidence that restructuring the health care system to obtain economies of scale and scope, implementing universal 'best practices', creating optimal financial incentives for providers and patients, and instituting appropriate oversight mechanisms will at best yield a one-time savings that will quickly be erased by continuing annual increases in health care spending.¹³

Long-term cost pressure is largely attributable to the development of new and expensive medical technologies, with aging of the population likely to become an important additional factor in the future. Experience has shown that only a small percentage of medical innovations are "definitive" technologies that prevent or cure otherwise costly illnesses. A vivid example is the polio vaccine, which rendered iron lungs and sanatoria obsolete almost overnight. Most inventions are "half-way" technologies, prolonging life and palliating suffering but increasing rather than moderating expense.

Our current preoccupation with health care spending therefore adds another layer of complexity to considerations of medical patent policy. Whereas laws granting patent monopolies unabashedly promote the development of technology, a cost-sensitive health care system is ambivalent toward new sources of health care spending and consequently wary of uncontrolled incentives for innovation.¹⁴

If society's health care resources are limited, any technological advance, especially one derived in part from publicly sponsored research, arguably should fulfill two conditions in order to merit encouragement. First, it should be cost-effective, meaning that the incremental investment

¹¹ See, e.g., Alain C. Enthoven, *The History and Principles of Managed Competition*, *Health Aff.*, Supplement 1993, at 24, 45-46 (advocating competition between managed care plans).

¹² See Steffie Woolhandler & David U. Himmelstein, *The Deteriorating Administrative Efficiency of the U.S. Health Care System*, 324 *New Eng. J. Med.* 1253 (1991) (advocating a government-sponsored "single-payer" system).

¹³ See William B. Schwartz & Daniel N. Mendelson, *Eliminating Waste and Inefficiency Can Do Little to Contain Costs*, *Health Aff.*, Spring (I) 1994, at 224.

¹⁴ See Victor R. Fuchs, *The Clinton Plan: A Researcher Examines Reform*, *Health Aff.*, Spring (I) 1994, at 102 (describing technologic and demographic pressures on spending).

required yields commensurate benefits.¹⁵ Second, it should be available equitably to potential users.

Using a cost-containment paradigm, new technologies would be assessed carefully before being introduced, with controlled initial distribution and widespread dissemination only if threshold tests of cost-effectiveness were satisfied. Moreover, if equity demands universal or near-universal availability of technologies which have been proved beneficial, cost-effectiveness determinations should reflect not only the consumption decisions of those able to afford the technology, but the election of society as a whole to purchase the technology for those who cannot afford it.¹⁶

At present, the patent system does not include either of these criteria. For example, the patent requirement that an invention be "useful"¹⁷ means only that an applicant must demonstrate to the Patent and Trademark Office ("PTO") its "practical utility."¹⁸ For many years, the PTO insisted (without clear support from the courts) on clinical test results for biotechnology patent applications, but subsequently relaxed its position.¹⁹ A patent applicant therefore faces an even lower burden than an applicant seeking approval of a new drug. The Food and Drug Administration ("FDA") requires the applicant to show both "safety" and "effectiveness."²⁰

This is not to say that the potential interaction between the patent system and the cost of health care has gone unnoticed. To the contrary, an obvious side effect of patent monopolies—like other monopolies—is to increase price and decrease output. As a result, patented inventions may

¹⁵ Note that only definitive technologies are likely to be cost-beneficial. "Half-way" technologies invariably increase cost within the health care system, and their external benefits are seldom monetizable.

¹⁶ It is important to note that, despite the cost pressures created by medical innovation, the bulk of "excessive" health care spending arises from existing treatments, most of which are both unproven and unregulated. See Duane M. Ilstrup, *Randomized Clinical Trials: Potential Cost Savings Due to the Identification of Ineffective Medical Therapies*, 70 *Mayo Clinic Proc.* 707 (1995) (discussing the lack of data supporting most clinical practices).

¹⁷ 35 U.S.C. § 101 (1996) (requiring patented invention to be "useful").

¹⁸ See, e.g., *Cross v. Iizuka*, 753 F.2d 1040 (Fed. Cir. 1985) (applying the "practical utility" test); see also David G. Perryman & Nagendra Setty, *The Basis and Limits of the Patent and Trademark Office's Credible Utility Standard*, 2 *J. Intell. Prop. L.* 509, 509 (1995) (indicating that the practical utility standard stems from *Brennar v. Manson*, 383 U.S. 519 (1966)).

¹⁹ Perryman & Setty, *supra* note 18, at 525; see also Request for Comments on Proposed Utility Examination Guidelines, 60 *Fed. Reg.* 97 (1995) (setting forth Patent and Trademark Office Guidelines for Examination of Applications for Compliance with the Utility Requirement); cf. *In re Langer*, 503 F.2d 1380, 1392 (C.C.P.A. 1974) (clinical testing in humans not required to prove utility).

²⁰ 21 U.S.C. § 355(d) (1996) (standards for new drugs).

not be affordable to those who need them. If equity is a concern in the provision of health care services, awarding patents—especially for breakthrough therapies—tends in the opposite direction.

This issue came to the fore in 1989 over the pricing of the AIDS/HIV drug AZT (Retrovir) by the pharmaceutical giant Burroughs Wellcome.²¹ Although AZT was the first drug to prove effective at prolonging survival in persons with AIDS, its price was so high that few HIV-positive individuals could afford it. This prompted a public outcry, saber-rattling in Congress about imposing price controls on the pharmaceutical industry, and for federally funded research, the adoption of a “reasonable price” requirement by the National Institutes of Health (“NIH”) for inventions arising from Cooperative Research and Development Agreements (“CRADAs”).²²

Similar considerations regarding equity and affordability have driven the debate over the patentability of medical procedures.²³ The American Medical Association’s (“AMA”) Council on Ethical and Judicial Affairs recently concluded that it was unethical to patent procedures which could benefit a larger number of patients if performed without regard to ownership.²⁴ Supporting the AMA’s stance is the fact that most physicians can reap the rewards of clinical innovation through the provision of personal services even without a patent monopoly. Because this is less certain as the medical marketplace becomes more competitive, and corporate entities vie for patient care contracts, process patent applications for medical procedures have been increasing. However, recently litigated cases have gone against those claiming proprietary rights,²⁵ and Congress recently amended the patent law to restrict enforcement of procedure

²¹ The high cost of HIV treatment remains a critically important issue. Combination drug therapy, which has been proved effective at slowing the progression of the disease, costs up to \$18,000 per year. See Deborah L. Shelton, *Rising Hopes, Rising Costs*, Am. Med. News, Sept. 16, 1996.

²² See Baruch Brody, *Public Goods and Fair Prices: Balancing Technological Innovation With Social Well-Being*, Hastings Center Rep., Mar.-Apr. 1996, at 5 (describing AZT pricing debate). Under pressure from industry, NIH reversed its policy in 1995 as excessively burdensome and exerting a chilling effect on the creation of CRADAs. See Biotechnology Industry Organization, *Technology Transfer and the Biotechnology Industry: Basic Scientific Research Applied to Human Needs 1 (1995)* (report to the President and the Congress summarizing recent developments and advocating liberal technology transfer policies).

²³ See Wendy W. Yang, Note, *Patent Policy and Medical Procedure Patents: The Case for Statutory Exclusion from Patentability*, 1 B.U. J. Sci. & Tech. L. 5 (1995).

²⁴ See Joel J. Garris, *The Case for Patenting Medical Procedures*, 22 Am. J.L. & Med. 85, 86 (1996).

²⁵ See, e.g., *Pallin v. Singer*, No. 2:93-CV-202, 1996 WL 274407, at *1 (D. Vt. Mar. 28, 1996) (order declaring all patent claims made in infringement suit involving patented procedure for “stitchless” cataract surgery invalid).

patents against medical practitioners.²⁶

A final example of equity concerns in medical innovation is the Human Genome Project. NIH appears to have rethought its earlier attempt to patent gene sequences and, according to a leading scientific publication, currently requires grant recipients to sign a written pledge assuring open access to research results.²⁷ Although the agency's stance is no doubt a principled one, it runs directly contrary to the intent of the Bayh-Dole Act and other federal policies encouraging technology transfer.

II. PRIVATE AND PUBLIC SECTOR INFLUENCES

The point of the preceding section is that current patent policy may contribute to cost and inequity in the health care system. However, before burdening the patent system with broad health policy concerns—considerations seemingly antithetical to its traditional function of encouraging investments in innovation—one should ask whether more effective approaches to the problem are available. Three possibilities come to mind, one involving the private sector and two involving government. First, the private insurance and health care industries are being transformed by managed care, the primary function of which is cost containment. Second, federal and state governments have become the largest purchasers of health care services through the Medicare and Medicaid programs, giving them both a substantial interest in and significant leverage over the availability and pricing of services. Finally, with appropriate modifications to their statutory mandates, existing regulatory agencies such as FDA might adapt their missions to consider cost. Although each of these possibilities might promote cost-effectiveness to a limited extent, none is likely to ensure an equitable distribution of beneficial medical technology.

A. *Managed Care*

The term “managed care” subsumes virtually any attempt to bring market discipline to an industry beset by information deficits, third-party payment, professional dominance and other factors that confound the incentives and behavior of buyers and sellers. Like all insurance companies, managed care organizations employ risk management strategies such as consumer cost-sharing and medical underwriting. In addition, however, they make full use of clinically oriented tools such as utilization review, practice guidelines, drug formularies and provider compensation

²⁶ Omnibus Budget Reconciliation Act of 1996, P.L. 104-208, 1996, H.R. 3610, § 616 (1996).

²⁷ Eliot Marshall, *Genome Researchers Take the Pledge*, 272 *Science* 477-78 (1996).

based on cost-conscious performance. Over the past decade, managed care organizations have successfully reduced insurance costs for their corporate and individual clients.

If new medical technology is a significant source of expense, one would expect managed care organizations to fund only those innovations which have been proven cost-effective. Indeed, managed care pays frequent lip service to technology assessment, and a few organizations, such as the Technology Evaluation Center ("TEC") of the Blue Cross and Blue Shield Association, have taken substantive actions.²⁸ These activities are likely to become more common in the future as individual organizations serve larger populations, and the industry as a whole learns to share and process quality-related information more effectively.

Nonetheless, managed care on the whole has a disappointing track record on technology assessment. There are many reasons for this, not least of which is the sheer technical difficulty of conducting methodologically sound evaluations. For example, statistically valid clinical trials take longer than American health care consumers are accustomed to waiting for potentially useful therapies, involve more participants than are available to most managed care organizations and, ideally, require participation on a randomized basis, which is unacceptable to many patients.

Assessing cost is also problematic. For some technologies, costs appear higher in the initial stages of distribution than when manufacturing processes have been perfected, marketing expenses have stabilized and larger than expected quantities are being sold. For other technologies, managed care organizations may underestimate expense because manufacturers have incurred large sunk costs (often in reliance on reimbursement policies which are no longer in effect), and are therefore willing to supply the managed care industry at a deep discount.

Adding to the practical difficulties for managed care organizations is the uncertainty of relying on technology assessments to enforce provisions in health care benefits contracts that exclude "experimental" or "investigational" treatments. Courts frequently favor severely ill plaintiffs on the equities, and construe terms of insurance contracts accordingly.²⁹ As a result, managed care organizations tend to rely on the more sweeping protection from benefits-related liability offered by ERISA

²⁸ See, e.g., General Accounting Office, Health, Education, and Human Services Division, Report to the Hon. Ron Wyden, *Health Insurance: Coverage of Autologous Bone Marrow Transplantation for Breast Cancer*, Apr. 24, 1996 (GAO/HEHS-96-83) (describing Technology Evaluation Center's assessment of high-dose chemotherapy with autologous bone marrow transplantation).

²⁹ See generally Mark A. Hall & Gerard F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. Pa. L. Rev. 1637 (1992) (summarizing coverage litigation involving medical necessity and experimental or investigational treatments).

rather than concentrating their attention on the clinical consequences of coverage policies.³⁰

An even thornier problem is that any social gain achievable through managed care in assuring the cost-effectiveness of new technology would probably be negated by social losses in the availability of health care services. The bulk of managed care's economic success has been accomplished by a simple expedient: negotiating price discounts with health care providers in exchange for contractual assurances of volume. This has been possible because of the substantial excess capacity of hospital beds, "me-too" prescription drugs, high-technology equipment and specialist physician services that had developed as a by-product of several decades of consumer cost-insensitivity.

In the long run, squeezing out excess capacity through private bargaining that channels savings to managed care organizations and their customers reduces the availability of services for the uninsured. The principal explanation for this is that cross-subsidies that had been buried in high health care prices and used to shift costs from non-paying to paying patients are being exposed and, in many cases, eliminated. As a result, health care providers who previously were able to treat significant numbers of charity patients may be forced to limit uncompensated services, or to close or relocate their practices.

Managed care's attack on cost-shifting is important for technology assessment as well as for access to technology. The largest cutbacks in health care research funding are not coming from government, but from the private sector.³¹ Employers concerned about health insurance costs and the managed care companies that serve them are increasingly resistant to subsidizing clinical research, either directly by covering investigational treatments or indirectly by paying higher prices at academic health centers or similar institutions which shift otherwise uncompensated re-

³⁰ For a brief summary of ERISA as applied to claims involving managed care, see Robert L. Roth, *Recent Developments Concerning the Effect of ERISA Preemption on Tort Claims Against Employers, Insurers, Health Plan Administrators, Managed Care Entities, and Utilization Review Agents*, *Health Law*, Early Spring 1996, at 3, 4. The lack of consistency with which private insurers address experimental treatment is described in William P. Peters & Mark C. Rogers, *Variation in Approval by Insurance Companies of Coverage for Autologous Bone Marrow Transplantation for Breast Cancer*, 330 *New Eng. J. Med.* 473 (1994).

³¹ See Robert E. Mechanic & Allen Dobson, *The Impact of Managed Care on Clinical Research: A Preliminary Investigation*, *Health Aff.*, Fall 1996, at 72. According to a prominent health care technology consultant, "Ironically, the growth of managed care has highlighted the value of and need for technology assessment while diminishing the funds available to pay for it." Greg Borzo, *HMOs Value Research—If Others Pay for It*, *Am. Med. News*, Nov. 20, 1995, (quoting James Anderson, partner, Andersen Consulting).

search expenses to private payers.³² Substantial amounts of clinical research—including research that could form the basis for cost-effectiveness studies—may be jeopardized as a result of these pressures.³³

B. Public Payers

If the ability of the private managed care industry to promote cost-effectiveness and equity in health care technology is limited, one might wonder if the public sector can do better. Government currently pays approximately forty percent of the health care dollar, primarily through the federal Medicare program for the elderly and through federally supported but state-administered Medicaid programs for poor families and the disabled.³⁴ The benefits and reimbursement standards of these programs therefore determine to a considerable extent the structure and behavior of the health care industry as a whole.

Unfortunately, Medicare and Medicaid have done little to rationalize health care spending by assuring either the effectiveness or the equitable availability of technology. To the contrary, a fundamental tenet of the political compromise that allowed Medicare's enactment in 1965—although one increasingly honored in the breach—was that federal law would not disrupt the autonomous practice of medicine by physicians.³⁵ As a result, cost containment has been approached largely through across-the-board reductions in provider payment (for both Medicare and Medicaid) and changes in eligibility criteria (for Medicaid) rather than by selective coverage of services demonstrated to be cost-effective.

In recent years, Medicare has attempted to expand its technology assessment activities through the issuance of national coverage determinations to supplement often inconsistent decisions by the carriers and intermediaries who review Medicare claims under government contracts.³⁶

³² Several states have considered mandating coverage of investigational treatments. See, e.g., 1996 Cal. Legis. Serv. 979 (West), available in Westlaw, CALEGIS database (to be codified at Cal. Health & Safety Code § 1370.4 and Cal. Ins. Code § 10145.3) (requiring independent review of coverage denials).

³³ Nearly one quarter of original research published in major medical journals is unfunded, suggesting that substantial costs are borne indirectly by third-party payers and others. See Michael D. Stein, Louis Rubinstein & Tom J. Wachtel, Who Pays for Published Research?, 269 JAMA 781, 782 (1993); see also Managing to Care, Economist, Sept. 23, 1995, at 70 (analyzing cost-shifting, medical research, and managed care).

³⁴ See Levit, et al., *supra* note 9, at 139.

³⁵ 42 U.S.C. § 1395 (1995) (prohibiting federal interference with the practice of medicine).

³⁶ See, e.g., Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. 4,302 (1989) (to be codified at 42 C.F.R. pts. 400, 405) (proposed Jan. 30, 1989); Process For Health Care Technology Assessments and Recommendations For Coverage, 58 Fed. Reg. 63,988

As one might expect, many coverage decisions reflect politics as much as policy. On the whole, courts have been mixed in their reaction to restrictions on Medicare and Medicaid coverage, in some cases deferring to administrative determinations of “reasonable and necessary”—the statutory coverage standard³⁷—but in others prohibiting regulatory interference with the judgment of the treating physician. In addition, Medicare recently decided to disallow patient care costs incurred in connection with clinical trials of medical devices, but was reversed by a federal court in a lawsuit brought by academic health centers.³⁸

Save for the enactment of Medicare and Medicaid, government has also been only a half-hearted champion of equitable access to health care. Taxpayers often seem even more reluctant than paying patients to subsidize care for the uninsured. For example, Medicare and especially Medicaid have a long history of below-market reimbursement, shifting a portion of their own costs to the private sector. Public support for deficit reduction as an independent political objective has further decoupled cost containment from access to services, although its influence may be fading. The Republican victory in 1994 and the 1995-96 federal budget impasse attest to the primacy of “savings” over “value” in health care entitlement programs for a large portion of the electorate.

C. FDA Regulation

As the only federal regulatory body with premarketing authority over medical therapy, FDA might seem a natural choice to help ensure cost-effectiveness and wide availability of health care technology. Among other virtues, FDA has the institutional competency to analyze complex data and considerable experience working with all sectors of the health care industry, from large manufacturers to individual physicians.

Unfortunately, support to broaden FDA’s mandate to consider cost as well as safety and effectiveness would not be easily forthcoming.³⁹ FDA

(1993); see also General Accounting Office, Program Evaluation and Methodology Division, Report to the Hon. Ron Wyden, Chairman, Subcommittee on Regulation, Business Opportunities, and Technology, Committee on Small Business, House of Representatives, Medicare Part B: Regional Variation in Denial Rates for Medical Necessity (Dec. 19, 1994) (assessing inconsistencies among carriers).

³⁷ 42 C.F.R. § 411.15(k)(1) (1996) (limiting coverage to services “reasonable and necessary . . . [f]or the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”).

³⁸ *Cedars-Sinai Med. Ctr. v. Shalala*, 939 F. Supp. 1457, 1465 (C.D. Cal. 1996) (holding that the Department of Health and Human Services had failed to comply with the Administrative Procedures Act in adopting its policy); see also Julie Johnson, *Battle Over Device Coverage Moves to Courts*, Am. Med. News, Oct. 23, 1995 (describing legal challenges to payment policy for medical research in the federal courts).

³⁹ See Peter J. Neumann, Darren E. Zinner & A. David Paltiel, *The FDA and Regulation of Cost-Effectiveness Claims*, Health Aff., Fall 1996, at 54, 68 (urging caution

has expanded its regulatory scope over the past half century only with great difficulty, usually in response to high-profile public health threats such as sulfanilamide in the 1930s and thalidomide in the 1960s. For example, despite heart valve fractures and other well-publicized malfunctions, FDA has only limited jurisdiction over medical devices, and the "food supplement" lobby continues to resist FDA regulation of products such as melatonin.⁴⁰ Efforts by FDA to delay dissemination of new health care technologies pending proof of cost-effectiveness would have such high visibility that short-sighted political compromises would be inevitable.

Even with expanded authority and sufficient political cover, attempts by FDA to perform cost-based technology assessment would suffer from the same technical difficulties that plague managed care organizations. For example, comparative information on the effectiveness of new drugs is often limited to closely related chemical compounds—such as calcium-channel blockers for heart disease or H₂-receptor blockers for peptic ulcers—whose manufacturers are competing for the attention of physicians or for placement on restricted formularies. Relatively few studies are designed to compare widely disparate treatment modalities, where the social importance of the comparison would likely be the greatest.

III. PATENT INCENTIVES AND BIOMEDICAL RESEARCH

The foregoing sections suggest that neither managed care, government reimbursement programs, nor reconstituted regulatory mechanisms are likely to counterbalance fully the incentives for unbridled innovation and consequent cost pressures created by the Bayh-Dole Act and other federal laws that encourage the private patenting of publicly funded research. A related problem is that these policies may have untoward consequences for the conduct of research itself. Private licensing or purchase of academic patents, with sizeable payments to universities and individual faculty members, represents a clear departure from past practices, and creates real risks for universities and the functions they are designed to serve in society.⁴¹

As Professor Eisenberg observes, universities did not occupy a primary role in the original Bayh-Dole scheme. The Bayh-Dole Act only permitted universities to acquire patent rights in order to attract private industry to university-developed products and processes. Nonetheless,

and flexibility in dealing with pharmacoeconomic claims).

⁴⁰ See David A. Kessler et al., *The Food and Drug Administration's Regulation of Tobacco Products*, 335 *New Eng. J. Med.* 988 (1996).

⁴¹ See Henry T. Greely, *Conflicts in the Biotechnology Industry*, 23 *J.L. Med. & Ethics* 354, 357-58 (1995).

universities have proven to be skilled intermediaries in the transfer of inventions from the public to the private sector, especially for biotechnology. As a result, the Bayh-Dole Act has been a major factor in the development of strategic alliances between academics and industry. Such relationships are now widespread, and several universities have earned large sums from patent royalties and joint venture payments.⁴²

One potential problem is that scientists hoping for financial gain may be more secretive about the results of their research, or may be required to be so by their corporate partners. In theory, receiving patent protection requires public disclosure and, by conferring a patent monopoly, diminishes incentives to conceal information. In practice, obtaining a patent is a long and risky process, during which applicants are extremely reluctant to share information regarding their inventions. Empirical evidence suggests, for example, that academic-industry relationships have led to an increase in trade secret claims.⁴³ This is in sharp contrast to both the academic and medical traditions of prompt and wide dissemination of research results.

Secrecy may be particularly likely in genetic research—a common basis for industry-university affiliations in the life sciences—because the patentability of genetic material remains uncertain in some instances.⁴⁴ Consequently, routine disclosure of work for which applications have been filed but are not ultimately granted is tantamount to giving away valuable information. Moreover, because patentability requires “non-obviousness” and any published information becomes part of the “prior art” against which obviousness is gauged, disclosure regarding a genetic innovation whose patentability is premature (perhaps because it does not have an “established use”) may reduce the chance of a subsequent refinement being patentable.

In extraordinary circumstances, the promise of financial gain for individual institutions and researchers may tempt scientists to circulate misinformation about a project’s likelihood of success or even to commit outright fraud. More generally, financial interests in academic inventions that do not lead to actual abuse nonetheless create an apparent conflict of interest, potentially decreasing public confidence in the research establishment.

⁴² See, e.g., Hassaun Jones-Bey, Biotech’s ‘Gold Rush’, 13 *Stan. Med. J.* 5 (Winter 1995-96) (describing successful products patented by Stanford students and faculty).

⁴³ According to one study, biotechnology faculty with industry support were more than four times as likely as colleagues without such funding to report trade secrets resulting from their work. See David Blumenthal, *Academic-Industry Relationships in the Life Sciences: Extent, Consequences, and Management*, 268 *JAMA* 3344, 3346 (1992).

⁴⁴ For a brief survey of patentability, see J.R. Rudolph, *Patentable Invention in Biotechnology*, 14 *Biotechnology Advances* 17 (1996).

Current financial arrangements for technology transfer have worsened the problem. In the past, promising a share of patent royalties to research scientists was seldom ethically compromising because only a truly successful product would generate revenues, and only after a protracted period of research and development. Recently, however, industry has paid large lump sum amounts up-front to universities for the long-term rights to specific inventions. These windfall payments increase the temptation to overstate results.

Many organizations, including research institutions, funding entities and scientific journals, have issued guidelines to address conflicts of interest by prohibiting or requiring disclosure of particular arrangements.⁴⁵ For example, several divisions of the United States Department of Health and Human Services have implemented or proposed rules regarding the financial interests of research investigators.⁴⁶

A longer-term concern is that the off-budget character of patent subsidies may be a politically attractive alternative to direct government funding of university research, particularly because political rhetoric continues to emphasize budgetary belt-tightening and privatization. Financing universities to a substantial degree from entrepreneurial sources may distort the national research agenda even more than the aggregate of individual incentives might suggest. For example, university departments and individual researchers may elect to pursue applied rather than fundamental research, and to concentrate on work that can be quickly patented and converted to industry use. In fact, as Professor Eisenberg notes, the line between basic and applied biomedical research seems to be blurring.

Moreover, supporting research through the promise of patent royalties is much like addressing poverty with a state lottery. If patent royalties become a major funding source for biomedical research, a few universities may feast but the rest are likely to starve. Research science is by its nature an uncertain endeavor, requiring deliberate, disciplined pursuit of knowledge whose practical utility is seldom imagined where the greatest breakthroughs occur. Even merit-based, peer-reviewed grant funding

⁴⁵ See, e.g., Columbia University, Procedures for Compliance: Annual Disclosure Statement of Officers Concerning Conflict of Interest (Feb. 29, 1996) (on file with The Virginia Law Review Association); see also Michael D. Witt & Lawrence O. Gostin, Conflict of Interest Dilemmas in Biomedical Research, 271 JAMA 547, 548-49 (1994) (analyzing then-existing conflict of interest guidelines).

⁴⁶ See, e.g., Objectivity in Research, 60 Fed. Reg. 35,810, 35,815-16 (1995) (to be codified at 42 C.F.R. § 50.604) (requiring institutions that apply for Public Health Service funding to monitor the financial interests of their employees); Financial Disclosure by Clinical Investigators, 59 Fed. Reg. 48,708, 48,717 (1994) (to be codified at 21 C.F.R. § 54.4) (requiring sponsors of new drugs and devices to submit information regarding the financial interests of clinical investigators) (proposed Sept. 22, 1994).

may imperfectly predict the potential usefulness of new fields of study. Royalty financing shifts the considerable risk of basic research from a large, fully diversified entity—the government—to substantially smaller ones. One can imagine few spheres of human labor less amenable to the stark, incentive-based compensation scheme produced by patent royalties.

Fortunately, however, both expert opinion and empirical data provide some reassurance that public dollars will continue to predominate in supporting life sciences research.⁴⁷ Nonindustrial sources provide approximately ninety percent of academic life science research funding.⁴⁸ Moreover, despite the efforts of Congressional deficit hawks, the most recent federal budget increased NIH's \$11 billion annual appropriation by nearly six percent.⁴⁹

IV. LINKING PATENT POLICY AND HEALTH POLICY

What can be done to moderate current incentives for the private appropriation of publicly funded medical technology given their potentially adverse implications for the cost of health care, its equitable distribution, and the biomedical research establishment? One possibility is to reassess technology transfer laws such as the Bayh-Dole Act.

The basic notion is that patents transferred to industry might contain recoupment provisions—obligations imposed upon patent holders that would serve to repay government for its initial investment in research and development. As Professor Eisenberg observes, the concept of recoupment derives from public concern over paying twice for the same invention—once for the research and again for the patented product. Recoupment provisions have been discussed since the inception of federal technology transfer policy.⁵⁰

⁴⁷ See, e.g., Bernadine Healy, Shattuck Lecture—NIH and the Bodies Politic, 330 *New Eng. J. Med.* 1493 (1994) (advocating continued public support of biomedical research); Harold Varmus, Shattuck Lecture—Biomedical Research Enters the Steady State, 333 *New Eng. J. Med.* 811 (1995) (suggesting that NIH funding will tend to stay constant rather than grow as it has in the past).

⁴⁸ A recent survey revealed that 59% of companies conducting life-science research provide academic institutions with an estimated total of \$1.5 billion annually, or approximately 11.7% of all research and development funding. David Blumenthal, Nancyanne Causino, Eric Campbell & Karen S. Louis, *Relationships Between Academic Institutions and Industry in the Life Sciences—An Industry Survey*, 334 *New Eng. J. Med.* 368, 369 (1996).

⁴⁹ See *US NIH Wins 5.8% Budget Rise*, Marketletter, Jan. 29, 1996, available in LEXIS, Health library, IACMH file.

⁵⁰ For example, in a general context not linked to health care spending, a recoupment requirement was debated and rejected by Congress in 1994. See *Patents, Bayh-Dole Act Has Met Its Tech Transfer Goal, Witnesses Tell Panel*, B.N.A. Daily Report for

What is new is the idea that recoupment provisions in technology transfer laws might help promote equitable utilization of expensive medical technologies.⁵¹ For example, companies receiving patent royalties on medical technology might pay a percentage to be used to fund health care for the indigent. Alternatively, those companies might be required to make their invention available free or at a discount to patients unable to pay. These costs would be factored into companies' decisions to go forward with new products, and would be passed on in part to their customers, restoring to some degree a cross-subsidy for the uninsured.

In addition to expanding access, revenues derived from patent holders might be used to verify the cost-effectiveness of new technology. A percentage of revenues might be channeled to technology assessment programs, many conducted by academic health centers whose clinical research budgets are increasingly in jeopardy (although care would have to be taken with respect to conflicts of interest at testing institutions). Similarly, compulsory licensing might be instituted to allow broader "experimental use" of proprietary technologies and more rapid development of competitive alternatives.

Of course, none of these changes to federal technology transfer policy would come close to solving the real-world problems of cost and access in health care. As in other policy contexts, real solutions can only come from grappling with difficult political and economic trade-offs. Nevertheless, recognizing and addressing potential inconsistencies between regulatory schemes such as the Bayh-Dole Act and larger social policy objectives would move a step closer to acknowledging the communitarian nature of health care.

Executives, Apr. 20, 1994, available in LEXIS, BNH library, DREXEC file (describing recoupment debate).

⁵¹ Other commentators have proposed similar uses of recouped funds. See, e.g., Brody, *supra* note 22, at 9-11; Michael J. Malinowski & Maureen A. O'Rourke, *A False Start? The Impact of Federal Policy on the Genotechnology Industry*, 13 *Yale J. on Reg.* 163, 233-34 (1996).