Research and Health Care Costs

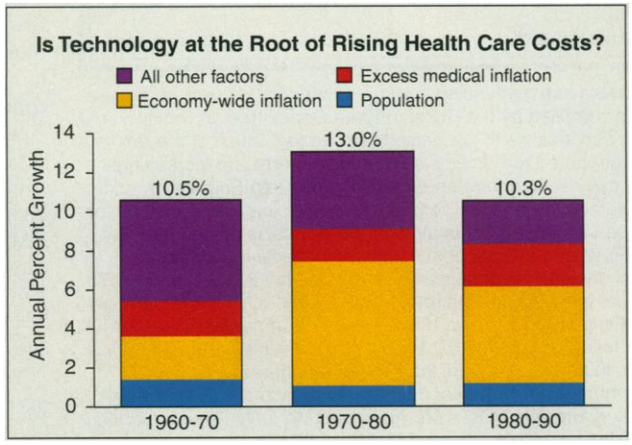
As health care costs go through the roof, scientists are trying to prove that biomedical research is part of the solution rather than the problem

As the White House searches for ways to hold down the rising cost of health care, the components of the national health care system are being divided into two categories: those that drive costs up and those that reduce them. But experts can't agree on where to put biomedical research. Some argue that research invariably leads to new and more expensive technology without regard to its utility, while others say that new knowledge generates more efficient and cost-saving medical care.

Scientists are worried that this ambiguity, along with a desire by the Clinton Administration to emphasize research with clear payoffs, may result in a weakening of political support for biomedical research. That, in turn, could translate into a loss of funding or a shift from basic to applied research. But increasingly, these scientists aren't just complaining to their colleagues over coffee. Instead, some groups are conducting economic studies that attempt to show how biomedical research can pay off in health care savings and are working hard to disseminate the results. Already, the Federation of American Societies for Experimental Biology (FASEB) has released the results of one such study, and the National Institutes of Health (NIH) is embarking on a series of similar analyses.

This new strategy is risky, however: If scientists defend their research by applying an economic yardstick, some ask, won't politicians do the same thing and support only that research most likely to have a tangible and short-term payoff? Elizabeth Marincola, executive director of the American Society for Cell Biology (ASCB), knows how hard it can be to make a convincing economic argument. After a heated debate, her society, along with the Genetics Society of America, the Biophysical Society, and the American Society for Biochemistry and Molecular Biology, hired the consulting firm KPMG Peat-Marwick to tackle the issue. But the groups were so unhappy with the product—a revisiting of the history of the polio vaccine—that they decided not to release it.

Nevertheless, the results of this debate promise to shape the future of U.S. biomedical research. Although no one in the White House has publicly claimed that spending more money on biomedical research fuels escalating health care costs, researchers see signs of that attitude in the Administration's anemic budget request for NIH and its apparent preference for technology.



SOURCE: HEALTH CARE FINANCING ADMINISTRATION

Finger-pointing. Economists believe that the availability and use of new medical technologies are the largest of "all other factors" that contribute to the annual rate of growth in what the public spends on health care. After economy-wide inflation, this component is the largest factor in health care cost growth over the past 3 decades.

As the debate gathers momentum, former NIH director Bernadine Healy believes that researchers must fight harder. "HCFA [the Health Care Financing Agency] is at the table, Social Security is at the table, but NIH is never there to hold its own," she told *Science* shortly before leaving the agency at the end of June. "So the debates are rather short sighted and simplistic—that somehow the investment in research drives up the cost of health care. It is somewhat shocking."

What's at stake

Healy's concerns are shared by many in the biomedical research establishment. Take Kenneth Shine, president of the Institute of Medicine (IOM) and a member of the expert review panel for the Health Care Task Force headed by First Lady Hillary Rodham Clinton. Shine told a FASEB conference earlier this year that "the anxiety is that the products of biology are driving up the health care costs and that one of the ways to resolve the problem is, in fact, to constrain the development of new ideas." He called that possibility a "serious, serious threat."

The biomedical establishment is running scared in part because of analyses such as those by Harvard economist Joseph Newhouse, who has estimated that new medical technologies account for more than half the annual increase in health care costs—more than $30 billion in the last year alone. Harvard sociologist Paul Starr (a member of the White House health care reform team whom *The Washington Post* described as Clinton's "professorial point man on health care reform") has written that "new technologies are the fulfillment of polices adopted decades ago to spur medical research. These policies may have indeed produced some of the benefits originally hoped for. But from the standpoint of cost containment, they are like a time bomb detonating years after being planted, setting off serial side explosions and side effects that no one foresaw."

What's worse, in the view of some basic researchers, is that these attacks are part of a trend in Congress and in the Administration toward encouraging research with an economic payoff. Since taking office, Clinton has stressed technology over basic research, and even science supporters in Congress are asking lobbyists for help in defending basic research in the face of economic and spending concerns. One Clinton adviser, speaking on condition of anonymity, forecasts that this environment will lead to a "redirection" of basic research. "For a long time," the adviser says, "the government has supported more basic research without regard to market forces. Maybe it's time to reexamine that."

A Health and Human Services (HHS) official, who also requested anonymity, says that the issue of potential economic payoff "is going to have more of an impact on NIH funding than it has in the past." One early sign, the official says, will be the $1 billion prevention initiative directed by the Centers for Disease Control and Prevention in Atlanta that the Administration intends to make the centerpiece of its biomedical research policy next year. As one of the few areas where the payoffs of research are perceived as being more certain, prevention is not coincidentally also one of the few areas of the NIH budget expected to grow.

HHS Secretary Donna Shalala, in an interview last month with *Science*, attempted to

Can Researchers Help to Lower Costs?

Most economists who blame technology for rising health care costs agree that the problem is not the existence of new technology but its use. They note that the health care system has encouraged physicians to use the best technology available, even if it is much more expensive and only marginally more effective than lower-priced alternatives. Although cost-cutting efforts have started to change that equation, the pace is too slow for many reformers.

One way to speed the shift, they argue, is with better cost-benefit analyses, done earlier in the process. Today, if it is done at all, the analysis is usually conducted by insurance companies or the government. But as Burton Weisbrod, an economist and director of Northwestern University's Center for Urban Affairs and Policy Research, explains, "when life itself is involved, it's very difficult to decide not to use a new technology after it has already been shown to work."

Weisbrod says that it would be better to do the analysis before the product is on the market—sometimes even before there is a product. This means, for example, that the cost and benefits of a drug would be evaluated somewhere between its discovery and its final approval, presumably by the sponsoring pharmaceuticals company and the U.S. Food and Drug Administration. In these cases, economic impact would effectively join toxicity and efficacy as a third criterion for approval.

No one expects basic researchers to start weighing the cost implications of every laboratory procedure, but there is increasing support for making them a partner in cost-control efforts. In May the National Science Foundation (NSF) announced a $2 million program with the private Whitaker Foundation to sponsor research on reducing health care costs. The program is intended to "get researchers to think in terms of their impact on costs," says Dov Jaron, director of NSF's division of biological and critical systems. The plan is to link biomedical engineers with economists, physical scientists, and health professionals in a search for ideas to lower health care costs.

The approach also has a supporter in Donna Shalala, secretary of the Department of Health and Human Services. "Rather than beating up on technology or slowing our investment in technology," she said in a recent interview with *Science* (2 July, p. 20), "what we need to do is to get scientists to think about the more appropriate use of that technology." The new president of the Institute of Medicine, Kenneth Shine, agrees: "As scientists we have never taken more than a casual interest in how those pricing and application decisions happen. I don't think that the average scientist is going to spend a lot of time on health care costs, but it's in the community's interest to see rational pricing."

Maybe so, but convincing scientists to get involved in the messy world of health care economics may not be easy. Weisbrod has a one-word answer to those who object: incentives. He and fellow Northwestern economist David Dranove argue that one approach would be for federal agencies to require an "economic impact statement" of health care technologies before they are submitted for approval. Another suggestion comes from Senator William Roth (R–DE), who has introduced legislation to modify the National Institutes of Health grant-review process to include consideration of the potential impact of a proposed research project on health care costs (see main story). These are radical ideas, Weisbrod and a Roth staffer concede, but the times seem to require nothing less.

–C.A.

reassure researchers that basic research would not lose out in health care reform. NIH's share of the prevention initiative, she said, would be predominantly basic, investigator-initiated research. Moreover, she added, "the last thing we should do is try to curb technology—or slow down our investment in science research—in our attempt to deal with costs."

Fighting back

In spite of such reassurances, biomedical scientists are taking defensive action. They are delving into the murky world of economics, hoping to prove what they already believe to be true: Biomedical research pays off. In May, FASEB announced the results of its first economic analysis: Tracing the development of monoclonal antibody technology from its origins in basic research of the 1970s to its use in HIV testing in the 1990s, FASEB concluded that the technology has saved the country tens of millions of dollars a year, a payoff each year some nine times the basic research investment (see table). FASEB plans to use the study as a model for a series of such analyses of the contributions made by other technologies rooted in basic research.

In the same month, 174 research and health groups sent a letter to key members of Congress offering economic arguments for increased NIH research and urging them not to blame science for rising costs. "Yes, some argue that new technologies drive up the cost of care," the letter said. "We contend that it is not the medical progress which has this effect, but the improper and often wasteful utilization of these technologies in our delivery system.... As the nation examines seriously health system reform and deals with pressures to contain treatment cost, failure to recognize heightened investment in medical research as part of the solution would be irresponsible."

The government is also getting into the act. Earlier this year, NIH completed an analysis of seven cases of applied research, part of a series on basic and applied research intended eventually to show the economic payoffs from NIH support of an entire field, such as vaccine development. It is creating

HOW BIOMEDICAL RESEARCH SAVES MONEY: THREE CASE STUDIES

Therapy	NIH funding (in millions)	Annual Savings (in millions)	Ratio	Source
Monoclonal Antibodies and HIV detection Discovery of monoclonal antibodies spawned hundreds of products, including one to test the blood supply for HIV; its use each year results in 890 fewer cases of HIV infection. Costs saved include treatment and lost income.	$6.7	$63.7	1:9	FASEB
PUVA Treatment for Severe Psoriasis NIH research determined that a combination of ultraviolet light in the A range (UVA) and a drug called psoralen (P) was an effective and inexpensive treatment of chronic psoriasis.	$19.5	$57.5	1:3	NIH
Antibacterial Peptic Ulcer Therapy NIH-funded research correlated a bacterium with chronic ulcers. An antibacterial drug was identified that can end an expensive lifetime battle with the disease.	$26.8	$760.0	1:28	NIH

an economic subcommittee as part of an advisory committee to the Science Policy Studies Center in the director's office. And the new NIH Strategic Plan calls for additional studies to "help NIH demonstrate and communicate the tangible benefits that can be traced to biomedical research. The information will be especially useful to the NIH leadership...in justifying [NIH's budget] request before Congress."

This new role does not come naturally to most biomedical researchers. Until recently, many feared that making an economic argument for basic biomedical research could lead to a shift toward applied research in which the payoff is even more obvious. When ASCB embarked on its economic analysis effort, says Marincola, "we heard from individual members who said that it embarrassed them that we'd been called down on this dirty playing field." Healy had the same experience during her 2-year effort to create a vision for the agency that included a role for economic analysis. "If there was one component of the Strategic Plan where we struggled the most with the scientific community," she says, "it was the issue of NIH's contribution to the nation's well-being. The scientific community was overwhelmingly resistant to emphasizing that."

Scientists' caution reflects the fact that cost-benefit analyses can be a two-edged sword. Earlier this year, Senator William Roth (R–DE) attempted to attach language to a bill reauthorizing NIH that would have required grant reviewers to consider, along with the scientific merit of a proposal, its potential to "increase the productivity of health care," a measure that includes its impact on costs. Although the provision was eventually removed, a compromise was struck requiring NIH's parent agency, HHS, to study methods in which the NIH scientific peer-review process could be changed to reduce health care costs. The department is negotiating with the IOM to carry out such a study, and the Senate Labor and Human Resources Committee plans to hold hearings on the issue next year.

The use of economic studies to prove the value of biomedical research, although a radical step, is not unprecedented. A cadre of economists have been trying for years to measure the benefits of basic research, but their efforts have not been very persuasive, says Burton Weisbrod, director of Northwestern University's Center for Urban Affairs and Policy Research. "Nobody's thought these things through enough to give a considered answer," he says.

One problem is that such studies are imprecise and open to alternative calculations. Innovations in basic research rely upon countless previous advances, and it is difficult to know how far back to trace the investment. It is equally hard to identify the products that may come from one breakthrough. Some groups doing such studies use citation analysis and other bibliometric techniques to trace the trail of innovation; others survey experts. Neither way is perfect, says James Schuttinga, an NIH economist.

There is also no consensus on so-called secondary benefits, such as the economic windfall to businesses supported by the manufacturer of the technology itself. In its study, FASEB used a "multiplier" calculated by the Department of Commerce that doubled its estimated benefit-cost ratio for monoclonal antibody-based HIV tests. NIH, on the other hand, does not factor in secondary benefits.

The studies also have their skeptics. Former House science committee chairman Don Fuqua once scoffed at the grand claims made for research's long-term payoff by noting, "If that were true, we could put all our money into research and eliminate the national debt." In addition, the success stories of known winners—in the case of monoclonal antibodies, including even a Nobel Prize—can hardly be applied to all of basic research. Indeed, in 1986 the congressional Office of Technology Assessment answered a simple no to the question posed by a report titled "Research Funding as an Investment: Can We Measure the Returns?"

But researchers seem determined to press on despite the odds. A lot more work needs to be done before the argument that basic biomedical research is good for the economy can rest on anything more substantive than faith. The big question is whether the political process can wait for a better answer.

–Christopher Anderson

EUROPEAN BIOTECH

Thumbs Down for Cattle Hormone

The European Community's (EC) executive, the European Commission, last week angered the biotechnology industry by proposing a 7-year ban on the use of bovine somatotrophin (BST)—a genetically engineered hormone that increases milk yields in cattle. The proposed ban has nothing to do with safety concerns. Instead, the commission wants to keep BST off the market because it could undermine the EC's efforts to reduce farm surpluses.

Industry sources say the unprecedented proposal to ban a product on economic grounds creates a climate of uncertainty that will drive biotech investment from the EC. The industry is already smarting over tough new rules on genetic engineering adopted by the EC in 1990, and the proposed BST ban is "another nail in the coffin," says Brian Ager of the Senior Advisory Group on Biotechnology (SAGB), a Brussels-based industry lobby group. For Eli Lilly and Monsanto, the U.S.-based multinationals that produce BST, the situation is particularly galling: In January, the two companies won a 5-year battle to prove that BST is safe and effective, when the commission's Committee on Veterinary Medicinal Products ruled that there is no scientific case for banning BST.

Monsanto and Lilly will now try to convince agriculture ministers from the 12 EC states—who will consider the commission's proposal in the fall—that they should oppose the ban. The companies' lobbying effort is likely to focus on the commission's economic analysis, which concludes that the widespread use of BST would increase milk production enough to lead to the slaughter of 4% to 6% of dairy cattle in the EC, given current milk quotas—a development that would add to beef surpluses. But Ken Baker, director of public policy with Monsanto Europe, claims that these calculations are flawed. In countries such as Brazil, where BST is on sale, he says, the hormone is used by a minority of farmers as a "management tool" to even out yields over the year, rather than to achieve large overall increases in production.

If the ministers can't be won over, the result will be a policy paradox: BST will be made by U.S.-based companies in the EC, where it can't be sold, largely for export to the United States, where it probably will be on the market soon. Both companies have set up BST plants in Europe—Lilly near Liverpool in England; Monsanto near Innsbruck in Austria, which is moving toward EC membership. The U.S. Food and Drug Administration should deliver its verdict on BST any day now, and as it is limited to considering safety and efficacy questions, most observers expect the hormone to be approved for sale in the United States.

The biotech lobby fears that the commission's opposition to BST will make large investments in European biotech a thing of the past. But some observers, such as Mark Cantley who follows biotech policy for the Organization for Economic Cooperation and Development, believe that the commission's action should not necessarily be viewed as a precedent. They point out that in 1990, commission agriculture and environment officials were pressing hard for socioeconomic criteria to be applied routinely in the evaluation of biotech products (*Science*, 7 June 1991, p. 1366). But that idea was thrown out in a high-level commission document published in 1991. EC farm commissioner Rene Steichen has now successfully argued that BST is an exceptional case, but Cantley predicts that biotech opponents won't be able to play the same card again any time soon.

–Peter Aldhous