Medical Innovation Meets Healthcare Reform

BY JANE H. WHITE

One area that stands to be greatly affected by healthcare reform, but has not thus far been widely discussed in the health policy community, is medical innovation. Signs that the innovation community is anticipating change have already shown up on Wall Street, however. A new study in *Health Affairs* reports:

> According to Alex Brown and Sons, a Baltimore firm, the prices of many biotechnology stocks fell 30-40 percent in 1993, before recovering somewhat in the fourth quarter. Some of this was undoubtedly due to disappointing news on some key biotechnology products in development, but large pharmaceutical stock prices also lost 10-20 percent of their value last year, suggesting that the market capitalization of the entire industry was negatively affected by the climate of health care reform.[1]

This column focuses on some of the anticipated changes in medical innovation as a result of healthcare reform and on actions to date in Congress regarding medical research. It also examines policy analysts' concerns about the effect of medical technology on rising healthcare costs—one of the driving factors behind the current push to reform the U.S. healthcare system.

For this discussion, I use definitions set out by Richard A. Rettig of the Institute of Medicine: "Innovation in medicine means the scientific, technological, and clinical developments that result in new medical products, processes, or procedures, whether diagnostic, therapeutic, preventive, or administrative."[2] Medical technology includes drugs, devices, medical or surgical procedures, and organizational or support systems for provision of such care.

Congressional Debate on Innovation

The major healthcare reform bills introduced in Congress this spring all included some federal commitment to technology assessment and outcomes research. The National Health Policy Forum (NHPF) reported that "bills introduced by the Clinton administration, Sen. John H. Chafee (R-RI), and Reps. Pete Stark (D-CA) and Jim McDermott (D-Wash) all propose a significant expansion of AHCPR's [the Agency for Health Care Policy and Research's] involvement in appropriateness and effectiveness research of alternative clinical strategies."[3]

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The report also notes that the proposal by Rep. Jim Cooper, D-TN, would create a new Agency for Clinical Evaluations to develop specific guidelines for healthcare services. This new agency would assume the responsibilities for clinical evaluations and effectiveness research now housed in AHCPR, the National Center for Health Statistics, the National Institutes of Health (NIH), and the Health Care Financing Administration. Taking a different tack, Rep. Ron Wyden, D-OR, according to the NHPF report, "has developed draft legislation that seeks to encourage private-sector companies to conduct their own assessment and outcome studies by offering them the incentive of an FDA [Food and Drug Administration] fast track and market exclusivity of the devices."

In addition to this attention to technology assessment and outcomes studies, Congress has discussed whether the overall level of federal funding for medical research is adequate both now and in the various reform proposals. During the past decade, the percentage share spent by the federal government on healthcare research and development (R&D) has steadily eroded. In 1985 NIH was the source of 36 percent of health R&D funding, and other federal sources totalled 14 percent. Industry in that year was responsible for 39 percent of R&D funding, with other sources making up the remaining 10 percent. Projections for 1993 put the NIH share at 32 percent, other federal sources at 7 percent, and industry investment in health R&D at 50 percent.[4] Other sources fund the remaining 11 percent.

Sens. Tom Harkin, D-IA, and Mark Hatfield, R-OR, introduced an amendment on February 28, 1994, to provide additional medical research funds as part of any comprehensive health reform package. This bipartisan "Health Research Act of 1994" would create a national Fund for Health Research similar to the set-aside funds for graduate medical education and academic health centers proposed in the president's healthcare reform plan. The revenue would come from a 1 percent set-aside fund from each health insurance premium paid into the health alliances. The amendment also proposes a voluntary "check-off" on federal income tax forms for additional contributions to the research fund.

Hatfield testified May 12, 1994, before the Senate Finance Committee that the bill would yield $4 billion to $5 billion a year in additional funding for the NIH. Hatfield and Harkin, along with cosponsors Sens. Edward Kennedy, D-MA, and Nancy Kassebaum, R-KS, have asked the Congressional Budget Office for an "official reading" on these funding estimates, however. Hatfield summarized their concern at the hearing as follows: "Over the past several years, as the cry for healthcare reform has grown louder and louder, there has been a deafening silence when it comes to the role of medical research. Reformers are missing the point: Healthcare reform will not be complete without a research component."

Effect of Reform on Innovation

Beyond this relatively selective attention to technology assessment and research funding levels, the current debate in Congress has not seriously focused on how the major reform proposals will affect the complex process of medical innovation. In the current issue of *Health Affairs*, policy analysts Jane E. Sisk and Sherry A. Glied of Columbia University predict:

> Health care reform proposals will affect innovation primarily indirectly, by containing costs and altering the composition and extent of health insurance coverage. Proposals that incorporate regulatory cost containment, including the [president's] Health Security Act and single-payer proposals, almost certainly will reduce the extent of the market for costly new technologies.[5]

Sisk, formerly a senior analyst at the congressional Office of Technology Assessment, and Glied, who served on the president's task force on health reform, continue:

> Proposals that emphasize competition, such as insurance reform and managed competition, will provide incentives to shift away from cost-increasing technologies. . . . Proposals that expand the scope and extent of insurance coverage, through comprehensive standard benefit packages and universal coverage, are likely to expand the market for preventive and pharmaceutical innovations, even under cost containment.

The time it takes to earn FDA approval and bring a new product to market makes it difficult for drug companies to respond quickly to new reform-driven market incentives.

Given their sensitivity to market influences, pharmaceutical, medical device, and biotechnology companies are all likely to respond to incentives inherent in whatever reform package passes. The question is how quickly they would be able to respond and whether sufficient venture capital for ongoing R&D will continue to be available.

For drug companies, the time it takes to earn FDA approval and bring a new product to market makes it difficult to respond quickly to new reform-driven market incentives, such as greater emphasis on cost-containing technology. The average FDA drug approval time stood at 26.5 months in 1993, down 10 percent to 15 percent since the mid-1980s.[6] However, when one adds this to the development and clinical testing time, total R&D time may stretch to 10 years or more. Given this long lead time for development, the full effects of any healthcare reform plan may take some time to show up.

Even with the long R&D lead time and with the uncertainty surrounding the final outcome of the reform debate, some changes are already apparent. Columbia University's Annetine Gelijns and Nathan Rosenberg report that:

> The growing importance of economic considerations in hospital purchasing and clinical adoption decisions is influencing technological change in the direction of explicitly developing cost-reducing technology. . . . Interviews with pharmaceutical firms underscore that they are reallocating their R&D expenditures toward finding solutions for costly chronic care (for example, Alzheimer's disease). By contrast, research in therapeutic categories that will be well served in the coming decade by generic drugs will be deemphasized, mainly because managed care purchasers and hospital formulary committees will encourage generic substitution."[7]

Gelijns and Rosenberg are quick to point out some caveats, however, to the apparent reaction of the technology industry to signals from the market and government to emphasize cost reduction. They note that the high degree of uncertainty in medical research, and even in the early

development and adoption stage of a new technology, means that cost implications are not always clear. Also, "new medical technologies, once developed, often interact with other technologies in unexpected ways," they explain. New uses may develop; the technology itself will likely evolve after use and feedback from clinicians; and intensity of use for the technology may vary.

Another effect of reform already present in the drug industry is a press advertising campaign and lobbying effort to highlight the industry's research and the cost-reducing effects of using drug treatment instead of surgery or other therapies for a variety of illnesses. Indeed, the industry association—the Pharmaceutical Manufacturers Association—changed its name in May 1994 to the Pharmaceutical Research and Manufacturers of America (PhRMA). The association has been lobbying hard to keep price controls out of a reform package, and companies have voluntarily reduced prices or limited increases. The industry has scrambled to explain its high profit levels by pointing to its high level of R&D, now surpassing the federal government's investment. PhRMA reported that its members spent $12.6 billion on health R&D in 1993, up 13.5 percent from the prior year. For 1994, however, the industry increase in R&D is expected to rise only 9 percent, for a total of $13.8 billion, the first year of under double-digit growth since 1977.[8]

Is Innovation Driving Cost Increases?

Finally, a question at the heart of the matter is whether innovation is a key culprit in driving up U.S. healthcare spending. A number of economists and policy analysts have attempted to quantify the effect of technology on healthcare costs. Little empirical evidence exists. One widely cited study, by Harvard economist Joseph P. Newhouse, uses a "residual" approach. He first adds together the possible causes of healthcare spending growth: aging population (accounts for 7 percent of the overall rise in health spending); spread of health insurance (10 percent); increased income (5 percent to 25 percent, though Newhouse leans toward the smaller figure); more physicians and physician-induced demand (no clear empirical correlation); more defensive medicine (1 percent); administrative costs; spending on the terminally ill; and lagging productivity in the medical care service industry.[9]

Newhouse claims the residual reason for rising costs is increased innovation, or "the march of science." He offers three reasons. First, factors such as more elderly, more insurance, and higher incomes should have raised demand for hospital and office visits even if technology did not change. Yet, "the great increase in hospital cost has not occurred because more people have been going to the hospital but because they spend more when they arrive. This is consistent with the perception that more is being done to them or for them when they get to the hospital and not consistent with the notion that medical care costs are a simple tale of increased demand," he notes.

Harvard economist Joseph P. Newhouse argues that Americans' willingness to pay for the "enhanced capability" offered by medical innovation is a key factor in rising healthcare costs.

Data from the Health Care Technology Institute in Alexandria, VA, confirm Newhouse's view.[10] Hospital inpatient admissions have dropped almost 20 percent since 1982, despite a 10.2 percent increase in the U.S. population. Occupancy has fallen from 75.9 percent in 1980 to 62.1 percent in 1992. Juxtaposed with these trends, the value of hospitals' movable capital, which includes such innovations as lithotripters and MRI units, has grown much more rapidly than that of fixed capital. From 1975 to 1991, movable capital averaged a growth rate of 12.4 percent per year, versus 5.7 percent for fixed capital. Movable capital thus grew to 36.2 percent of hospitals' capital stock in 1991, up from 17.5 percent in 1975.

Two additional reasons Newhouse cites for technology being the "residual" growth factor are (1) health maintenance organization (HMO) costs are being driven up at a similar rate as fee-for-service medicine, with technology a common factor; and (2) other developed countries show similar rates of increase, though different baselines, in healthcare spending, and again technology is a common factor among the countries.

After making his case that medical innovation is indeed a prime factor in rising healthcare costs both in the United States and abroad, Newhouse then asks whether we are willing to pay for this "enhanced capability." He argues that to date, Americans have demonstrated a willingness to pay, and thus are themselves a factor in the upward cost spiral. As evidence of willingness to pay, he cites (1) the failure of HMOs—"the closest thing we have to a market test of willingness to pay"—to offer a plan with lower levels of technology, (2) public opinion polls that show a majority saying we spend too little on "improving and protecting the nation's health," and (3) international comparisons of similar rates of rising healthcare spending. As Newhouse elaborates, "If countries with very different financing institutions than those in the United States show similar rates of cost increase, they are evidently willing to pay for the technology, albeit not to the same level of intensity."

The question now before the nation and the medical-industrial complex as Congress struggles to pass a health reform bill is: Are we still willing to pay for ever-increasing medical innovations? Or are we ready to set some limits or shift some

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incentives to encourage more cost-effectiveness?

If cost containment is a primary goal of reform, some changes in the current system of innovation seem warranted. Yet, can we set some limits without irreparably suffocating innovation in healthcare? As Sen. David F. Durenberger, R-MN, and his senior legislative assistant Susan Bartlett Foote, warn, "Health reform must not inhibit our system's ability to improve so that it can provide the American public with value for its precious health care dollars."[11] □

NOTES

1. J. Leighton Read and Kenneth B. Lee, Jr., "Health Care Innovation: Progress Report and Focus on Biotechnology," *Health Affairs*, Summer 1994.
2. Richard A. Rettig, "Medical Innovation Meets Cost Containment," *Health Affairs*, Summer 1994.
3. Donald L. Zimmerman, "Medical Technology and Health Reform: Devising Policy for the Medical Device Market," *Issue Brief*, no. 649, May 20, 1994.
4. National Institutes of Health, *NIH Data Book*, 1993, Figure 2.1. It is important to note that the decrease in 1993 for other federal spending reflects the transfer of National Institute on Alcohol Abuse and Alcoholism, National Institute on Drug Abuse, and National Institute of Mental Health activities from the Alcohol, Drug Abuse, and Mental Health Administration into NIH, thus also increasing the relative NIH figure. However, the overall government share of health R&D has decreased compared with the industry share.
5. Jane E. Sisk and Sherry A. Glied, "Innovation under Federal Health Care Reform," *Health Affairs*, Summer 1994.
6. Read and Lee.
7. Annetine Gelijns and Nathan Rosenberg, "The Dynamics of Technological Change in Medicine," *Health Affairs*, Summer 1994.
8. Read and Lee.
9. Joseph P. Newhouse, "An Iconoclastic View of Health Care Cost Containment," *Health Affairs*, Supplement 1993, pp. 152-171.
10. Health Care Technology Institute, *1994 Reference Guide for the Health Care Technology Industry*, Alexandria, VA, 1994.
11. David F. Durenberger and Susan Bartlett Foote, "Technology and Health Reform: A Legislative Perspective," *Health Affairs*, Summer 1994.