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Perspective

Preserving The Milieu For Medical Innovation
by Glen D. Nelson

More than thirty years ago, as a medical student, I frequently had to draw blood from youngsters suffering from leukemia who were being treated in a chemotherapy research program. Treating these children was heartbreaking because we all knew—students, physicians, and parents alike—that leukemia was a killer. Only about one patient in ten survived. Over the years society continued to dedicate resources to leukemia research. As a result, today’s therapeutic advances, which include bone marrow transplants, enable more than 70 percent of these children to survive this deadly disease.

In their early stages of development, treatments such as chemotherapy and bone marrow transplants had limited effectiveness. But as physicians and scientists worked to perfect these therapies through an iterative clinical process, they achieved safer and more effective outcomes. Had society not provided a high level of funding for this research thirty years ago, physicians would not be curing as many of these children as they are today.

One must wonder, however, what would have happened if chemotherapy and bone marrow transplants had faced an assessment process such as the one that Jane Sisk and Sherry Glied discuss in their paper, “Innovation under Federal Health Care Reform.” Three decades ago, would the benefits of these therapies have been sufficiently apparent to win their approval?

Or, consider the possible fate of some of the many medical devices that have contributed to improved medical care over the years. In the 1950s large-diameter vascular grafts permitted the replacement of dangerously weakened major blood vessels. In 1958 the first electronic device, the cardiac pacemaker, was implanted. This revolutionary technology stimulated the heart experiencing bradycardia to a rate approximating the normal resting heartbeat. Without pacemakers, patients typically had sharply limited ability to conduct daily living tasks, suffered from fainting episodes, and died prematurely. The 1960s saw the emergence of the mechanical heart valve as a practical replacement for defective natural valves.

Implanted medical devices such as these offered therapy where previously none was available. Perhaps the clearest example of the lifesaving capacity of medical devices has been the development of implanted defibrillators. Carefully selected patients who now receive such devices would likely have been victims of sudden cardiac death. Other technologies such as drug delivery systems, orthopedic joint implants, shunts for hydrocephalus, and intraocular lens implants have restored patients to fuller and more productive lives.

The impact of medical devices has been profound and far-reaching. In the cardiovascular arena alone, more than a million procedures are performed each year to open blocked arteries with balloon angioplasty, restore heart rhythms with implanted pacemakers and defibrillators, provide respiratory and circulatory support during open-heart surgery, and repair blood vessels with synthetic grafts.

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Today's remarkable medical technologies and therapies are the direct result of an innovation process that takes place not so much in quantum leaps but more in steady, iterative steps. This continually improving, evolutionary cycle is neither linear nor predictable. Rather, it is a dynamic, complex course marked by uncertainties and unexpected twists and turns. No one—including government regulators charged with evaluating technology's potential-no matter how informed or prescient they may be, can foresee the ultimate uses of every technological innovation.

It takes time, persistence, constant refinement, and frequently a bit of luck to bring technology to its full potential. Among the factors influencing innovation are market forces, patients' needs and demands, federal policies (including reimbursement), product liability concerns, device approval times, patent protection, and the interaction between physicians and manufacturing companies.

This interchange between medical specialists and device manufacturers spawns continued evaluation of and incremental improvements to both new and established medical technologies. New ideas about applications, enhancements, refinements, or entirely new products flow continuously between users and manufacturers as medical devices are put to work in everyday clinical practice. Even breakthrough technologies need continued fine-tuning to deliver enhanced benefits and reduce costs. The direction of all this advancement is sometimes dictated by the whims of serendipity. We should recognize this unpredictability as we seek assessment approaches, formulate developmental guidelines, and propose health care reforms that could affect the availability of research funding and investment.

Reductions in investment and funding for research and development (R&D) is a problem for all medical device makers but is particularly so for small medical device companies, which must rely heavily on venture capital. This type of funding is becoming more difficult to obtain in today's environment of increasing regulatory burdens and uncertainties about reform. The effect on small companies is particularly troublesome, because they account for more than 70 percent of the 10,500 companies that make up the medical technology industry.

Sometimes these smaller companies can partner with larger firms to develop new devices. Larger corporations, in addition to their breakthrough advances in technology, are frequently the companies responsible for bringing about incremental changes in technology—the added features, reduced size, and process improvements that often yield cost savings.

Medical innovation springs from many sources: the individual scientist, physician, and researcher; the university or teaching hospital; the small device company; and the multinational corporation. This dynamic and complex structure has worked extremely well in bringing a startling array of new medical devices to market. Because of robust R&D programs, the United States has been a leader in innovating and providing medical devices for the entire world. Last year American medical device manufacturers exported almost $10 billion worth of equipment and devices—nearly a quarter of their production—thus making medical devices an important contributor not only to world health, but also to U.S. economic growth.

The medical device industry, however, is highly dependent on good financial performance to continue the remarkable progress of the past fifty years. Current changes in health care delivery and financing seek to impose more order and predictability on the innovation process. In the drive toward cost-effective care, reimbursement or even product approval will be determined by demonstrable outcomes research data. Under virtually any system of health reform, payers and providers will demand much more information from medical technology manufacturers. This likely will include more clinical data, and it certainly will include more cost-effectiveness and outcomes data. Few would argue against this approach, but we also must apply the outcome scalpel delicately so that we do not excise promising solutions before they can demonstrate true efficacy.

In addition to the far-reaching effects...
that any system of health reform will have on medical technology, the demand for reliable information could have a subtle, self-selecting impact on innovation. Outcome studies will cost money and take years to complete. Innovators may be forced-much earlier in the development stage-to make hard decisions about which products to pursue. Such demands may encourage companies to develop those products most likely to be received favorably by the market—that is, those that can save money or whose cost-effectiveness can more easily be proved. The riskier breakthrough R&D necessary to produce major advances may be thwarted.

The uncertainties along the path of innovation are already substantial, but health reform introduces a new set of unknowns. Among other things, reform proposals make innovators ask: What kinds of new products will be accepted? What new demands will be made of products or the companies that manufacture them? How will these demands change development time or costs? How will they change financial risk or the ability to raise capital? How will the nature of the market change or the expectations of the customer be altered? These are questions not easily answered.

I concur with other commentators that “in a modern medical setting, technology is health care.” So, I believe that health care reform will unavoidably affect technological innovation. To what extent is not entirely clear. It certainly will not mean that innovation will cease. Medical device companies have learned to be adaptable. But an increasingly uncertain environment and redeployment of resources could well curtail innovation in high-risk areas and among smaller companies. Product development could also shift to other countries where the regulatory and reimbursement climate is more nurturing of invention.

The optimist would say that health care reform will make us question paradigms and force us to look for more precise diagnostic tools and more effective therapeutic technologies. But even the optimist would have to question whether these goals can be achieved by redirecting essential resources from research and innovation to primary and preventive care. Such an approach would be counterproductive, since technology is best used to improve the cost-efficiency of complex specialty care, freeing up resources to provide even more care.

Reemphasizing primary care and preventive medicine is a laudable goal. Yet, as Sisk and Glied point out, innovation in medical care is linked more closely to the clinical investigatory work of specialists than to primary care physicians. Primary caregivers diagnose and treat patients at the interface between health and illness, the lower-cost end of the spectrum. Those with major illnesses—the most costly to treat—such as cancer, complicated diabetes, heart disease, acquired immunodeficiency syndrome (AIDS), and chronic degenerative diseases are usually referred for specialty care. It is no coincidence that these are the diseases on which we need to focus our innovative efforts. We should not “eat our seed corn” by financing preventive approaches with the resources needed to advance the therapies for diseases that cause real pain and suffering.

Health care reform cannot begin to achieve its true potential without continued technological innovation. Innovation cannot proceed without the ability to bring technologies from incipient stages of development to higher levels of refinement. This process requires collaboration between medical specialists and the medical device industry. The fundamental relationship between specialists and manufacturers has been a major reason for society’s progress against some of medicine’s greatest challenges. Preserving this milieu provides a platform—which cannot be replaced by more primary care—for continuing this progress.

NOTES
2. Ibid., 7.