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Raymond H. Kahn

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Raymond H. Kahn, PhD*

The world is undergoing a biological revolution that has made unparalleled demands on the American health care system. This demand for health care and its escalating costs provide abundant incentives for reducing the cost through better technology. Recent developments in medical technology include the CAT scanner, nuclear magnetic resonance (NMR), as well as new advances in prosthetic devices. Most biomedical research and development takes place at not-for-profit institutions, such as universities, hospitals, and private foundations, much of it supported by federal funding from such sources as the National Institutes of Health. But, today, the institutions are in danger of major cutbacks in funding at a time when inflation has already endangered the resources available for biomedical research. One potential solution to this problem is to encourage a better relationship between industry and the research community; in a period when federal support is obviously leveling off, industry can provide the vital margin while simultaneously encouraging a continued federal commitment.

Unfortunately, the objectives of research do not parallel those of industry. Scholarship traditionally has been devoted to the transfer of information by publication, while industry responds to the proprietary needs of a corporation and reflects a commitment to the profit motive. Clearly, any "marriage" of industry with the scientific research community as a cooperative venture will require some innovative thinking on the part of both.

While only recently appreciated, the world is undergoing a biological revolution, a revolution which will rival the industrial revolution. The impact of this upheaval will far exceed the consequences of industrialization, for it will affect not only the quality of life but life itself. Until now, the U.S. has been the unparalleled leader in the life sciences, as a direct result of the public support initiated by the National Institutes of Health (NIH) 30 years ago. In 1950, less than 0.06% of our Gross National Product (GNP) was invested in research and development. Largely fostered by Congress, that support has increased more than five-fold so that it now stands at 0.31% of the GNP (1).

Increased Costs of Health Care

When compared to the expenditure for health care, which is over $200 billion annually (2), this nation's commitment to research and development in the life sciences pales into insignificance. This cost is a 16-fold increase over the same 30-year period and now accounts for more than 9% of our GNP (3). This sharp increase in our health care cost is a function of a number of factors (4), including a significant population increase that has been exacerbated by a shift in aging (3). Today, 11% of our citizens are over 65 years of age, and this percentage is increasing with time so that by the year 2000 about one fifth of the nation will be over 65. Another factor which affects health care costs is pre-paid health insurance and general affluence, both resulting in greater public expectation and demands on the health care system. Probably the most important factor is that health care is labor intensive. While the number of support personnel varies from hospital to hospital, depending on whether it is a community hospital or a tertiary care center such as Henry Ford Hospital, two to three employees are required for each patient bed, excluding physicians and residents. It is noteworthy that health care is the only industry that does not support its own research and development.

This demand for health care and the explosive costs of such care provide abundant incentives for reducing the cost through better technology. Until quite recently, the transfer of information from the research laboratory to the bedside was slow and frequently undirected. But the pace from invention to practice has quickened as a direct result of the commercialization of a few highly visible technical advances such as genetic research (4), aided by a large force of scientists trained with federal grants. The result is an explosion of laboratory innovation fostered by sophisticated instrumentation. Monthly, more than 25,000 journals are published in biology and medicine; the average scientist must scan titles retrieved by computer simply to keep

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* Director of Research, Henry Ford Hospital

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Address reprint requests to Dr. Kahn, Research Office, Henry Ford Hospital, 2799 W Grand Blvd, Detroit, MI 48202

up in the field. Clearly, technology has affected major changes in the cost of health care (5).

Human suffering notwithstanding, consider for a moment the financial impact of the polio vaccine. Developed over a number of years, this vaccine became medically accepted and widely distributed in 1955. Without it, over half a million people would have contracted the disease in the past 25 years. Of those, 8% would have died, 24% would have been totally disabled, and the rest either partially or mildly affected. Based on these rough estimates of disability and projecting for inflationary increases, it would have cost the U.S. over $100 billion in medical charges and loss of income. Since the total cost of the vaccine and the field trials was $41 million, the savings to date are 200,000 times the cost. Comparable figures can be cited for the incidence of tuberculosis, measles, or whooping cough. However, success with infectious diseases has not been universal, and the current cost of gonorrhea and hepatitis can only be surmised. Since heart disease remains by far the number one killer, with cancer not far behind, it is clear that there are numerous opportunities for an expanding and cost-effective market.

Recent Advances in Medical Technology

Diagnostic devices

To look at what opportunities do exist, it seems worthwhile to briefly comment on a few of the advances that have occurred in recent years, emphasizing that many of these were not even conceived 10 years ago. A classic example of new technology is the computerized axial tomography (CAT) scanner, a machine with the capacity to synthesize normally uniplanar x-rays into multiplanar views of the body. This diagnostic tool is only now being appreciated and made available. Somewhat less well known but with a great deal of potential is the use of ultrasound waves to generate structural images. Sonography was undertaken as a direct outcome of sonar developed during World War II. Although its resolving power needs significant improvement, the capability it provides to view the fetus in utero noninvasively or to see heart valves in action portends important breakthroughs. One that is already a reality, albeit primitive, is the Positron Emission Tomography (PET) scanner, which visualizes injected radioactive agents as they localize within the body. Once again, this instrument depends on the computer to recreate a two-dimensional picture, yielding a cross-sectional view of the head or body. It is important to recognize that the PET scanner responds to the functional status of the patient, rather than depending solely on the structural changes visualized by ultrasound on the CAT scanner.

Among other diagnostic devices that we can envision as both feasible and useful to the health care industry will be a device that can monitor a whole host of metabolic parameters noninvasively, (e.g., topical magnetic resonance). It would be extremely useful to be able to assess blood flow and pressure continuously, rather than to rely on intermittent readings taken in the doctor's office. As another example, our current understanding of the chemistry of blood clotting is truly embryonic. Theoretically, blood chemistry should be a good indicator of clotting tendencies and should therefore be able to predict such illnesses as a stroke or heart attack. These new health parameters would provide a better understanding of the ranges and consequences of bodily functions and would most likely redefine normal values. Similarly, more sophisticated techniques for analyzing cell and tissue structure routinely and automatically would reduce the cost of diagnosis. Image analysis has that potential, for it quantifies any photograph or visual image into a digitized pattern. Conceivably, automatic scanning of cells such as the Pap smear or human chromosomes by image analysis to distinguish and predict potential congenital defects would not only reduce costs but could expand our current expertise.

Hybridoma techniques

Any discussion of diagnostic possibilities must highlight the current excitement over hybridomas. Techniques to foster the fusion of cells in tissue culture have been recently discovered. Consequently, cells with the ability to make specific antibodies can be isolated after fusion has taken place with a myeloma cell as a hybrid. As a malignant cell, the myeloma cell can propagate continuously. Thus, this new technology provides for the continuous propagation of specific antibodies.

It follows that we shall soon have the ability to detect markers on diagnostically important cell types and, as we shall see, in the near future generate specific human antibodies on a production basis. Combined with image analysis, new horizons in diagnosis can be projected. However, the technology for fabricating, distributing, and marketing antibodies is still to be defined. Finally, I would note that a series of laboratories are actively pursuing chemical factors with the potential to diagnose selected cancers. These include alphafetoprotein, carcino-embryonic antigen (CEA), and others.

Half technology versus full technology

In any discussion of potential changes with respect to therapy, it is important to distinguish between therapeutic techniques that are "substitutive", or act as replacements, and those that truly cure the disease. Lewis Thomas in his recent book, Lives of the Cell, compares these two by

referring to the former as "half technology", while defining therapies which remove the cause of a disease as "full technology". A heart transplant or any prosthesis that mimicks the heart, such as the left ventricular assist devices (LVAD), are not directly addressing the problem. An individual may need a replacement heart because the coronary vessels are occluded or portions of the heart muscle are destroyed beyond repair. While the transplanted heart or the prosthetic device solves the person's immediate need, it clearly has not solved the fundamental problem, namely, the changes in the structure and function of the blood vessels or heart musculature. As Thomas points out, half technology, e.g., kidney translants, is glamorous and expensive. On the other hand, full technology is far less expensive and quickly becomes mundane. Consider how readily we accept insulin therapy, antibiotics, or the Salk/Sabin vaccine. Half technology for the treatment of poliomylelitis in contemporary terms would have yielded a computerized iron lung.

With respect to curative therapy, much interest has evolved in the last few years for procedures to enhance radiation therapy that will selectively destroy cancer cells. One concept that has significant potential is the technique of hyperthermia, which raises the temperature in a specified region of the body and permits a lower dose of radiation to be effective. A second technique combines fiberoptics with laser light sources to bring specific wave lengths into play in order to modify the chemical structure of materials selectively placed at the site of a cancer or lesion. As noted previously, the availability of specific antibodies derived from hybridomas which would bind with foreign protein, be it an infectious agent such as a virus or a toxic chemical such as bee venom or PBB, would also provide a specific cure to the problem. Thus, within the foreseeable future, specific antibodies to provide passive immunity and/or generate unique vaccines against hepatitis, herpes, and other viral or foreign proteins will become feasible. Graft protection for the transplanted kidney, heart, or other organs as well as tumor rejection can be anticipated as well. In this same category, current research has identified a series of materials that appear to be specifically antiviral, most notably a substance called interferon.

Prosthetic devices

With respect to prosthetics, much can be reported, and I will necessarily limit my discussion to a few examples. One such instance is the development of new, nonthrombogenic blood vessels by lining fabricated tubes with living cells derived from the potential recipient. This technique would enable the surgeon to tailor-make vessels of any diameter or configuration. Obviously, there are other instances of trauma or disease that will never respond to curative therapy. While the problem of the traumatized knee or hip has been addressed frequently over the years, the perfect solution has yet to be defined. It is especially difficult to maintain prostheses over a long period of time in a fixed structural relationship with bone. While cosmetically acceptable replacement limbs for the amputee are available, they still lack the needed mobility. Conceivably, this established technology can be combined with microelectronics and ultimately with sensors to nerve endings to produce highly sophisticated systems of limb control. In this connection, the ability to transplant muscle and even stimulate new muscle growth has real promise.

Problems which are actively being addressed include refinements of materials that are compatible with living tissue, including biocompatible glues, plastics, ceramics, and carbons. Devices that will transmit energy across the skin to power pacemakers and obviate invasive surgery; mechanisms to process neural information and transmit that information to the brain enabling feedback; recalcification of teeth; artificial hearing and visual prostheses—all are in the earliest stages of development. Solutions to these biological problems will undoubtedly be the impetus to new directions in technology. As a scientist, I have a real sense of excitement at being at the frontiers of discovery. But there are frustrations as well.

Risks for Biomedical Research

The not-for-profit research institutions, such as universities, hospitals, and foundations, are responsible for much of the biomedical research and development in the U.S., since scholarship is a prime objective and an integral part of their programs. In a very real sense, this country's leadership in biomedical technology, as in many other fields, depends on the survival of these institutions. This leadership is best evidenced by the repeated recognition the world has given to American scientists, not the least of which has been the frequency with which Americans have been awarded the Nobel Prize. Moreover, the research created at such research institutions is of the highest quality and has cost relatively little. In the best fiscal sense, American research has been a bargain!

Loss of federal funding

However, these research institutions are in trouble. As noted previously, until now the federal government has been largely responsible for the support of research and development and for the training of new scientists. In the last decade (1), NIH has significantly reduced its support of research in constant dollars, while at the same time many time-consuming and costly regulations have been promulgated. Currently, the nation is facing severe fiscal con-

straints, and research and development are especially susceptible to cost-cutting as one of the few remaining so-called "discretionary" expenditures. In an inflationary economy, biomedical research is especially vulnerable. Only 2% of the budget of the Department of Health and Human Services is currently attributable to research. Most of the Department's budget is "fixed entitlements" that are committed to supporting the Social Security system or required for Medicare and Medicaid through the Health Care Finance Administration (HCFA). The danger is that research institutions will be deprived of one of their major sources of support at a time when they are least able to cope. As you know, the state of Michigan is particularly susceptible to this loss as a reflection of our dependence on the automotive industry. With fiscal stringency, moreover, philanthropic support and/or state general funds have become increasingly difficult to maintain. However, technology cannot accept a hiatus in funding, for innovation is not something one can create, allow to die for lack of funding, and expect to resurrect without an extended delay and much pain.

The "Marriage" of Research and Industry

One potential solution is to promote a better relationship between industry and the research community (7). That relationship has to be assertively pursued by this community as well as by industry and supported by venture capital (8). The catalytic effect of bringing together the counseling, peer review, legal expertise, marketing experience, and venture capital could foster many new and profitable industries.

Unfortunately, the objectives of research do not parallel those of industry. Scholarship traditionally has been devoted to the transfer of information by publication. Industry, on the other hand, must respond to the proprietary needs of a corporation and reflect a commitment to the profit motive. Clearly, any "marriage" of industry with the scientific research community as a cooperative venture will require some innovative thinking on the part of both. At the outset, the not-for-profit institutions will have to more readily accept a more liberal attitude and recognize that consultants and patents, aside from personal profit, represent a significant contribution to society. Moreover, scientists will have to accept that the free exchange of information may require a delay at least long enough to protect ideas and inventions by the patent process. For some reason, many individuals view this process as demeaning (9). In fact, patents are designed to facilitate the exchange of information, and such reticence on the part of the scientists and scholars is surprising. For its part, industry must recognize the importance of excellence, objectivity, and impartiality to the researcher. The benefits would be the rapid diffusion of technology to society with financial returns to the innovator, to the institution that provides the environment, and to industry. Whatever the mechanism, it lies within the power of the aforementioned to make this cooperative venture a reality.

To make this marriage of science and industry work, we have to be realistic. As Dr. Donald S. Frederickson, former NIH Director, warned in a recent address to the Royal College of London: "Much of the basic research on which profitable development depends cannot be supported by industry or any other private sources" (1). I would agree. Surely, industry cannot afford to support all basic research or provide the necessary clinical assessment of every prospective device and therapeutic material. Nor can industry expect to compete with the current national investment of better than $3 billion in research. However, I would emphasize that if the expertise we have gained heretofore is to be sustained, then it is in the best interest of industry to support a continued national commitment to research and development. In a period when federal support is obviously leveling off, industry can provide the vital margin while simultaneously encouraging a continued federal commitment. The recently passed law on patents provides research institutions with special privileges and will mandate uniform regulations. Moreover, the current impetus to provide tax incentives for industrial investments to research institutions should further serve to encourage their cooperation.

The future of health care is tied to the well-being of our research community, and both are important to all elements of our society.

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