

HOW TO FUND SCIENCE: THE FUTURE OF MEDICAL RESEARCH

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PREFACE

**The
Future of
Medical
Research**

This report presents the results of a two-and-a-half-day workshop organized by the American Association for the Advancement of Science (AAAS), sponsored by the Funding First Program of the Mary Woodard Lasker Trust and cosponsored by the Burroughs Wellcome Fund. Funding First is a new education and advocacy program of the Mary Woodard Lasker Trust. Its goal is to stimulate a long-range national commitment to funding medical research. The Burroughs Wellcome Fund is an independent private foundation established to advance the medical sciences by supporting research and other scientific and educational activities.

The workshop, entitled “How to Fund Science: The Future of Medical Research,” was held February 14-16 at the Aspen Institute’s Wye River Conference Centers. Workshop participants were selected on the basis of their knowledge and experience and the institutional perspectives that they brought to the table. The group heard expert presentations, which were followed by plenary discussions, and then by breakout groups where recommendations for action were debated. A list of workshop participants and the program agenda can be found at the end of this report. The texts of the presentations are available on the AAAS website at www.aaas.org/spp/dspp/cstc/fundscience.htm.

The views represented at the meeting were diverse and no effort was made to force consensus on the group. However, a sense of the meeting developed, which is reflected in the findings and recommendations of this report. Participants recognized the importance of sufficient and assured funding for medical research, defined in the broadest possible sense. While they were aware of the primacy of the appropriations process for the funding of medical research, most felt that secondary sources of funding outside the regular discretionary budget could help to assure steady and uninterrupted funding of medical research and supported initiatives aimed at developing such sources.

This report was circulated in draft to the participants, and the final version has incorporated comments and suggestions received in response to the draft. Readers should note, however, that neither the individuals who took part in the meeting nor the organizations with which they are affiliated have given universal approval of specific recommendations.

The Honorable Mark O. Hatfield
Chairman
Funding First

Dr. Leon E. Rosenberg
President and CEO
Funding First

Dr. Albert H. Teich
Director
AAAS Science and Policy Programs

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EXECUTIVE SUMMARY

For two-and-a-half days in mid-February 1999, more than thirty experts in the federal budget process, public policy, and several areas of scientific research met to discuss alternative funding mechanisms for medical research outside the traditional appropriations process. The objective was to stimulate a dialogue about these mechanisms, their potential advantages and disadvantages, and the barriers to their implementation. More importantly, the workshop was designed to move that dialogue beyond the conventional level of debate to the question of whether such alternative mechanisms are both feasible and compelling as a means of securing dedicated support for medical research.

Why seek alternative mechanisms and why now? After all, health-related research has enjoyed relatively uninterrupted growth since the early 1960s. Federal funding in the broad field of health-related research has increased from approximately \$2 billion in fiscal year (FY) 1960—in constant, inflation-adjusted (FY 1999) dollars—to slightly less than \$16 billion this fiscal year. Similarly, R&D investments by research-based pharmaceutical companies have grown from \$2 billion in 1980 to \$21.1 billion in 1998. The future for federally supported research, however, is far more uncertain than its record of growth might imply. The National Institutes of Health (NIH), the major source of federal dollars for medical research, and other federal research agencies rely on the annual decisions of congressional authorizers and appropriators. These decisions are subject to the fits and starts of current economic and political conditions and, in the future, outside pressures may upset the long-term stability that this field has enjoyed.

The extreme volatility of the budgetary environment can dramatically change the fiscal landscape within which priority decisions are made. For example, in the budget process for FY 1999, Congress appropriated a substantial 15 percent increase in NIH's budget. Due to tight budgetary caps placed on discretionary spending, President Clinton's FY 2000 budget proposal for NIH provides barely enough additional support to offset the effect of inflation during the coming year. The administration's intention, based on policy statements, would have NIH funding increase 50 percent by FY 2004. The hopes and expectations of the medical research community have been raised. The reality is that issues such as Social Security, tax cuts, and Medicare are in the foreground, and the remaining discretionary pool of programs, within which research programs are funded, must live within budgetary constraints even in a time of anticipated multi-billion dollar surpluses.

Compounding the fiscal and economic unpredictability of federal funding for medical research is its growing complexity. Increasingly, advances in research to improve public health build upon basic research in other fields such as physics, chemistry, engineering and mathematics, all of which are supported by agencies other than NIH. Some of these agencies also contribute directly to medical advances through life sciences research in support of their own missions. The interdependence of research among many scientific and engineering disciplines requires long-term, stable commitments to ensure that a balanced portfolio of research programs is maintained. Stability in research funding among the various disciplines is needed

to lay a solid foundation for securing our national intellectual capital through the creation of new knowledge, an educated workforce, and advanced tools.

Participants in the workshop on “How to Fund Science” were selected on the basis of their knowledge and experience and the institutional perspectives that they brought to the table (but not as representatives of those institutions). The group heard expert presentations on the federal funding environment for research; funding from both for-profit and non-profit sources; trust funds and entitlements; and research funding through private and public payer insurance, Medicare, and tax credits. The presentations were followed by spirited plenary discussions and then by breakout groups where recommendations for action were debated. While no effort was made to force consensus on the group, a sense of the meeting developed, which is reflected in the findings and recommendations below.

As Senator Mark Hatfield stated in his opening remarks, “History is composed of moments of opportunity for bold, creative, new, risky solutions to meet national needs.” This workshop is just a first step in this process.

FINDINGS AND RECOMMENDATIONS

General Finding. Medical research is an interdisciplinary, multi-agency effort involving the federal government, academic institutions, and the private sector, and requiring progress in many diverse fields of science and engineering to succeed. Therefore, medical research should be defined in the broadest possible sense, encompassing not only NIH but life sciences research in other agencies, health care and health services research in the Department of Health and Human Services, enabling research in other scientific and engineering disciplines, and infrastructure and facilities as well.

Recommendation 1. The primary source of federal funding for medical research should remain within the discretionary portion of the federal budget and should be allocated through established authorization and appropriations processes. Participants agreed that the existing funding system, while not perfect, does exemplify the democratic process upon which the principles of our government are based. While several potentially attractive ideas for supplementary funding mechanisms were discussed, none was seen as capable of replacing the current system. However, it will not be possible to accommodate significant growth in research under the Balanced Budget Agreement of 1997 without reductions in other important programs. Lawmakers should candidly and realistically address current limits on discretionary spending as Congress completes action on the FY 2000 budget.

Recommendation 2. A secondary source of funding, in the form of a trust or reserve fund for medical research, in addition to the regular discretionary budget, could provide an important supplement to annual appropriations. Any secondary source of funding should complement and not replace the annual appropriations, and should be analyzed for cost-benefit impact and political viability. Potential mechanisms for such a fund, which should feature a dedicated funding source, could include: a) taxes on tobacco products or allocations from state tobacco settlements; b) assessments on private health insurance premiums; c) fees on medical products

resulting from federally funded research, in the form of payments in exchange for patent extensions; and d) federal reallocation of funds within the existing highway trust fund. These mechanisms are not listed in any priority order and the level of importance placed on them varied among the workshop participants.

Recommendation 3. Public and private insurance systems should be mandated to pay the cost of health care services for beneficiaries participating in federally-supported clinical trials. Insurance providers should be exempt in cases where a patentable product is foreseen or commercial profit can be specifically linked to the outcome of the trial.

Recommendation 4. The research and experimentation (R&E) tax credit should be made permanent and expanded to include research in clinical trials. The basic research credit, which applies to industry-academic research contracts, should be restructured as a flat credit at a 20 percent rate and enhanced with incentives to better encourage partnerships between industry and academic institutions.

INTRODUCTORY REMARKS

THE HONORABLE MARK O. HATFIELD

History is composed of moments of opportunity for bold, creative, new risky solutions to meet national needs. The National Highway System provided a statewide infrastructure to support our national defense interests, and as a result we now have a National Highway Trust Fund. The GI Bill of Rights created avenues for soldiers to pursue higher education and became the model for other forms of financial aid such as Pell Grants. During World War II, the Doctor Draft Act provided free medical school training with the understanding that graduates would continue in military service. In the mid-1960's the Medicaid Trust Fund was established, and more recently, Congress created the Violent Crime Reduction Trust Fund for crime prevention programs.

Medical research competes annually with other worthy domestic spending priorities for its share of our national budget. On the whole, funding for medical research has grown steadily since its inception, but it has been threatened from time to time. I believe that medical research is the responsibility of the national government, it is integral to the values for which we defend the country and one in which the federal government is uniquely positioned to take the lead. In my view, the opportunity exists to create some strategic options, but I am not naïve about the challenges. Long-term strategic options aren't favored in the congressional environment unless they come in the crux of a crisis. Medical research is on the crest of significant opportunity if we choose to maximize it. I believe we must seek to do so now.

DR. LEON E. ROSENBERG

I am often told that medical research is regularly favored over other areas of scientific research, and that, therefore, it is not fair to advocate on behalf of the medical research enterprise. I am told, too, that the system isn't broken so why attempt to fix or improve it. My answers: people with disease and disability do not think we are doing all we can do on their behalf; the amount we, as a nation, spend on medical research--from public and private sources--is miniscule compared to what we spend on health care; and there are many ways to make a good system better.

Medical research has fared better than most other areas of science because people care so much about the quality of their lives and hope that medical research, in its broadest sense will help them live longer and healthier lives. We must respond to that public yearning by taking a broad, not narrow, view; by realizing that the physical sciences form a foundation for the life sciences, and the life sciences, in turn, for the medical and clinical sciences.

I do not accept the view that it is time for advocates of medical research to get out of the way and let others have a chance. Rather, I think we should ask whether the nation's investment in medical research is all it should be--in size, form, source, purpose, implementation, and accountability--and whether we keep uppermost in our minds the good of the people.

SUMMARY OF PLENARY AND BREAKOUT DISCUSSIONS

As the workshop participants represented a diverse group of individuals, the plenary sessions and paper presentations were organized to provide all workshop participants a “level playing field” in order to ensure a thorough and candid discussion.

Papers on historical funding trends from federal, private for-profit, and private non-profit sources provided a foundation on the state of research funding. In total dollars, the support is certainly strong. Federal support for the broad category of health-related research has grown from \$2 billion to slightly less than \$16 billion since the 1960's. Within the private-sector, pharmaceutical companies that conduct research have increased their R&D support from \$2 billion to an estimated level of \$21.1 billion in 1998. Non-profit, non-governmental organizations also provide significant support to health-related activities. As of 1995, the top twenty-five independent foundations provided a total of \$1.2 billion in grants, of which the share for medical research was 22 percent.

While the appropriation of monies to support medical research has been relatively stable, the political environment has not. Even though funding increased significantly in the past few years, it has not come close to matching the rhetoric on the subject. The 15 percent increase in FY 1999, may just become a spike in the historical record, regardless of the fact that our nation appears to be operating in a surplus environment. As it turns out, the politics of surpluses is not that different from the politics of deficits.

The alternative funding mechanisms (*i.e.*, outside the existing appropriations process) that were presented and discussed centered on five general sources: trust funds, entitlements, public- and private-payer insurance, Medicare, and tax credits. These five sources are already utilized in some fashion to fund federal programs and activities.

It was noted that converting medical research from discretionary to mandatory funding would be a difficult task, given that most congressional leaders would not want to cede authority over the budget. Another important point was that automatic obligation of funds, for example in the case of a trust fund, does not necessarily guarantee that it will be removed from appropriations oversight. Even mandatory spending programs have their own political constituent base, and still would compete with other national priorities within the mandatory portion of the federal budget. Another concern raised was the assumption that the surplus will actually remain in the future. If the surplus disappears, one must consider the impact that additional mandatory spending will have on other discretionary programs. In the case of Medicare, a portion of its trust fund is expected to be depleted by 2001. Generally, the employer's costs to Medicare are offset by lower wages. Employees would therefore have to carry the burden in their payroll taxes. Other funding streams, for example private insurance premiums, may not be available to fill the gap. Premiums pay for products beyond general health care delivery, such as research con-

ducted at teaching hospitals, medical schools, and universities. However with the increased use of managed care organizations it has become difficult to balance the costs of patient care with the benefits associated with broader public good investments. Finally, research tax credits are considered by some to be too small a pool of funds to significantly impact medical research spending.

Nevertheless, arguments were made in support of the creation of alternative funding mechanisms. Public and congressional pressure to fund disease-specific projects could imperil basic scientific research that provides an underpinning of knowledge across the spectrum of diseases and health needs. Independence from the discretionary appropriations process could ensure that the underpinnings of basic research remain strong. In the case of clinical research trials conducted in academic institutions or other non-profit institutions, pressure is growing within the private insurance community to reduce financial support. Even Medicare, which can benefit from the generation of shared knowledge, often does not cover the cost of treatment. Our nation risks creating a gap in an important element of research if it relies strictly on the private-sector to support clinical research trials. Therefore, new and alternative mechanisms for public-sector funding may be warranted. In the case of research and experimentation tax credits, an argument could be made to strengthen incentives for private-sector firms to collaborate with academic institutions on basic research. Building partnerships between academia and industry may reduce the need for federal support in some areas, and in the case of clinical research trials, it may help to bridge any potential gaps.

Whichever alternative mechanism is utilized, questions still remain as to how much additional revenue should flow to a non-discretionary program: Who should pay for it? How should it be allocated? What are the fiscal impacts on the discretionary budget? What additional costs, if any, will be carried by private individuals and institutions? Balancing any near-term costs to the public with the long-term benefits arising from investments that the public will reap is a major challenge.

Following the presentations and initial plenary discussions, the conferees were divided into three breakout groups in order to discuss further the various mechanisms that had been presented and to consider specific recommendations regarding alternative sources of funding for medical research. These groups met twice: on the afternoon of the second day and on the morning of the third. Each included a discussion leader and rapporteur, and each gave a report to the final plenary session, the results of which are described in the following section.

It became obvious in the discussions of funding, whether by public or private sources, that the definition and scope of health-related activities varied. Within federally supported activities, support for research came under the term life sciences. Philanthropic organizations broaden their perspective to include hospitals, medical care, public health, and health policy. Private, for-profit firms conduct research in pharmaceuticals, vaccines, and medical devices. Even the performance of R&D is conducted within a wide array of venues including public and private labs, academic institutions, and hospitals.

There was general recognition of the fact that progress in medical research depends on more than just increased funding for NIH. In addition to NIH, the Department

of Health and Human Services supports research at the Centers for Disease Control, the Agency for Health Care Policy and Research, and the Health Care Financing Administration. Medical research is embedded in the fabric of science and engineering. It is an interdisciplinary, multi-agency effort. Advances in such fields as chemistry, physics, electronics, and mechanical engineering, supported by the National Science Foundation, the Department of Energy, the National Aeronautics and Space Administration, and the Department of Defense, among others, illuminate medical science and provide instruments and insights that complement it. Other agencies should not treat areas that address medical issues as solely NIH's bailiwick, and advocates for medical research should not ignore the contributions of agencies other than NIH and the importance of addressing their budgetary needs.

Participants entered the breakout sessions with a general sense that the current system of annual appropriations within the discretionary budget was the best vehicle for overall continued federal funding of medical research. And while each discussion group approached the problem of alternative funding mechanisms differently, there was a consensus opinion that any alternative mechanisms that might be proposed should supplement the current process in a complementary fashion rather than replace it. Funding mechanisms outside the current system were recognized as useful tools to provide a modicum of stability to such an important research area. The main concern about the current budgetary process was that the caps on discretionary spending had become too restrictive and were not adequate to meet essential program needs.

Among the ideas that emerged from the breakout groups were the following:

Establish a trust fund for medical research. The idea would be to create a dedicated funding source in order to buffer medical research from any drastic changes in funding through the discretionary process. One group suggested that the trust fund be given a specific, targeted mission supplementary to medical research such as infrastructure development, funding for clinical trials, or support for behavioral science research. Suggestions for revenue sources for the trust fund included "sin" taxes on tobacco; fees for medical products resulting from federally funded research in the form of patent extensions; and a tax on private insurance premiums.

Reallocate the costs of clinical trials to free up federal research dollars. Clinical trial funding should be absorbed or at least shared by those who would profit from the trials. Suggestions for payers included pharmaceutical companies and public and private health care payers.

Dedicate portions of the individual states' tobacco settlements to medical research. One idea proposed was to withhold the amount of each state's settlement from its federal Medicare payments. It was noted that the settlement formula varies from state to state, and therefore any withholding would likely require a sliding scale to parallel state settlements.

There was **strong sentiment**, not just in the discussion groups but during all the proceedings of the conference, **for providing additional resources for medical research infrastructure.** Apart from establishing a trust fund, one

group suggested a government-backed borrowing authority to lower the cost of non-government investments in equipment and construction. This could involve issuing bonds, subsidized loans for equipment or facilities, or a guaranteed student loan program.

A novel idea that came out of one group was to **earmark funds from the Highway Trust Fund for medical research**. This money could go to medical research in fields related to motor vehicle injuries, such as spinal cord injury, treatment of trauma, or alcoholism. An extra tax on gasoline could also be added for this purpose.

Finally, one group devoted a considerable amount of attention to the need to **revise the research and experimentation (R&E) tax credit and make it permanent**. This group recommended that the credit should be altered to strengthen incentives for industry partnerships with universities as well as clinical research. Also, the credit should be a flat credit rather than an incremental one. These ideas found considerable support in the final plenary session.

The findings and recommendations outlined in the next section of this report are based on discussions from which these points were derived. They are the ideas that, in the view of the workshop staff, received general support among the participants in the meeting. This should not be taken to mean that all of the ideas met with universal approval. Most of the debates on the various funding concepts centered on their political viability, definition and scope of the research objective, and the cost-benefit ratios. The level of importance placed on these issues varied among the diverse group of workshop participants.

Some participants suggested, for example, that using taxes on insurance premiums to support a medical research trust fund would be regressive and ultimately increase the cost of health care. So-called “sin” taxes were discussed and viewed by some participants in the same manner. Others argued that if the objective were narrowly defined to support research in behavioral science, infrastructure development, and models of care delivery, for example, it could ultimately work to lower health care costs. In the case of using the tobacco settlement, some participants felt that such an account should be required to support research directly related to health impacts from tobacco products. Others felt that funds made available should benefit research in all relevant areas, including health services research and prevention studies.

Nevertheless, to the extent that there was a “sense of the meeting,” the authors of this report have tried to reflect it fairly and objectively. The circulation of this report in draft to the participants has, hopefully, helped to assure that this has been accomplished.

FINDINGS AND RECOMMENDATIONS

This section is based on a distillation of the ideas that were discussed at the concluding plenary session of the workshop.

General Finding. Medical research is an interdisciplinary, multi-agency effort involving both the federal government and the private sector, and requiring progress in many diverse fields of science and engineering to succeed. Medical research should be defined in the broadest possible sense, encompassing not only NIH but life sciences research in other agencies, health care and health services research in the Department of Health and Human Services, enabling research in other disciplines, and infrastructure and facilities as well.

Recommendation 1. The primary source of federal funding for medical research should remain within the discretionary portion of the federal budget and should be allocated through established authorization and appropriations processes. The existing appropriations process, while not necessarily perfect, does exemplify the democratic process upon which the principles of our government are based. While several potentially attractive ideas for supplementary funding mechanisms were discussed, none were seen as capable of replacing the current system.

Participants also recognized, however, that it is not possible to accommodate significant growth in research under the existing Balanced Budget Agreement of 1997 without reductions in other important programs. Some congressional leaders have stated, both explicitly and implicitly, that the discretionary caps are likely to be ignored. It is essential that lawmakers candidly and realistically address current limits on discretionary spending as Congress completes action on the FY2000 budget.

Recommendation 2. A secondary source of funding, in the form of a trust or reserve fund for medical research featuring a dedicated funding source, in addition to the regular discretionary budget and perhaps with appropriations review, could provide an important supplement to annual appropriations. Potential sources for such a fund, which could be employed either individually or in combination, could include:

Federal recoupments from the existing state tobacco settlements, federal legislation against tobacco companies on behalf of the Medicare program, and taxes on the sale of tobacco products.

Assessments or taxes on private health insurance premiums. A portion of public insurance premiums already goes toward graduate medical education, for example, and legislative proposals exist to expand that to private insurance payers. It may be worth pursuing a similar mechanism to support medical research.

Fees on medical products resulting from federally funded research, in the form of payments in exchange for patent extensions. This funding source would benefit from public and private-sector collaborations where the private sector is able to generate a new product for commercial sale. Medical research would

benefit from increased revenue streams, and the private sector would benefit from additional market exclusivity.

Federal reallocation of funds within the existing highway trust fund to support research in transportation-related injuries (e.g., spinal cord injury, neural trauma, physical therapy).

Recommendation 3. Public and private insurance systems should be mandated to pay the cost of health care services for beneficiaries participating in federally-supported clinical trials, except in the case of trials which are specifically linked to a patentable product or commercial profit directly related to the outcome of the trial. There are many instances where research trials are conducted for which there are no derived products expected, and hence they receive no private-sector support. Since these trials still generate knowledge, and contribute to improved public health, an argument can be made that public and private insurance funds should contribute. Therefore, funding for federally-supported clinical trials should be absorbed or at least shared by those who benefit from them.

Recommendation 4. The research and experimentation (R&E) tax credit should be made permanent and expanded to include research in clinical trials. Temporary extensions of the credit, as have been in effect during the past several years, make it difficult for firms to use it in a long-range manner. The basic research credit, which applies to industry-academic research contracts, should also be restructured as a flat rather than an incremental credit at a 20 percent rate and enhanced with incentives in order to encourage greater collaboration between private firms and academic medical centers.

ABSTRACTS OF PRESENTATIONS*

The
Future of
Medical
Research

A HISTORICAL PERSPECTIVE ON FEDERAL SUPPORT FOR MEDICAL RESEARCH

Kei Koizumi

American Association for the Advancement of Science

Trends in federal funding of nondefense research and development (R&D) over the past four decades reveal the changing priority of various national missions. In the 1960s, funding for space research and development increased dramatically as the United States sought to be the first nation to land a man on the moon. Energy R&D increased in the mid-to-late 1970s, closely tracking national concerns over dependence on foreign oil. Federal support for health-related R&D, however, has grown steadily and virtually uninterrupted over the past four decades.

The primary supporter of health-related R&D is the Department of Health and Human Services (HHS) with nearly 95 percent of its R&D funds going to the National Institutes of Health (NIH). In the late 1950s and early 1960s, NIH represented a relatively small part of the federal government's R&D portfolio, but during the past fifteen years, the NIH budget has doubled in inflation-adjusted terms, with real increases nearly every year. In FY 1999, NIH funding reached \$15 billion.

It is important to note that agencies such as DOE, NSF, and NASA also support life sciences research conducted in support of their missions, but with potential medical applications. And not all NIH funding is categorized as life sciences; it also supports research in engineering, social sciences, psychology and physical sciences. According to NSF statistics, life sciences research totaled \$13 billion in FY 1998, of which 71 percent came from NIH. The trend in life sciences research is remarkable when contrasted with other disciplines such as engineering and physical sciences. Of the total federal research portfolio of \$33 billion (excluding development and R&D facilities) in FY 1999, nearly 44 percent went to life sciences research, compared with less than 30 percent in FY 1970.

THE FUTURE OF PHARMACEUTICAL FUNDING

Bert Spilker

PhRMA

R&D investments by research-based pharmaceutical companies have grown tremendously over the last two decades, from \$2.0 billion in 1980 to an estimated \$21.1 billion in 1998. Approximately 36 percent of the world's private-sector pharmaceutical R&D is carried out in the United States, and U.S. firms hold approximately 33 percent of the worldwide commercial market.

Pharmaceutical companies spend a much larger percentage of their sales on R&D than most other firms. The industry average for pharmaceuticals is 20.8 percent,

*The texts of these presentations may be found at the Center for Science, Technology, and Congress web site: www.aaas.org/spp/dspp/cstc/fundscience.htm.

as compared with 4.1 percent in the automotive industry, 5.1 percent in telecommunications, and 3.7 percent in aerospace and defense. Of the total amount that the pharmaceutical industry invests in R&D, approximately 80 percent is devoted to research and development for the advancement of scientific knowledge and the creation of new products, versus 20 percent for applied research and development to improve and/or modify existing products.

In the past, most pharmaceutical R&D support of clinical trials has been carried out in academic medical centers. Recent trends suggest that the share of clinical research conducted in non-academic organizations has been growing at the expense of academic medical centers, in part due to delays caused by institutional review boards and legal barriers. From a public policy perspective, the key issues impacting the pharmaceutical industry are tax credits, mergers, patent reform, and price controls.

THE FUTURE OF PHILANTHROPIC SUPPORT FOR MEDICAL/HEALTH RESEARCH
Enriqueta C. Bond, Martha G. Peck, and Melanie Scott
The Burroughs-Wellcome Fund

Foundations are non-profit, non-governmental organizations that are classified into one of four general types—independent, operating, community, and corporate. Overall, there are 41,588 grant-making foundations in the United States. Their support of medical research is quite modest, only about 22% of total health grants. These dollars, however, are nonetheless important because they provide critical “venture capital.”

As of 1995, the top twenty-five independent foundations provided a total of \$1.2 billion in grants to the broad category of health (e.g., hospitals, medical care, reproductive health, public health, health policy, and management). The share of medical research was 22 percent. The future outlook for increased giving from foundations already in existence is very good, and with a booming U.S. stock market, this should result in continued double-digit growth.

The role of philanthropic funding in strengthening health research is vital in that it carries the unique capacity to invest in innovative and creative risk-taking projects. With increasing federal commitment, foundations can substantially leverage a growing national effort and quickly move to fill gaps within the system. Gaps and opportunities that currently exist that could be filled by foundations include: training physicians and Ph.D. researchers to adapt to changing needs; support for emerging fields and interdisciplinary research; support for risky or politically unpopular research; speeding research from bench to bedside; behavioral research; public understanding of science; and new partnerships.

THE POLITICAL ENVIRONMENT

**Norman J. Ornstein
American Enterprise Institute**

President Clinton's January 1999 State of the Union Address stands in stark contrast to last year with respect to medical research. In 1998, the President called for a plan to double the NIH budget, contingent upon tobacco legislation. In 1999, only a passing reference to medical breakthroughs and Parkinson's disease could be found in the transcript of the President's remarks. Even more significantly, the President's budget request called for an increase of only 2.1 percent for NIH, barely above the rate of inflation. While funding has increased significantly in the past few years, it has not come close to matching congressional rhetoric on this subject.

One reason, of course, is budgetary. It turns out that the politics of surpluses is not that different from the politics of deficits. The Balanced Budget Act of 1997 still must apply the pay-as-you-go (PAYGO) rules, reinforcing the fact that discretionary budgets are tight and continue to operate in a zero-sum environment. Compounding this zero-sum game are the demands of Social Security and Medicare that squeeze discretionary budget items.

Within R&D, other zero-sum games can be found, adding layers to this complicated formula. Due to its stable and increasing funding levels, medical research "competes" with other nondefense and defense R&D programs, as a political priority. Competition exists between NIH and other units of the Department of Health and Human Services, reinforcing a "politics of resentment." Compounding this is the "disease-of-the-month" phenomenon, under which various advocacy groups vie for the attention of legislators and shares of the health research budget.

Congress must change the debate over Social Security and Medicare in the next year, before it can deal with the task of research funding. Even if more funding is forthcoming, the continued squeeze on discretionary spending, along with other political dynamics, means that funding will likely come with more, rather than fewer strings. Getting medical research on the agenda means separating it enough from other budget categories so that it can be considered on its own merits. Create the focus and the climate for more research funding will be enhanced. But it remains a daunting task.

FEDERAL FINANCING FOR MEDICAL RESEARCH THROUGH TRUST FUNDS AND ENTITLEMENTS

**Roy T. Meyers
University of Maryland, Baltimore County**

Most federal funding for medical research is provided through the annual appropriations process, commonly known as the discretionary portion of the budget. Converting medical research from discretionary to mandatory funding would be a very difficult task. Most members of the appropriations committees would be reluctant to cede their authority over the budget and those within the budget committees

would be concerned that mandatory status for medical research would decrease their flexibility to manage the aggregate budget.

However, fear about the future of medical research is very reasonable given the recent changes in the health sectors. For example, the widespread adoption of managed care has reduced important cross-subsidies for teaching and research—will this continue? Discretionary appropriations for medical research are threatened by uncertainty at both the micro-budgetary and macro-budgetary levels. At the micro-budgetary level, the dysfunctions of the appropriations process are widely known. At the macro-budgetary level, discretionary spending caps loom and could force even those who have pledged to increase medical research funding to do the opposite. The assumption that the caps will remain in force is a major contributor to the large surpluses that are now projected. However, in my view, the budgetary outlook held by most Washington policymakers is too optimistic and projected future surpluses are not a sure thing.

This general budgetary environment may provide the rationale for alternative mechanisms. There is no technical guidebook or overarching law on mandatory funding in general, and on trust funds and entitlements in particular. The details of a given program are governed by the specific law that creates it. The essence of both trust funds and entitlements is that, by law, either the receipt of funds by a program or the obligation of those funds becomes automatic.

It is very important to note that automatic obligation of funds is not necessarily guaranteed, however, and some trust funds and entitlement programs are still subject to annual appropriations. If the goal of a trust fund is to provide stable growth in financing, this might be prevented by unpredictable variation in dedicated revenues, and by the possibility that politicians will substitute dedicated revenues for discretionary appropriations. In addition, the revenue gains of dedicating financing for medical research should be compared to the impacts of doing this. Some recent proposals for dedicating funds, if adopted, would likely have been regressive and would have reduced access to medical care.

In either case, the question remains as to the type of revenue stream that will flow into a non-discretionary account. Some feasible sources of revenues could come in the form of taxes on insurance premiums, and taxes and/or royalties on sales from medical tools and products. A tax on insurance premiums would be similar to a mechanism that is currently being discussed for financing medical education. In this case, a policy decision would be required to determine what rate(s) to impose, in order to solve the problem of having to set funding levels for each outyear. A tax or royalty on medical products has been proposed by some manufacturers of proprietary pharmaceuticals. If granted up to ten years of additional market exclusivity for certain drugs and antibiotics, the companies would make royalty payments (as a percentage of sales) to the government for medical research.

Even with these mechanisms, questions remain as to how much additional revenue should flow to a non-discretionary program, who should pay for it, and how should it be allocated. There is a perception that mandatory funding gives program advocates absolute independence from the “squalid political process.” However, those who pay into a fund generally believe they should hold greater political say in how

it is spent. And the creation of new mandatory spending must still conform to the “PAYGO” rules that require offsets. This creates a new political constituent base and an additional layer of complication to the discretionary appropriations process.

THE FUTURE OF ACADEMIC MEDICAL CENTERS UNDER INCREASED MARKET PRESSURES: PRIVATE PAYER POLICY CONSIDERATIONS FOR THE NEXT

MILLENNIUM

Allen Dobson

The Lewin Group

An increasingly competitive health care delivery system calls for reconsideration of Academic Medical Center (AMC) payment policies. Competitive markets make payers more sensitive to the higher costs of AMCs. And a shift in the location of care under managed care to community settings challenges AMCs to redirect their clinical training and research efforts to outpatient settings.

Public and private payers do not fully understand the social missions and related public purposes of AMCs. Payers feel a need to separate the financial support of public goods from the purchase of clinical care. Unfortunately, it is difficult for payers to understand that they are paying for joint products from AMCs in the form of clinical care, teaching, and research, all of which are conducted in a multi-institutional environment involving teaching hospitals, medical schools, and universities. Therefore, to what extent should payers distinguish care provision for their patients from costs associated with broader public good components?

The research function within AMCs is by far the least understood. The payer community wants to know how research impacts the cost of clinical care for private pay patients. Managed care organizations increasingly question the extent to which they need to participate in clinical trials to meet enrollees’ and community expectations. Mechanisms for measuring research productivity and accountability for what is purchased are uncertain, especially the flow of funding. Hence, the benefits of research, whether in the form of improved patient care or return on investment to the local economy, are not clearly communicated.

FUNDING MEDICAL RESEARCH THROUGH MEDICARE

Joseph P. Newhouse

Harvard University

The search for alternative funding mechanisms for medical research will naturally lead to the Medicare trust fund. It is only natural to expect some funding from a source which stands to save costs through the innovation of medical research. The author believes that Medicare funding of medical research is not feasible except perhaps in the case of funding clinical trials through Medicare.

It should be acknowledged that Medicare already provides funds outside its basic mission of providing health care services. Medicare also pays for a share of salaries

for hospital residents in order to defray costs for graduate medical education. In fact, these funds could already be paying indirectly for some clinical research. In addition, Medicare pays additional funds to hospitals in order to provide health care access to low-income populations.

There are three reasons for recommending against the use of Medicare funds for medical research. First, whether a portion of medical research warrants an important enough mandate to be placed outside the discretionary portion of the budget is arguable. There very likely would be tremendous dissension from other competing interests such as the advocates of paying down the national debt. Second, Medicare is simply running out of money. The Part A Trust Fund, presumably the source from which a medical research fund would come, is projected to be depleted by 2001. Third, the source of Medicare's revenue is from payroll taxes that are split between employers and employees. Generally, the employer's costs are offset by lower wages and it is the employees who bear the burden of the tax. Therefore, a Medicare fund for medical research would entail payment by employees only. This would re-allocate costs differently than if medical research funding remained in the appropriations process.

It is also argued that Medicare should pay for clinical trials involving beneficiaries of Medicare. The reasoning is that Medicare would pay for the care of those patients if they did not participate in the trial. The clinical trial could provide valuable insights as well as cost-saving remedies for those patients.

THE APPLICABILITY OF TAX CREDITS TO MEDICAL RESEARCH AND DEVELOPMENT

**Kenneth Whang
National Science Foundation**

The research and experimentation (R&E) tax credit is intended to encourage companies to increase investments in research by lowering their marginal costs. As it was structured in the 1980s, the research credit stimulated as much as two dollars of additional R&D investment for every dollar of tax expenditure. As the credit stands today, it has become difficult for many firms to reap any incentive value for increases in R&D. In particular, its value as a stimulus for academic-industry partnerships is minimal.

Companies can claim credit for their research expenses using a regular credit or an alternative credit. The 20 percent regular credit is based on a firm's increment in research investments over a fixed historic base. The alternative credit is based on a three-tiered rate schedule (1.65 to 2.75 percent) and is independent of the firm's previous history of research investment.

Two other credit provisions are of special interest for medical research. A provision of the R&E credit known as the basic research credit is an incremental credit for research contracts with academic institutions. The orphan drug credit is a flat credit for clinical testing of drugs for rare diseases.

In recent years, the R&E tax credit has been renewed on a year-to-year basis. A major criticism of the credit is its lack of permanence, which limits its value for long-term investments. Other aspects of the credit further reduce its effectiveness. The basic research credit does not apply to academic-industry R&D with a “specific commercial objective.” Unfavorable phase-in rules for the regular credit reduce its value for small start-up firms. And the fixed base creates a problem of winners and losers who are arbitrarily included or excluded from the regular credit.

There are several proposals from legislators that seek to make up for some of these shortcomings. Some specifically target certain deficiencies by creating a 20 percent flat credit for firms’ contributions to public benefit research consortia or creating tax credits for clinical research partnerships.

The two most comprehensive bills for revamping the credit would make it permanent and would modify the commercial objective clause to accommodate university-industry partnerships and expand the types of qualifying partnerships. These bills would also address the problems associated with the fixed base. One bill would do so by improving the alternative credit, so that all credit users could have access to a 20 percent marginal rate, plus a 3 percent rate for maintained research intensity. R&D would be defined according to the Financial Accounting Standards definition, and the basic research credit and credit for research consortia would be restructured with flat rates.

APPENDIX A

WORKSHOP AGENDA

FEBRUARY 14, 1999

- 12:45 pm **INTRODUCTION**
The Honorable Mark O. Hatfield
Funding First
- 1:00 pm **WORKSHOP GOALS AND OBJECTIVES**
Dr. Albert H. Teich
AAAS
- 1:30 pm **PLENARY SESSION ONE**

A Historical Perspective on Federal Support for Medical Research
Mr. Kei Koizumi, AAAS
The Future of Pharmaceutical Funding
Dr. Bert Spilker, PhRMA
The Future of Philanthropic Support for Medical/Health Research
Dr. Enriqueta Bond, Burroughs Wellcome Fund
The Political Environment
Dr. Norman J. Ornstein, American Enterprise Institute
- 3:45 pm **DISCUSSION OF PAPERS**
Discussants
Dr. Frank Lichtenberg, Columbia University
Ms. Martha Peck, Burroughs Wellcome Fund
Ms. Susan Quantius, Association of American Universities
- 5:15 pm **ADJOURN**

FEBRUARY 15, 1999

- 9:00 am **PLENARY SESSION TWO**
Federal Financing for Medical Research through Trust Funds and Entitlements
Dr. Roy T. Meyers, University of Maryland Baltimore County
The Future of AMCs under Increased Market Pressures: Private Payer Policy Considerations for the Next Millennium
Dr. Allen Dobson, The Lewin Group

11:00 am **DISCUSSION OF PAPERS**
Discussants
Mr. Nick Littlefield, Foley, Hoag, and Eliot LLP
Dr. Gilbert S. Omenn, University of Michigan Health System
Dr. Michael Telson, Department of Energy



1:30 pm **PLENARY SESSION THREE**
Funding Medical Research Through Medicare
Dr. Joseph P. Newhouse, Harvard University
The Applicability of Tax Credits to Medical Research and Development
Dr. Kenneth Whang, National Science Foundation

3:15 pm **DISCUSSION OF PAPERS**
Discussants
Ms. Susan Bartlett Foote, Public Policy Partners
Dr. Howard Rosen, Joint Economic Committee
Mr. Michael Stephens, Van Scoyoc Associates

5:00 pm **FIRST BREAKOUT SESSION**

FEBRUARY 16, 1999

8:30 am **SECOND BREAKOUT SESSION**

10:30 am **CONCLUDING PLENARY SESSION**

11:30 am **SUMMARY REMARKS**

12:00 pm **ADJOURN**

APPENDIX B

WORKSHOP PARTICIPANTS

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The Honorable Mark O. Hatfield
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