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The Structure and Financing of Medical Research in the United States

An Overview

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Foreword

The United States is often used as a benchmark in the Swedish research policy debate. The scope and quality of American research, the ability to commercialize research results and the entrepreneurial spirit are some reasons for this.

Against this background the Swedish government commissioned the Institute for Growth Policy Studies (ITPS) to undertake a study on the science system and policies in the United States. The ITPS Office at the Swedish Embassy in Washington D.C. was assigned to conduct the study. The results of the project will serve as an input to the next Bill on Research that will be presented to the Swedish Parliament 2004-2005. The results are presented in this report and three others*.

The structure of medical research in the United States in a research policy perspective is in focus in this study. The financing and performance of research, the distribution of funds by the National Institutes of Health (NIH), the degree of competition for funds and the relationship between higher education and research are discussed and analyzed.

Stockholm, March 2004

Sture Öberg,
Director-General

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- "American Science – the Envy of the World? An Overview of the Science System and Policies in the United States", by Kerstin Eliasson.
- "From Doctoral Student to Professor – The Academic Career Path in the United States", by Eva Karlsson.
- "Commercialization of Research Results in the United States – An Overview of Federal and Academic Technology Transfer", by Magnus Karlsson.

Content

1 Summary

The United States invests more than any other country in the world in the medical sciences. Support from the government, industry and the public has increased significantly since the post war era. In 2001, approximately 82 billion dollars were spent on health research (including e.g. medical research, bioengineering, and biology). The amount is estimated at around 100 billion dollars today. These big investments are a contributing factor to the U.S. success in this field.

This report focuses on the structure and financing of medical research in the United States. An overview of the research system and research policies is given. Research at the universities and the role that different kinds of funding play in university research are included. The crucial role of the National Institutes of Health (NIH) in the funding of biomedical research in the United States is the reason for the particular attention devoted to the NIH in the report.

Increasing Funds for Medical Research

- The structure and organization of medical research have taken shape mostly after World War II, when the government and the public accepted the proposition that federal investment in basic biomedical research would benefit public health. Most research is carried out at the universities and colleges all over the U.S. The NIH is the most important institution of the federal government in supporting basic biomedical research.
- The end of 2003 will complete the doubling of the NIH budget. The budget has increased from 13.6 billion dollars in 1998 to 27.2 billion dollars in 2003, an annual increase of 15 percent during the last five years.
- The federal government is a major funding source of medical research in the U.S. In 2002, the total federal R&D support was estimated at 103 billion dollars of which 24.7 billion dollars was spent on health R&D.
- The funding from private industry has accelerated during the last few decades and has bypassed the federal government's investments. Industry supports more than half of all medical R&D in the U.S. The share of the government is approximately one third. However, the vast majority of private industry funding is devoted to development, not research. The federal government remains the major funder of basic biomedical research. The government in Sweden contributes with about 25 percent of the funding of medical R&D and Swedish industry with approximately 50 percent.
- Private industry in the U.S., i.e. the pharmaceutical and biotechnology companies, spends roughly 46 billion dollars a year on R&D.

- The U.S. has a long history of private giving and medical research has always been a large recipient. Of all contributions by foundations, approximately 20 percent go to medical research.

The Dominant Role of the NIH

- Through the doubling of the budget, the NIH has been able to support more investigators. No other civilian federal agency has seen its budget increase as much.
- The NIH supports both basic and clinical research that is performed intramural and extramurally. The National Cancer Institute (NCI) receives the greatest share of the budget, approximately 4 billion dollars in 2002.
- The NIH is composed of 27 institutes and centers and is located in Bethesda, Maryland, where most of the intramural research is conducted. Intramural research receives approximately 10 percent of the NIH budget. The NIH employs about 18,000 full-time employees, of whom 4,000 hold professional or research doctorate degrees.
- The extramural research, which receives about 80 percent of the budget, mostly takes place at universities and colleges. Of the extramural budget, 60 percent goes to medical schools and teaching hospitals. The NIH is also the largest supporter of medical research at the universities and colleges.
- The organization of the NIH is decentralized and the institutes are diverse in their mission, size and activity. They are similar in the way they are organized and the way they support research. The Office of the Director is responsible for setting policies, planning and coordinating programs and activities at the NIH.
- About 65,000 grant applications are reviewed annually for all of the NIH. About 45,000 applications are reviewed and rated by the Center for Scientific Review and the rest by the institutes and centers. The institutes make the decisions about funding. About one third of all reviewed proposals are granted.
- In 2002, the NIH financed 49,700 awards worth 19 billion dollars. The average cost of a research grant in 2002 was 384,000 dollars. In Sweden, the awards by Scientific Council for Medicine are given to individual researchers at an average amount of 360,000 SEK (approximately 42,000 dollars), which only covers part of a research project. Only a small number of applicants receive awards of 1 million SEK.
- An NIH grant normally runs for four years. Therefore, a major part of each institute's budget is already committed to ongoing projects. Approximately 25 percent of the annual budget is spent on new research projects.

- Recently, the NIH director Dr. Elias Zerhouni has announced his "roadmap initiatives". The roadmap has been created to meet the challenges the NIH and the scientific community faces today, and which a single institute cannot meet alone. The roadmap suggests initiatives like interdisciplinary research, high-risk research, innovator awards, and public-private partnerships.

The Role of Universities in Medical Research

- After the World War II, the federal government made universities and colleges the main performers of medical research and training of researchers.
- Of all R&D expenditures at universities and colleges, approximately 60 percent is spent within the life sciences. This amounted to 19 billion dollars in 2001 and 53 percent of those investments, i.e. 10 billion dollars went to the funding of medical sciences.
- The federal government is by far the largest funding source, followed by institutional funds. Federal support in 2001 for the life sciences is estimated at 11 billion dollars, out of which 6 billion dollars supported the medical sciences. The NIH is the most important federal agency for the universities and colleges as it contributes approximately 85 percent of all life science research. About half of the NIH's extramural budget goes to 20 medical schools.
- Public and private medical schools compete for research funding. In general, public schools get more support from the federal government than do private schools. However, it is important to keep in mind that there are far more public schools than private schools. On average (per school), the private schools receive more NIH money than the public schools.
- Attending medical school in the U.S. is very expensive and by graduation many students have large debts. Average debt estimated 104,000 dollars in 2002. This affects many physicians' interest and ability to conduct research, as research is time consuming and the income tends to be less than that of the highest paying medical specialties.
- The federal government funds indirect costs in most cases. Indirect costs average about 30 percent of total extramural NIH funding, and this ratio has been quite constant for about 15 years. The rate varies between institutions and regions in the U.S. and is renegotiated every third year. Public universities usually get lower rates than private universities because they receive funds from the states, which private schools do not.

- As medical research has received greater funds, the number of graduates has also increased. The number of biomedical Ph.D.s has increased in the U.S. in recent years but the number of physician-scientists has not kept the same pace. This has become a problem for the research community in the U.S.
- The average time it takes to receive a Ph.D. has increased and is currently about six or seven years. A generation ago it took four years.
- The available positions in academia today are different from two decades ago. Nearly all Ph.D.s in 1975 were tenured or tenure-track faculty members. Only about 10 percent were post-doc positions. In 1997, 18 percent held a post-doc position and 55 percent were tenured or were in tenure-track positions.
- Employment conditions for young researchers are often tough, with low salaries and few benefits. Research labs do not want to permanently engage researchers because of the uncertainties involved in external funding. In universities, the departments have annual budgets and a fixed number of faculty positions, and the number of research students produced annually greatly exceeds the number of vacant faculty positions. The number of older faculty members is high as there is no mandatory retirement under U.S. law.

Policy Issues in U.S. Medical Research

- Policy issues in biomedical research are the leveling of future funding, the organizational structure of the NIH, the lack of physicians conducting research, the challenge of multidisciplinary research and translation of discoveries into health benefits for the population.

It is difficult to make comparisons between the United States and Sweden, because of size, culture and tradition. There are similarities, but also differences. Strong support from volunteer organizations, patient advocacy groups, and other research interest groups and associations, have added to the large investments by the federal government and private money. This has led to great success and prominent medical research in the U.S. However, the American medical research community is facing challenges just like many other countries.

2 Introduction

In recent years, there has been a debate in Sweden about funding for medical research. Studies have shown that during the last decade funding for other scientific areas has grown more than funding for medical research. Here the United States has been used as a benchmark. Some proponents of increased funding for medical research have argued that the United States spends more than fifty times as much per inhabitant on medical research as Sweden does.

The Swedish Government commissioned the Institute for Growth policy Studies (ITPS), a newly created governmental agency in Sweden, to undertake a study on research system and policies in the United States with a focus on medical research. The ITPS branch at the Embassy in Washington was assigned to conduct the study. The results of the project will serve as an input to the next Bill on Research that will be presented to the Swedish Parliament 2004-2005.

The purpose of this study is to give an overview of the research system and research policies. This report deals with the structure and financing of medical research. The structure of medical research in the United States from a research policy perspective is the focus in this report. The financing and performance of research, the distribution of funds by the National Institutes of Health (NIH), the degree of competition for funds in the funding processes, the different costs to be covered by the funding and grants, earmarks, and, finally, the relationship between higher education and research are treated and analyzed. Research at the universities and the role that different kinds of funding are playing in university research are included. The crucial role of the NIH in the funding of medical research in the United States makes it necessary to devote particular attention to the NIH in this report.

Various terms, i.e. medical research, biomedical research, life sciences research, and health research are used throughout the report. Different sources use different terms. The terms used in this report has not been changed from the original source to maintain accuracy. These terms will be defined throughout the report when deemed necessary.

3 Increasing Funds for Medical Research

Over 82 billion dollars were spent on health R&D[1] in the U.S. in 2001. This was about 6 percent of the 1.42 trillion dollars spent on health care in the U.S. during the same year (Research America 2002)[2]. These figures, as well as the number of U.S. scientific Nobel Prize winners are examples of the strength of U.S. medical research.

The end of 2003 will complete the doubling of the National Institutes of Health's (NIH) budget. This has taken place in a five-year plan initiated at the time of Clinton's Presidency in 1998 and finalized by the Bush administration as one of the President's campaign promises. The doubling campaign was initiated by Congress to support the biomedical research sector in the country. That investment in research doubled the NIH budget from 13.6 billion dollars to 27.2 billion dollars. Supporting medical research has become an important issue on the political agenda. The US has a community of baby boomers and elderly who are concerned about their health. This part of the community also represents a strong and large group of voters. By the end of 2003, the NIH will have received an annual increase of 15 percent the last five years.

The NIH is by far the premier medical research institution in the world and is a symbol of the importance of the medical research field in the U.S. Medical research has, since the post war era, gained more and more support from the federal government as well as industry and others. The government and the public accepted the proposition that federal investment in basic biomedical research would benefit public health.

The federal government is a major funding source of medical research in the U.S. In 2002 the total federal R&D support (basic + applied research, development and R&D facilities and capital equipment) was estimated at 103 billion dollars of which 24.7 billion dollars were spent on health R&D (Includes health R&D in the Department of Health and Human Services and the Department of Veteran Affairs). Approximately 5 percent of the Department of Health and Human Services' (HHS) total budget was spent on life sciences R&D[3] in 2002. The NIH, which is part of the HHS, received 22.7 billion dollars of the federal R&D money. Other federal agencies like the Agency of Healthcare Research and Quality (AHRQ), the Center for Disease Control (CDC) and the Department of Veterans Affairs (VA) also invest significantly in health R&D (AAAS 2003).

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[1] *Estimates of money invested in health research including e.g. medical research, bioengineering, and biology.*

[2] *The investments in medical research are diverse, making it difficult to find an exact number. These figures are high estimates of investments in the U.S. according to Dr. Propst at ResearchAmerica.*

[3] *The term life sciences constitute the categories of agricultural sciences, biological sciences, medical sciences and other.*

The NIH supports R&D in the U.S. but also research in other countries. In 2002, approximately 26 million dollars went to the EU, out of which 3.3 million was awarded to researchers in Sweden. These numbers are increasing, and in 2003 Sweden is estimated to receive approximately 4 million dollars. The United Kingdom ranks the highest among the EU recipients with an estimated 20 million dollars in 2003 (European Commission Delegation 2003).

The federal government is the major supporter of basic biomedical research and the NIH is the agency with the largest budget for basic research. Basic research is conducted primarily at the academic institutions, federal laboratories and different private research institutes and organizations. However, as research priorities in the U.S. are basically set with the intention to meet national goals, the NIH has received larger increases in the recent years for applied research. Priority areas are cancer and counter-bioterrorism research.

In the 1960s and 1970s the federal government accounted for approximately 60 percent of the annual investment in medical research. Industry contributed approximately 30 percent. The federal budget for health-related R&D increased significantly between 1982 and 2001, including the doubling of the NIH. The real annual growth rate between 1982 and 2001 was 5.8 percent. Health represented about 28 percent of the non-defense budget in 1982, but increased to 50 percent of the non-defense budget in 2001 (NSF 2002a).

While federal investments increased in the 1980s, the support from private industry also accelerated. This had much to do with advances in biotechnology, pharmaceuticals, and medical instrumentation. The industry share of health-related research support passed the federal government, and by 1995, it supported more than half of all health-related R&D. (AAMC 1997) Private industry in the U.S., i.e. the pharmaceutical and biotechnology companies, spends roughly 46 billion dollars a year on R&D. (Research America 2002) However, the vast majority of private industry funding is devoted to development, not research. Private industry directs their funding towards applications and development of health-related technologies, and most funding is given to commercial laboratories. The Federation of American Societies for Experimental Biology (FASEB) estimated that in 2000, of the total resources for medical research, 27 percent came from the NIH, 58 percent came from private industry, 12 percent came from other federal and state local governments, and three percent came from nonprofit organizations (FASEB 2001).

Other funding sources, besides the federal government and industry, spend approximately 10 billion dollars a year on health research. (Research America 2002) The U.S. has a long history of donations and charity for which medical research always has been an important recipient. There are private foundations, public charities, community foundations and corporate grant makers. The grant making foundations in the U.S. have shown a dramatic growth the last few years and health giving has doubled since 1995. Of all investments from foundations, approximately 20 percent go to medical research. (Lawrence 2001) This is partly explained by a strong economy, a record growth in the stock market and many new creations of health foundations. These sources are only a minor part of the funding community, but believed to be essential as they support areas that the federal government and the NIH is neither able nor best suited to support. This kind of research can be politically controversial, cutting-edge or a support for new researchers. Many foundations are disease-specific and therefore most of their support goes to research areas where a result may have a great impact on the specific disease. The research is generally more basic in nature than the research that industry is supporting. Examples of well-known foundations in the U.S. are the Carnegie Corporation of New York and the Robert Wood Johnson Foundation. The latter is the largest health sponsor in the U.S.

Another generous foundation is the Bill and Melinda Gates Foundation, which have invested substantially in the health field the last few years. The foundation had assets worth 32.8 billion dollars in 2001 and gave away a total of 1.1 billion dollars the same year (The Foundation Center 2003). As one example, in the beginning of 2003, Bill Gates and the foundation announced a 200 million-dollar grant to identify challenges in global health and to increase research on diseases in developing countries. This will take form as a partnership with the NIH and the Foundation for the NIH (FNIH)[4], and is a groundbreaking public-private partnership. (Grand Challenges in Global Health 2003)

Also, think tanks, research hospitals and research institutions support research, of which Howard Hughes Medical Institute (HHMI) is an example. The HHMI is somewhat unique in its structure with laboratories across the United States and grants programs throughout the world. Its endowment in early 2002 was approximately 11 billion dollars and it currently has about 350 investigators who serve for a five or seven year term (HHMI 2003). The HHMI tries to enhance science education at all levels and directs its support towards young people and research in medical schools. The HHMI employs independent investigators at its laboratories and therefore mostly does not grant awards to investigator-initiated research. The scientists who are selected from universities and academic health centers all work for HHMI, but also serve as faculty members at the institutions with which HHMI collaborates.

According to NSF, there is no consensus as to why the health sector receives such huge funds in the U.S. but it can be traced to the time after the WWII. Science then became a focus for public and congressional support and funding. The investments have been rather disease-specific, recognizing cancer in the 1970s and AIDS in 1980s. The trend is to fund other disease areas, although cancer and AIDS continue to receive much support. It is said that the growth of health-related R&D funding is also partly due to novel opportunities in biotechnology and influences from lobbying groups that are disease-specific. (NSF 2002a) These trends, as well as funding statistics, indicate that disease-specific research has a higher success rate in federal funding than not disease-specific research. Disease-specific research also enjoys strong support from the public, as the benefits for public health are

[4] *FNIH is a non-profit corporation established by the United States Congress in 1996. It builds and fosters collaborative relationships with philanthropy, industry and academia to support the mission of the NIH.*

more easily understood. Private donors are also supposed to be more generous towards medical research with a disease-specific focus.

Even though there are several "players" within medical research in the U.S., the NIH is undoubtedly the most significant institution. The recent increases have even further strengthened the position of the NIH. The enlarged funds have allowed the NIH to expand both basic and clinical research. Successes like the sequencing of the human genome and advancements in research technologies have been realized through the extra support. An important question for the NIH is what will happen now that the increases are phased out? How will this affect the future of medical research in the U.S., the NIH, and the ability to recruit young people to careers in medical research?

It can be argued, “the health of the biomedical research enterprise is inseparable from the health of the NIH” (The Scientist 1988). NIH-supported scientists, among them eighty Nobel laureates, have made many important scientific discoveries. These discoveries have been translated into practice, e.g. in the areas of heart disease, vaccines and drugs for HIV. The importance of the NIH for medical research in the United States and in the world cannot be neglected.

4 The Dominant Role of the NIH

4.1 History of the NIH

The largest single funder of biomedical research in the world today is the National Institutes of Health, NIH. The mission of the NIH is to uncover new knowledge, which will lead to better health for everyone. The NIH works toward that mission by conducting research in its own laboratories (intramural research), by supporting the research of non-federal scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad (extramural research), and by helping in the training of research investigators and fostering communication of medical information.

The NIH's budget in 2003 amounts to 27 billion dollars. In this section, facts and figures will be presented that can explain why the NIH is so dominant in the U.S. research enterprise and how it accomplishes its mission through its organization and grant mechanism procedures.

The federal engagement in biomedical research originated through the needs of the military during the eighteenth and nineteenth century. The origin of the NIH was a laboratory at the Marine Hospital Service. This institution was given an additional task when the great number of immigrants came to the United States. A Hygienic Laboratory was founded on Staten Island in New York and this was moved to Washington, D.C. in the early 1890s. This laboratory tested the quality of air and water in the Capital and was also supposed to carry out research on infectious and contagious diseases and matters pertaining to the public health.

In the 1930s, the Hygienic Laboratory was transformed into the National Institute of Health. Congress gave this institution the task of awarding stipends for promising medical researchers at academic institutions. In this way the institute was supposed to function as a medical research council, not only providing funds for its own laboratories. In 1937 the National Cancer Institute, NCI, was formed. From the beginning it was supposed to be separate from the NIH but through the National Health Act in the mid 1940s it was made part of the NIH. The NIH was allowed to award grants, fund research fellowships and traineeships, and to establish an outside advisory council to review projects. The 1944 Act also granted the NIH the ability to conduct clinical research.

Other institutes were also created. After World War II, voluntary health organizations and congressional allies influenced the Congress to authorize the creation of several institutes, such as the National Institute of Mental Health (NIMH) and the National Heart Institute (NHI). The belief at that time was that institutes, which were disease-oriented, had a better chance of being funded by the Congress, a belief that may be true even today. Most of the NIH institutes today are disease-oriented, and not set up to fund and carry out basic research, something which makes them different from the situation in other countries, such as Sweden. Each institute is highly affected by its history in that the older institutes seem to have a broader set of activities and programs than the institutes created more recently. The newer institutes spend less money on intramural research projects, research grants and R&D contracts and more on basic and clinical research than the old institutes. (NAS 2002)

In twenty years the budget of the NIH increased from a few million dollars to more than 1 billion dollars in the mid 1960s. The so-called extramural support, i.e. support to academic institutions outside the NIH, had grown to 1 billion in the mid 1970s. The expansion mainly took place during the Presidency at the NIH of Dr. James A. Shannon from 1955 to 1968. The growth was largely achieved through a powerful cooperation between Shannon, some public activists and members of Congress. Dr. Shannon took the initiative to create not only specialized disease-oriented institutes but also the National Institute of General Medical Sciences (NIGMS), which has a focus on basic research.

When President Nixon declared a "war on cancer" in 1971, substantial increases were awarded the NCI. There were discussions and debates in Congress whether to separate the NCI from the NIH. Objections were raised in the scientific community to this proposal, as there was a fear that funding for the NIH would suffer if the proposal was realized. A compromise was reached in that the NCI got a more independent position within the framework of the NIH. The Director of the NCI is for example the only of the NIH institutes' Directors who is appointed by the President.

Medical research as a popular cause gained momentum in the 1950s and after World War II. Research results benefited the public. Congress realized the importance of research and its impact on the nation's health, and initiated support for the NIH, which increased the NIH budget at a steady pace resulting in a doubling every ten years. Health research is still an important issue on the politicians' agendas in the U.S. and will most likely remain so in the foreseeable future.

4.2 Organization of the NIH

The NIH is one of eight agencies of the Public Health Services, which comes under the Department of Health & Human Services (HHS). Examples of other agencies are the Center for Disease Control & Prevention (CDC) and the Agency for Healthcare Research & Quality (AHRQ). The actual R&D budget for the HHS was 24 billion dollars in 2002 of which 97 percent was awarded to the NIH (AAAS 2003).

The NIH is mainly located in Bethesda, Maryland, very close to Washington, D.C. The NIH is a decentralized organization with 27 institutes and centers, employing about 18,000 full-time employees, of which over 4,000 hold professional or research doctorate degrees (see Appendix). The staff includes scientists, physicians, nurses, and administrative and support personnel. The number of institutes is 20, including the National Library of Medicine. The other seven are called centers. The NIH is the only government agency, which has a separate item for each institute and center in the congressional budget. The budget of the NIH is thus the sum of the different institutes' budgets. Each institute or center conducts research and/or related activities on human health. Every institute and four centers award research grants, mostly to scientists at universities and non-federal research institutions. Besides the role of supporting intramural and extramural research, the NIH is distributing health information to professionals and the public and is also involved with transfer of research results to the private sector.

The Office of the Director

The Office of the Director (OD) is responsible for setting policies, planning and coordinating programs and activities at the NIH. The Director gives advice and reports directly to the Secretary of the HHS. The President appoints the Director of the NIH.

The way the Director exercises his or her leadership has varied during the years but in any case the Director has a very important role despite the autonomy of the institutes and centers. As the institutes have grown so has their power in relation to the Director of the NIH. The Director has three Deputy Directors (extramural OER, intramural OIR and management OM) that assist him and one Principal Deputy Director, who are second in command with the responsibility for much of the day-to-day management. There are a number of OD operations that assists the Director with planning, coordinating and managing programs of the institutes and centers. The OD also has six program offices; Office of Aids Research (OAR), Office of Research on Women's Health (ORWH), Office of Disease Prevention (ODR), Office of Behavioral and Social Sciences Research (OBSSR), Office of Dietary Supplements (ODS) and the Office of Rare Diseases Research (ORD). They stimulate specific areas of research throughout the NIH and plan and support research and related activities by funding research at the institutes. The deputy officers and associate officers (head of staff offices) meet weekly with their counterparts in the institutes and centers for problem discussions and policy setting. Furthermore, the Director meets weekly with the directors from the institutes and centers, but the overall management and leadership is provided within the different institutes.

Research priorities in a broad sense are of course also influenced by the views of the Administration, the Congress, advocacy groups and the public. Besides the National advisory councils, which include public representatives, the NIH has formed the Council of Public Representatives (COPR) to respond to a request for a formal presence of the public. COPR is a group of 20 men and women, representing patient and advocacy groups, students and public officials of different ages, geographic belonging and ethnicity. They meet with the Director of the NIH to discuss the overall development of the NIH's policies and research programs.

Institutes and Centers

As stated above, there are 20 institutes within the NIH, which are quite diverse in some respects, such as in mission and scope of activity and size, but similar in the way they are organized and the way they support researchers. The institutes are differently categorized. Several are disease-oriented, such as the NCI. Some refer to a specific organ, such as the National Heart, Lung and Blood Institute (NHLBI). Other institutes are geared towards a specific life stage, such as the Institute on Aging (NIA) and a few others are categorized by field of science, by profession or technology. Each institute is run by a director with a research background who is appointed by the Secretary of the HHS, with the exception of the Director of the NCI who is appointed by the President (National Cancer Act of 1971). The institutes are similarly constructed as the Office of the Director and include an office of intramural research, and an office of extramural research, administration, communications, legislation, personnel etc. Each institute has an advisory council with the task of advising the director of each institute on policies and priorities and to do the second review of extramural awards. The Secretary of the HHS appoints the members of the councils, except the members of the Advisory Council of the NCI who are appointed by the President. The councils, which meet three or four times a year, are composed of both scientific and public members with expertise relevant to the institutes' missions. All institutes and centers but three have an extramural program and all institutes but three, among them the National Institute of General Medical Sciences (NIGMS), have an intramural program. The NIGMS has a major focus on basic science, but does support trauma, surgery, burns, pharmacology, and other medical topics. The NIGMS also has a high focus on training. NIGMS's support for training makes-up about 27 percent of all NIH support of predoctoral and postdoctoral trainees. (Interview with Dr. Greenberg 2002)

There are two different types of centers, operational support centers and research support centers. Of the seven centers within the NIH, four (National Center for Research Resources, Fogarty International Center, National Center for Alternative and Complementary Medicine, National Center for Minority Health and Health Disparities) support research or research infrastructure. They are relatively small and have their own budgets. The National Center for Research Resources (NCRR) is supporting research centers and has no intramural program. Approximately 85 percent of its one billion-dollar budget goes to research centers and research infrastructure (Interview with Dr. Ramm 2003). The other three providing support to the rest of the NIH are the Clinical Center, the Center for Information Technology, and the Center for Scientific Review (CSR), the focal point of the peer review process at the NIH. The operational support centers are funded through part of the appropriations of the other units. They are paid for the service they provide. CSR's main funder is the NCI, which is to be expected since the NCI awards most RPGs[5] at the NIH (Interview with Dr. Ehrenfeld and Dr. Fisher 2003). Centers continue to be established within institutes and most recently, two centers

[5] *Research project grant for primarily investigator-initiated basic scientific research.*

were formed within the OD office: the National Center for Complimentary and Alternative Medicine (NCCAM) and the National Center for Minority Health and Health Disparities (NCMHD).

As described above, the NIH is a huge organization. Many mechanisms are used to keep the organization together, such as standardized processes like the peer review process (see 4.6) and management tools like the budget process (see 4.3). Advisory Committees to the Director of the NIH (ACD) and the Council of Public Representatives (COPR) as well as the advisory councils at the institutes and the system of inter-institute staff meetings also help keeping the NIH together.

4.3 The NIH Budget

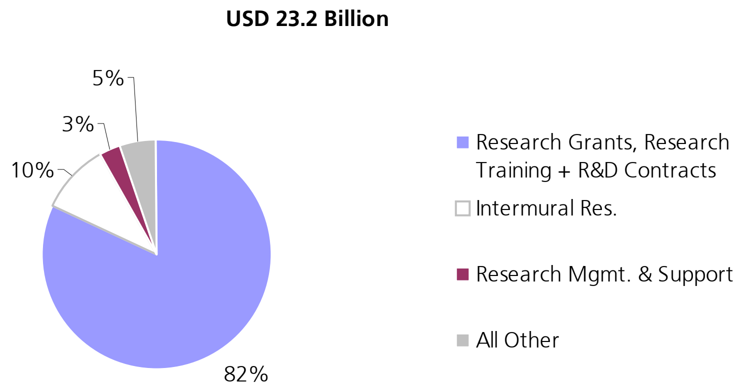
In 2002, the actual R&D budget of the NIH is estimated at 22.7 billion dollars. This part constitutes 97 percent of the total NIH budget; the other 3 percent are spent on training, management and support. As has been pointed out earlier, the NIH budget has doubled in the last five years. No other civilian federal agency has seen its budget increase as much. The NIH accounts for nearly a quarter of federal outlays for R&D and half of the civilian R&D budget. The NIH is the second largest contributor to federal R&D after DOD and the largest supporter of basic research, applied research, and R&D at colleges and universities (AAAS 2002).

The NIH takes a significant part in supporting and carrying out federal R&D obligations. Of these obligations, the NIH sponsored 30 percent of intramural research, 17 percent of industrial R&D, 63 percent of research at universities and colleges, 4 percent of R&D at nonprofit organizations and 10 percent of all other organizations in 2000. The NIH funded 76 percent of the federal obligations of R&D within the medical sciences. Additionally, the NIH is vital for psychology, chemistry research and biological sciences (NSF 2002a).

Approximately 82 percent of the NIH Budget goes to extramural activities, such as research grants, mainly the RPGs, research and development contracts, training and research centers (See Figure 1). Training constitutes approximately 20 percent of the total extramural support. Of the extramural budget, 60 percent goes to medical schools and teaching hospitals. No more than 10 percent is for intramural research programs. The proportion of the budget going to extramural and intramural research has changed in favor of the extramural programs (NIH 2003a). Approximately 3 percent of the budget goes to Research Management and Support (RMS); support for leadership, program guidance, planning, and evaluation for the overall management of NIH programs. Major categories of support include: salaries and expenses for Institute or Center Directors, their administrative staffs, and scientific program managers. In addition to administering, managing, and reviewing research grants, research training, and R&D contract portfolios, staff is responsible for developing research initiatives in areas of scientific promise.

FIGURE 1

Distribution of the NIH Budget



Note: Over 80% of NIH funds support extramural

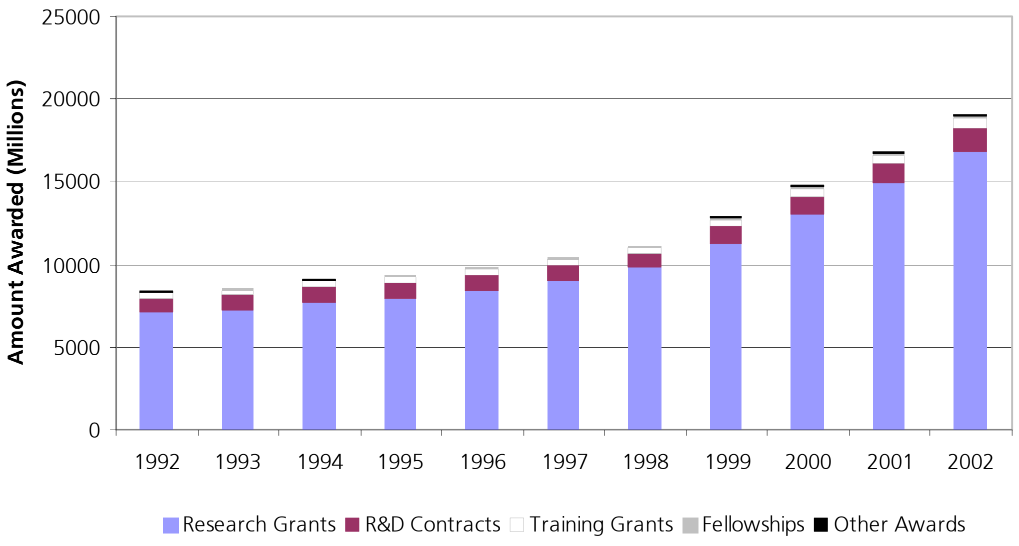
Source: NIH (2003b)

In 2002, the NIH issued awards worth 19 billion dollars. The total number of awards was 49,700. Of these awards, 43,500 were research grants worth 17 billion dollars, 1,000 R&D contracts worth 1.4 billion dollars, 2,100 awards for research training totaling 556 million dollars and finally 2,730 fellowships totaling 102 million dollars. The remaining funds were given to other awards (See Figure 2). The average cost of research grants (including the following mechanisms; research project grants, SBIR-STTR[6], research centers grants, and research career grants) in 2002 was 384,000 dollars. The cost for research center grants was significantly higher, 1.7 million dollars. The average cost per year has increased notably since 1997 when the average cost was 275,000 dollars. Training grants had an average cost of 265,000 dollars and the average cost for fellowships was 38,000 dollars in 2002 (NIH 2003b).

[6] *SBIR (Small Business Innovation Research) - an award to support projects from small businesses that may have commercial viability. STTR (Small Business Technology Transfer) – a program to foster technology innovations with commercial potential through cooperative efforts between small businesses and research institutions.*

FIGURE 2

NIH Awards by Fiscal Year and Mechanism



Source: NIH (2003b)

Within the NIH structure, the NCI received by far the greatest share of the budget, about 4.1 billion dollars, in 2002, followed by the National Institute of Allergy and Infectious Disease (NIAID) and the National Heart, Lung and Blood Institute (NHLBI) with approximately 2.5 billion dollars each. The National Institute for General Medical Sciences (NIGMS) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) also received significant portions of the total budget (AAAS 2003). The NCI issues awards worth approximately 2.6 billion dollars, which is about 18 percent of the total NIH budget and has been steady during the last few years. (Interview with Dr. Kalt 2003)

The Budget Process

The budget process is initially a matter for the NIH, but in later stages it involves the HHS, the President's Office of Management and Budget (OMB), the President and the Congress. The process is one of the most important tools that the NIH Director has at his or her disposal to keep the organization together. The preparation of the budget is somewhat similar between the institutes with the exception of the budget process for the NCI as it submits a budget request directly to the President (called a bypass budget). Each institute and four centers has its own annual budget decided and appropriated by the Congress, which means that they can set their own priorities somewhat independent from the other institutes and from the NIH Director's Office. There are a total of 26 appropriations. Besides the 20 institutes and four centers, the Office of the Director and the Building and Facilities office have separate accounts. The remaining three centers receive their funding from the other institutes and centers that uses their services.

The NIH submits a budget proposal to the President and to OMB simultaneously. The HHS can contest the proposal. The chairmen of the relevant committees in Congress call the NIH Director and the Directors of the various NIH institutes and centers to hearings. They defend the proposed budget from the President before the House and Senate Labor, Health and Human Services, and Education Appropriations Subcommittees. The directors are loyal with the budget proposal but can, on request, express their personal opinion on different budget items. At the NIH there are policies and commitments that need to be followed, which indirectly give guidelines and restraints to each budget. For example, as a NIH grant normally runs for four years, a major part of each institute's budget is therefore already committed to ongoing projects. Approximately 25 percent of the annual budget is spent on new research projects. Political and financial considerations are also taken into account before the Congress will approve, disapprove or change the proposal by authorization and appropriations bills about one and a half years after the budget process starts.

4.4 General Information about Funding at the NIH

The NIH supports both disease-specific research and basic research and their portfolio are large and diverse and no set amount of money goes to one specific disease. Research on one disease is not limited to one institute but is often carried out by different institutes at the same time. Disease-oriented institutes also support basic research and research results of the NIH funded projects are often relevant to more than one disease. The system is built upon the competitiveness of individual investigators as well as interdisciplinary efforts.

The funding of intramural and extramural medical research covers salaries of scientists and technicians, cost of equipment such as computers, cost of supplies such as chemicals and procedures conducted with research patients. The NIH also pays for associated costs like maintenance, electricity and salaries of support staff. Support staff deal with financial aspects of the grants and with establishing review panels in order to ensure that research patients are protected. These associated costs are called indirect costs (overhead) and run as high as around 30 percent of the total cost of a research project. Public universities usually get a lower rate than private universities, as they generally receive funds from their states, which private universities do not. The rate has been steady for about 15 years and is negotiated with a government agency, which has been assigned by the OMB to do this on its behalf (Interview with Dr. Kirschstein 2002).

Regular grant applications include requests for small to midsize instruments and these are regularly awarded. For very expensive instruments and buildings, there are separate grant applications through the NCRR. The application is reviewed by the NCRR's own Office of Review and the NCRR has the responsibility of monitoring the use of a building if it is funded by the center.

4.5 Different Types of Grants and Programs

To receive an award from the NIH is like a gold standard for researchers. The number of applicants has gone up, the number of awards has increased and the success rate has been stable. According to statistics, the NIH supports over 46,700 extramural research projects and more than 2,000 intramural research projects (NIH 2003c). The duration of awards may be as short as three months or as long as 10 years. Most projects and grants however run for 3-5 years. Therefore new projects only constitute about 25 percent of the extramural projects (Interview with Dr. Greenberg 2002). The Research Project Grants (RPG, see below) awards averaged 3.9 years. The NCI has an average total length of their awards of 8-12 years but they are reviewed after four years.

Applications are classified into competing and non-competing applications. An already ongoing project is twice as likely to be funded as a completely new application. Various codes are used to identify different kinds of support. General categories are research grants, contracts, training, and fellowships. Research grants are further divided into research project grants, research center grants, and other research grants (see below). The Office of Extramural Research in the Director's Office sets these policies and activity codes (including a letter and a number).

The main part of the extramural funding is distributed to so called investigator-initiated applications from individual scientists. These are called Research Project Grants (RPG) and range from cellular and molecular research to finding new drugs to treat human illnesses. Within this category, the so-called R01 is the most common. The R01 supports a single project and a single investigator. An R01 may also include support for a number of scientists including co investigators, postdocs, technicians and support staff. Other project grants are given to multi-disciplinary projects conducted by several researchers with different focus on the research problem and is called program project grants (P01). Multi-disciplinary projects and collaborating researchers are also supported by research center grants. These grants are awarded to research institutions and are headed by the center Directors. For example, the NCI has large centers in clinical and basic research, for example at the Columbia Medical School and at the University of North Carolina. Another strong supporter of research centers is the NCRR. The grants also support the development of research resources to integrate basic research with applied research and to promote research on clinical applications. Another grant in the extramural funding categories (as well as intramural funding) is research and development contracts. These are assignments requested and overseen by the NIH but carried out by non-profit and commercial organizations.

The NIH also supports training of young scientists at predoctoral and postdoctoral levels, either individually or via institutions, i.e. the medical schools and universities. Most of this support is for stipends to students and has in later years focused on increasing and improving the career opportunities for minorities. The NIH has in its grant portfolio the National Research Service Awards, (NRSA), fellowships (F), and training grants. These are awards to both individuals and institutions for research training. These are different for individuals having or earning a research doctorate and for individuals with or earning a health-professional doctorate. In medical schools individuals can apply for short term training grants and institutional training grants (T32) under their residency and specialty. In college, students can apply for institutional research training grants like Minority Access Research Careers (MARC) and predoctoral fellowships and training grants during graduate school. For both groups, postdoctoral fellowships and senior fellowships are applicable during postdoctoral/specialty or for an independent researcher. There are several different awards for career development, many directed towards clinical investigators. Another example of support is loan repayment programs, which have been established to attract physicians to clinical research. Some programs pay almost all of the physicians' student loans.

4.6 The Application Process

All applications in the extramural programs are sent to the NIH and the Center for Scientific Review (CSR). The CSR distributes them to the different institutes. About 65,000 applications are reviewed annually (Interview with Dr. Ehrenfeld and Dr. Fisher 2003). The final decisions whether an application is to be funded or not is made by the institutes. Before such a decision is made, the grant proposal has to go through several steps. This process is generally standardized across the NIH. These include rating criteria, policies and procedures in the conduct of review meetings and the use of standardized committees and special emphasis panels.

The CSR’s Division of Receipt and Referral receives all grant applications. The Referral Officers, who are also Scientific Review Administrators (SRAs), make the first important decision, which is to classify the proposal, assign it to an appropriate peer review group (Integrated Review Group, IRG) for the scientific review, and to an appropriate institute or center for funding. An SRA is a federal employee who, besides the above tasks, has to stay up to date with the research areas in question, recruit reviewers and manage the study section meetings. Sometimes the application is multidisciplinary and is therefore submitted to more than one institute. The applicant may also ask to be reviewed by a specific IRG or a study section, but the final decision is made by the CSR. An IRG includes a number of scientific review groups or study sections and reviews similar science proposals. There are 24 IRGs today within the NIH with over 125 study sections. When the IRG has been identified, the application is placed within a study section. These are not tied to any particular institute. The study sections at the NIH meet approximately three times a year in meetings closed to the public.

The Peer Review Process

The review process is made in three cycles to manage the workload at the CSR and at the institutes, and is carried out in two steps. In the first step, each application goes through a peer review process by the CSR so that the scientific merit of the application can be assessed. The study sections consist of 15-20 scientific experts, mostly active researchers within the biomedical sciences. The SRA nominates the members and tries to look for diversity in gender, race, geography etc. They occasionally include federal employees. The reviewers are paid only a small amount as compensation for their work during the multi-year terms they serve. Often it is difficult to combine groups to satisfy the breadth of the knowledge need and therefore temporary members are frequently brought into the study sections. The prestige that comes from being a NIH reviewer is the main reason for being part of a study section, as well as the chance to get an insight into and to learn about the review process at the NIH.

The research proposal is reviewed according to the following criteria (NIH 2003a):

1. Significance - the importance of the question;
2. Innovation - the innovation employed in approaching the problem;
3. Approach - the adequacy of the methodology proposed;
4. Investigator - the qualifications and experience of the investigator; and
5. Environment - the scientific environment in which the work will be done.

Each application is normally assigned to two or more members of the study section for detailed written review comments. Other members are designated as readers. A study section member is responsible for an average of eight full written reviews and four reader comments for each of the three meetings. The application is ranked with a numeric score from 100 to 500, 100 being the best. The score reflects the impact that the project is likely to have on the field based on the five criteria above (significance, approach, innovation, investigator, and environment). Only the upper half of the applications is discussed at the review meetings. The reviewers make the decision as to what applications belong to this category. After discussions at the review meeting, the SRA writes a summary statement that includes a final recommendation. In the application the applicant has described the different direct costs associated with the project. The study sections make a recommendation for an appropriate budget based on these costs, also securing the availability to move funds to different budget categories, as well as to the duration of support. This information, together with the evaluation, is forwarded to the institutes to which the application has been assigned. It is also sent to the applicant. CSR's control over the applications thereby ends. The first step takes approximately six months from the filing of the application to receipt of the statement.

The second step is carried out by the national advisory councils or boards at the institutes, including scientists and public members interested in health issues and/or biomedical sciences. These councils also meet about three to four times per year. Each institute has its own advisory council, mandated by Congress. The councils decide on the overall merit of research projects and set priorities in the research agenda of a specific institute. A council can never reverse the decisions of a study section (Interview with Dr. Ehrenfeld and Dr. Fisher 2003). However, it can recommend funding of applications, which have not received the highest scores but seem to be very important and meritorious. When the second step is finalized it will take several months before the funding reach the applicants.

About one third of all reviewed proposals are granted (NIH 2003a). The success rate has declined due to increased competition with a higher number of applications and reapplications. It is not common that a first time applicant is awarded funding from the NIH. In most cases the rejected applications are too wide in focus. Applications may be resubmitted twice (Interview with Dr. Ehrenfeld and Dr. Fisher 2003).

The review process above describes the process for R01 applications but most applications are reviewed in a similar way. However, some types of applications, SBIR (Small Business Innovation Research) and fellowships have an expedited review and Special Emphasis Panels with special expertise review SBIRs.

Intramural research, both basic and clinical research, mostly takes place on the campus in Bethesda, Maryland. Most institutes have intramural programs. The intramural research is not always disease specific but serves a broad set of objectives within the NIH's mission. The intramural programs are organized and administered by scientific directors, who themselves are scientists, together with the institute director. The directors are also in charge of organizing and administering both laboratory and clinical research. The programs are peer-reviewed by a Board of Scientific Counselors at each institute, which advice the institutes' directors of the importance and quality of the programs. They are not reviewed by the CSR as it only reviews applications for the extramural programs. The intramural programs and scientists are furthermore reviewed by the national advisory councils as well as occasionally by outside experts.

The NIH believes that its peer review system, which has existed for half a century, works very well. It secures that independent scientists make the judgments and decisions. Applicants therefore feel confident that their proposals are evaluated objectively, with no interventions from interest groups or political bias. The study sections review applications from different institutes as the application assignments are based on scientific discipline and not institute. The NIH believes that this reduces the differences in funding levels among the institutes and therefore makes the process even stronger.

4.7 The Future of the NIH

The organization and efficiency of the NIH have been discussed and debated since its foundation. Several studies about these issues have been made. One is currently ongoing through initiative by the NIH itself. The perspective on how the HHS is organized to improve health also influences the views on the standard of the NIH. Some believe that the decentralized organization makes it too rigid, others that it makes it flexible. There are concerns about the growing number of institutes and centers. Studies have always concluded that the then current number was enough, but despite this recommendation, the NIH has proliferated further. If the NIH should consolidate or continue to proliferate is still debated. The Congress, the Administration, disease advocacy groups and strong umbrella organizations like the American Association of Medical Colleges (AAMC), the American Association for the Achievement of Science (AAAS) and the Federation of American Societies for Experimental Biology (FASEB) all have their somewhat different views on the NIH.

The NIH has become the largest research agency in the world and is continuing its expansion through the doubling of its budget between 1998 and 2003. The use of this increase has also been debated. Some criticize that most of the doubling has been used to increase the number and size of R01 grants. Others, such as the scientific societies favor this development. There is also a discussion about the growing imbalance between clinical and basic research in favor of the latter, which means that animal rather than human studies are emphasized. This is also shown in the increased number of Ph.D.s compared to medical researchers. The NIH is working on how to get more physicians interested in research and has done so by initiating the K series career development grants and debt repayment programs. These programs take up about one percent of the budget. Another point of debate is the change from disease-oriented research to more basic and laboratory research.

To carry out great research and stay competitive, it is important to interact across disciplines. The present Director, Dr. Elias Zerhouni, believes there is a need for more multidisciplinary teams and crosscutting initiatives. In September 2003, the NIH released its ”roadmap”. The process to establish the roadmap has taken one year. Hundreds of biomedical researchers have been consulted. The process was meant to identify major opportunities and gaps in biomedical research that no single institute at the NIH could tackle alone. The ultimate goal was “to transform scientific knowledge into tangible benefits for people”. The directors of NIH’s 27 institutes and centers have approved of the roadmap strategy that features 28 initiatives. These can be grouped into three themes; new pathways to discovery, research teams for the future and re-engineering the clinical research enterprise. Included in the first theme is the need to understand complex biological systems and to gain knowledge about the interconnected networks of molecules of cells and tissues, as well as better “toolboxes” for biomedical researchers, such as technologies and databases. The research teams of the future will have to combine skills and disciplines in both the physical and biological sciences. Truly innovative and high-risk research will be promoted. Clinical research needs to develop new partnerships, clinical trials should be conducted jointly by several academic centers and new ways have to be found to organize the way clinical research information is recorded, new standards for clinical research protocols, modern information technology and new strategies to re-energize the clinical research workforce. All in all, approximately 2.1 billion dollars will be spent over six years, starting in 2004 (NIH 2003d).

The NIH further believes in increased collaboration with other agencies like the National Science Foundation (NSF) and the Department of Energy (DOE). There is also an effort to increase clinical research and improve its infrastructure, which is a recommendation from the US Senate (Washington Fax 2003).

Another important aspect of the NIH is the future funding level. Thanks to the doubling campaign, the NIH has been able to fund record levels of new research projects. During the doubling campaign, the average size of awards also increased greatly (more than 44 percent from 1998). This has resulted in a large commitment base and put the NIH in a vulnerable position for the next couple of years if the funding levels now become static. As a result, young people may refrain from choosing a medical research career, and the NIH may not be able to support new research ideas in the way they have been able to before.

5 The Role of Universities in Medical Research

5.1 History of Medical Research at Universities and Colleges

The public's support for the American university system, from the 1800s until today, stems from the instrumental value of research. The understanding that it is valuable to gain knowledge to solve practical problems has supported education and science, and has been vital to the economic growth of the U.S.

Two federal decisions laid the ground for academic medicine in the U.S. in the aftermath of World War II. First, support for basic research and training of researchers became a responsibility for the federal government. Before that, the funds for research were largely awarded universities, and the number of medical schools was limited and they were mainly concerned with the training of medical doctors. In this way, research would be combined with the education of future researchers. Post-war investments in biomedical and behavioral research transformed medical schools into large-scale research institutions and led to two American institutions, the research university and the academic medical center. The NIH was, and has continued to be, the main federal agency to implement this policy.

Second, the decision to establish Medicare[7] and Medicaid[8] increased the revenues to the teaching hospitals and academic medical centers. Before them, care to patient groups had been given without hardly any revenue. These reforms helping the poor generated significant income to the institutes that could be used for research.

Before the federal government anchored the responsibility for basic research, private institutions had played a major role in medical research. The Rockefeller Foundation had led the development in formulating strategies to maximize its own and others funding of research. The foundation initially concentrated its efforts on the establishment of public health and control of infectious diseases, which included grants to individual investigators. The positive results of this research were very important for the public health. This became apparent to the public and the demand for trained medical officers grew. This in turn resulted in the first School of Public Health, which was created by the Rockefeller Foundation and the Johns Hopkins University in Maryland. At the same time, the General Education Board (sponsored by the Rockefeller Foundation) carried out a reform of medical education and created some of the leading medical schools in the U.S., all with a faculty dedicated to research. Other schools chose to adapt to these changes or they

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[7] *Established by President Johnson in 1965. Medicare extends health coverage to almost all Americans aged 65 or older and provides coverage to two high-risk groups—disabled persons receiving cash benefits for 24 months under the social security program and persons suffering from end-stage renal disease.*

[8] *Medicaid is a program that pays for medical assistance for certain individuals and families with low incomes and resources. This program became law in 1965.*

closed. In conclusion, the support from the Rockefeller Foundation established the basis for research in medical schools and schools for public health, as well as institutional funding.

Today, there are about 125 medical schools in the U.S., private and public, with diversity in tradition and history, facilities, organizational structure and financial resources etc. The private universities dominate in the federal research budget, even though they lately have shown a decline in their ability to compete for federal research funds and public universities as a group performs better in federal research. Two important revenue streams for biomedical researchers since the mid 1960s, federal grants and revenues from patient care have supported medical schools and teaching hospitals. However, revenues from patient care are showing a decline.

5.2 Structure of Medical Research at Universities and Colleges

Medical education in the U.S. is carried out at the graduate level. It extends through a four-year program and continues with three to seven years of training. There is no open enrollment to medical schools. The students are selected according to their academic ability and personal qualifications. The number of applicants has increased since the mid-1960s and the number of women has increased substantially. The number of minorities entering medical schools has not increased as much, but has improved. Not only has the number of applicants increased, so too has the cost. The cost of attending medical schools is now extremely high and graduates are often in large debt. Average debt estimated 104,000 dollars in 2002.

Besides turning out doctors, many medical schools contribute to the production of Ph.D.s in biomedical sciences along with universities and colleges. Newly trained scientists are vital to a healthy research community. In 1997, the number of Ph.D.s awarded in the biomedical field was 5,400. Unless no major changes occur, the number is projected to grow at a rate of 3.4 percent annually (NRC 2003). Medical schools produce more than half of biomedical Ph.D.s. While the number of Ph.D.s is increasing, the number of physician-researchers is not and physicians primarily conduct clinical research. The general consensus in the scientific community is that there is a need for more M.D./Ph.D.s in the future. The long period of training (medical school, residency, and postdoctoral research training) affect the number of physicians wanting to conduct research as well as the attractiveness of a career in clinical practice. M.D.s are not trained to do research and few have time each day for research. Most of their income comes from their practice, not from research. The large debts also highly affect many physicians' interest and ability to conduct research, as the researcher's income tends to be less than that of the highest paying medical specialties. This has become a problem for the research community as few physicians can afford a research career after finishing medical school.

One example of a school where students can pursue a combined M.D./Ph.D is the John Hopkins School of Medicine (JHU). JHU has since 1991 been the number one recipient of research funding from the NIH among the American medical schools. The school dates back to 1893 and has many times been cited as "the innovator of research-based medicine”. In 2000, the R&D expenditures at the JHU within life sciences were estimated at 386 million dollars, of which 258 million dollars were spent in medical sciences. The expenditures increased significantly to 489 million dollars in 2002. Of the life sciences R&D spending in 2000, 305 million dollars were federally financed and federal funding covered approximately 79 percent of R&D in the medical sciences. Other important contributors are institutional funds and private industry and foundations. In 1999, the endowment for the school of medicine was 667 million dollars. (NSF 2002a) Total federal funding for the JHU amounted to 793 million dollars in 2000.

Universities and colleges support research through salaries, facilities, libraries and other infrastructure and by raising private money for research. Universities or medical schools do not specifically fund research projects. It is always the individual researcher who applies for funding from outside sources. However, if the applicant is granted an award the money will first pass through the university or the medical school. This is required by law. The NIH for example cannot give federal money directly to an individual. This process makes the schools accountable for the money and ensures that it is properly used. In fact, the NIH has a contract with the institution. No graduate student or postdoc fellow can apply for an award because only faculty members are eligible. This rule is set by the university/school, not by the funding agencies. However, graduate students can apply for an individual fellowship award for a multi-year project. These awards include funding for an individual mentor for the students. Furthermore, universities and colleges can apply for training grants for a faculty. These fellowships are for young researchers and for a limited time.

5.3 Funding of Medical Research at Universities and Colleges

Of all R&D expenditures at universities and colleges, 58.1 percent was spent within the life sciences in 2000. The federal government is by far the largest funding source followed by institutional funds. Even if federal research funds still represent the major component of direct support, it has declined as a percentage of the schools' revenues since it peaked in the mid-1960s. The NIH is the most important federal agency for the universities and colleges as the NIH contributes about 85 percent of all life science research, and provides nearly two-thirds of all federal funds to universities and colleges. (NSF 2002b) Approximately half of the NIH's budget goes to 20 medical schools (Interview with Dr. Korn 2003).

Even though private industry is the sponsor of the majority of health related R&D, its support to universities and colleges remains small. Support from private industry seems to be concentrated to drug trials sponsored by pharmaceutical companies. Other types of relationships between academia and industry seem to be gaining grounds however. Breakthroughs in university research have created opportunities that industry would like to explore commercially. Industry also wants to use medical schools for their research. This research is mostly short-term, product- and patent-oriented. In contrast, the research supported by the NIH is more fundamental and curiosity based. The academic community is now starting to view industry as a stronger source of funding of basic research.

The money spent within the life sciences at universities and colleges totaled 19 billion dollars in 2001. It has showed a steady increase; in 2000 the amount was estimated at 17.5 billion dollars. Of the money spent within the life sciences, 10 billion dollars was for funding of medical sciences. This is about 53 percent. Non-federal funding, such as state and local government, industry and institutional funds, amounted to 8 billion dollars in the life sciences, of which 4 billion dollars went to research within the medical sciences. Federal support estimated 11 billion dollars, out of which 6 billion dollars supported medical sciences (NSF 2002a).

In 2002, public universities spent about 12.6 billion dollars in the life sciences and 6.1 billion dollars in the medical sciences R&D. Out of this, federal funds totaled 6.5 billion dollars for life sciences and 3.4 billion dollars funded R&D in the medical sciences. Slightly more than half of the federal funding to public universities goes to life sciences. Federal investments in private universities amounted to 4.7 billion dollars in the life sciences in 2002 (medical sciences received 2.8 billion dollars). Total investments by private institutions were 6.6 billion dollars within the life sciences; 4.9 billion dollars of this sum went to the medical sciences (NSF 2002a).

Public and private medical schools compete for research funding. In general, public schools get more support from the federal government than do private schools. However, it is important to keep in mind that there are far more public schools than private schools. On average (per school), the private schools receive more NIH money than the public schools.

In both public and private universities the non-federal funding of R&D in the medical sciences is less than the federal. The amount invested is four times bigger in public universities than in private universities. However, the percentage share of non-federal funding spent on the life sciences and especially the medical science is larger in private universities than in public universities. Total amount spent for research equipment at universities and colleges in 2001 was estimated at 665 million dollars. The shares invested by federal and non-federal sources were almost equivalent (NSF 2002a).

Universities and colleges themselves also contribute to research funding, a share that has grown in the last few years. These sources are indirect support through state appropriations, R&D funding from university endowments, or funding through tuition and other forms of general revenues. Revenues from clinical practice are important for research and its indirect costs. Today, this type of funding totals nearly 20 percent of the research portfolios, much due to the fact that institutions' cost-sharing requirements on grants have increased (Eiseman et al. 2002). Universities and colleges have gained by the nation's commitment to biomedical research but the schools now face a tough challenge by changes in federal support and policy resulting in fiscal limits and resource constraints.

5.4 Funding Opportunities and Costs Covered

Research at the universities is generally funded through grants, not contracts, and these provide money and equipment to the researchers. Some federal agencies also like to have a cooperative agreement with the researcher when there is a substantial involvement in the particular research project. The National Cancer Institute for example makes agreements with the purpose to create interaction with its own scientists and university researchers. Money can also be given to a university in the form of a contract if the university is producing a product or providing a service.

Another example is funding by the Howard Hughes Medical Institute (HHMI) that has many programs supporting medical schools. Their Graduate Science Program provides fellowships and supports certain courses. Their Biological Sciences Education Program gives grants to selected undergraduate institutions.

Medical research is expensive and requires investments in buildings and equipment. This is costly for the universities and colleges to maintain, and therefore the federal government has shared these expenses with the schools. The costs are divided into two types of costs; direct costs and indirect costs (overhead costs). Direct costs are costs that come from a specific research project. Indirect costs are costs that are not exclusively for a specific project but are vital to support the infrastructure and administration.

The federal government funds indirect costs in most of its grants in most cases (approximately 70-90 percent). Indirect costs average about 30 percent of total extramural NIH funding, and this ratio has been quite constant for about 15 years. The indirect costs are harder to measure than direct costs, which constitute about two thirds of a research project. Normally, all costs in medical schools are added and divided by the number of grants. However, at some universities, medical schools are budgeted separately and have a different rate. The rate is normally higher due to higher costs associated with biomedical research. The amount is decided according to agreements between government and universities. This rate is applied no matter who funds a proposal. The rate varies between institutions and regions in the U.S. and is renegotiated every third year (Interview with Dr. Korn 2003). Institutional differences are due to real differences in the cost of facilities, geographic differences, age and condition of facilities, and the type of research conducted. The aggressiveness with which the universities are seeking reimbursements also explains the differences. Public universities usually get lower rates than private universities because they receive funds from the states, which private schools do not.

These indirect costs grew significantly in the 1970s due to the increasing complexity of research as well as demands on institutional resources. The burden on the universities and colleges has further increased due to various policy reforms, which has put a lot of stress on particularly research-intensive schools. The major change is the cap of 26 percent on administrative costs and other limits on allowable costs. At medical schools, clinical revenues have mostly covered these expenses.

5.5 The Relationship between Education, Research and Careers

In order to have excellent research you must have talented and well-trained researchers. The doubling of the NIH budget has sent a message to young scientists that medical research is an area for the future.

As the medical field has received greater funds, the number of graduates has also been higher than in many other fields. The growth in medical doctorates in the U.S. during the last decade was due to an increase of women and minority students of both sexes. The increase in full-time graduate students in health fields during the last decade was due to increases in foreign-born students, women and minorities. The U.S. has relied on non-citizens, women and a small number of minority students to sustain science graduates and doctorates. The population of biomedical Ph.D.s has increased in the U.S., but the number of physician-scientists has not kept the same pace. This has become a problem for the research community in the U.S. A study published in 2000, "Addressing the Nation's Changing Need for Biomedical and Behavioral scientists" by the National Research Council (NRC 2000), recommends that there should be no increase of research training and production of Ph.D.s in the biomedical field in the U.S. In the clinical research field, focus should be on training and retaining physicians so that the number of M.D./Ph.D.s increases substantially.

An important issue for the U.S. research community is to retain students, women and minorities, and young scientists in the research field. There are numerous of programs that have been established in order to do so as well as to attract physicians to conduct research and combine basic and clinical research. The NIH has, as an example, a "Bench to Bedside" award program where clinical researchers team up with Ph.D. basic scientists. Different institutes and/or laboratories are encouraged to establish partnerships between themselves and these have proven both popular and successful. The NIGMS has different programs to increase the representation of minorities in biomedical research. Minority physicians are costly to attract as they are generally faced with larger debt than majority students are if they choose a research career. The NIGMS also has a program called "Bridges for the Future" with the purpose of helping students make transitions at points where many drop out; from associate to bachelor's programs and from master's to Ph.D.s programs.

In order to be a researcher in the U.S. you have to be very dedicated. Life of a researcher is hard and getting a grant from the NIH can determine your future. There are issues and problems with the current work situation. Employment conditions for young researchers are often very tough, with low salaries and few benefits. Research labs do not want to permanently engage researchers to their faculty or institution in case they lose a grant. In universities, the departments have annual budgets and a fixed number of faculty positions, and the number of research students produced annually greatly exceeds the number of vacant faculty positions. The number of older faculty members is high as there is no mandatory retirement under U.S. law. The average time it takes to receive a Ph.D. has gone up and is today about six or seven years. A generation ago it took four years. A fellowship lasts approximately five years, a generation ago two years. There is a need to assist the young scientists with debt repayment, good mentors, recruitment of minority scientists, and training in translation research for Ph.Ds. The NIH has loan repayment programs where the NIH repays student loans for extramural clinical researchers.

The science workforce has grown faster than the civilian labor force and is expected to continue to grow. In 1999, 0.4 million were life scientists, many biologists. Industry is the largest source for jobs for scientists and the academia the second largest. However, in 1999, almost half of all life scientists were employed in academia just like the tradition. In the academic setting the positions available today are different from two decades ago. Nearly all Ph.D.s in 1975 were tenured or tenure track faculty members. Only about 10 percent were postdoc positions. However, in 1997 18 percent held a postdoc position and 55 percent were tenured or were on tenure track. Other positions like research assistants and instructors have also increased significantly. The U.S. depends on foreign-born scientists in the workforce and many more are expected to return to their home countries than before due to US immigration requirements among other things. This development may increase the pressure on the government to expand the domestic pipeline of scientists.

The relationship between education/training and the needs of the labor market have also been addressed by the Council on Competitiveness in 1998: “The aging of the national workforce has produced a massive requirement to replace a generation of skilled wage earners that will reach retirement age by 2005”. Investment in education and training is essential to solve the problem.

6 Policy Issues in U.S. Medical Research

American medical research is very competitive. In a comparative perspective, the U.S. is spending heavily on medical research. Even so, there are issues, which are debated and which deserve attention. The five issues discussed briefly below have repeated themselves during our interviews, in articles and in other reports.

6.1 The Leveling of Funding for Medical Research

The doubling of the NIH budget started 1998 and will end in 2003. The budget has increased annually by 15 percent during the doubling period and the Administration has now proposed an annual increase of 2.2 percent between 2004 and 2007 (Korn et al. 2002). To balance commitments, to initiate new projects and to fund new researchers have always been challenges to the NIH. The doubling has allowed the NIH to finance record levels of new projects but has also led to large commitments. To handle these commitments will be more difficult if funding levels become stagnating. Not only has the NIH been able to fund more projects, but the increased funding has also sent a message to future generations of scientists that it is worth pursuing a career in the medical research field. Stagnating levels of funding may make young researchers and students less likely to choose a research career, which could affect the medical science in a long-term perspective. It may also affect the NIH's ability to respond to new research ideas.

The doubling has also created a discussion about the funding level of other agencies. There have been moves both in Congress and elsewhere to invest substantially more resources in the National Science Foundation (NSF) and also in public health research.

6.2 The Organizational Structure of the NIH

The NIH has always been considered a great success. It has been called a "billion dollar success story" by President Lyndon Johnson in 1967 and "the jewel in the crown of the federal government" by former NIH director Harold Varmus (NAS 2002). Since the NIH was established, the number of institutes has grown at a steady rate. The NIH's organizational structure has been evaluated several times. Former evaluations have recommended that no additional institutes be established. Concerns about science fragmentation, the inability to control and lack of oversight by the Director, increased costs, etc. have been raised. Even so, institutes have continued to be established.

A recent report made by the National Research Council (NRC) and the Institute of Medicine (IOM) recommends that some institutes should be merged into others and that there should be more multi-institutes initiatives. One suggestion is to merge the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA) as their research areas are very similar. To continue to meet future challenges successfully, organizational changes are needed. However, to change the structure of the NIH may be extremely difficult since it has developed through cumbersome social and political negotiations and as changes would require legislation. Instead of merging institutes, another solution would be to give the Director more money to fund multi-institute. The latter is also something that the Director, Dr. Elias Zerhouni, has on his agenda and it is also part of his "roadmap" for the NIH (Kaiser 2003).

6.3 The Lack of Physicians Conducting Research

The workforce in basic biomedical research is far greater than is the clinical research workforce. In addition, there is an imbalance between Ph.D.s and M.D.s that conduct research in the clinical research workforce. The number of physicians who conduct research has declined, while the number of Ph.D.s has increased since 1975. As an example, of the grants that the NIH awards, 70 percent are given to Ph.D. researchers and 30 percent to M.D. or M.D./Ph.D. researchers (Zemlo et al. 2000). Physicians are more likely to bring an understanding of the health needs of the public to clinical research. Along with this issue, there is also a concern that minorities are under-represented in clinical research, which does not reflect the nation's increasing minority population. Regarding the imbalance of Ph.D.s and M.D.s, a recent study by the National Research Council recommended that the total Ph.D. production should not be increased but that the training and retaining of physicians in research should instead be in focus.

The reason for the declining number of M.D.s doing research is said to be salary differences between a research career and a career in private practice. Physicians feel that they cannot afford to do without patient revenues. Furthermore, they are faced with large debts from their time in medical schools since tuition has increased dramatically since the 1980s. Average debt of medical students graduating estimated 104,000 dollars in 2002. Finding time for research is also an issue for physicians. In addition, the length of clinical training, the difficulty securing research grants, and the uncertainties about promotion, since basic research often is valued more than clinical research, contributes to a lack of skilled researchers. The students who pursue a combined M.D./Ph.D. degree are in less debt as they get scholarships from the NIH. Even so, the stipends are less than what a medical resident would receive as his or her salary. The research community is well aware of these problems and the NIH is working to create a balance by offering training stipends and loan repayment programs in order to attract young physicians to research.

6.4 The Challenge of Multidisciplinary Research

Stimulating multidisciplinary research is another issue in the U.S. medical research community today. Research today requires collaboration from many disciplines and experts. The issue of organizational change at the NIH discussed above also addresses the importance for the NIH to support innovative interdisciplinary research. The report from the IOM and the NRC recommends that research at the NIH should cut across all of the institutes and centers. The Director of the NIH, Dr Elias Zerhouni, is working towards increased multidisciplinary research and trans-NIH initiatives. This is important in clinical research.

The roadmap has been created to meet new challenges that the NIH and the scientific community face today. Those challenges cannot be met by a single institute alone but has to be approached by several institutes. The roadmap suggests promoting initiatives, such as interdisciplinary research, high-risk research and innovator awards, and public-private partnerships that would enable the NIH to sustain its contributions to better health for the population.

6.5 Challenges Facing the Clinical Research Enterprise

Researchers and policy makers are concerned that discoveries in medical research are not translated fast enough into treatments and drugs for the benefit of the public. According to experts, clinical research in the U.S. faces high costs, slow results, lack of funding, regulatory burdens, fragmented infrastructure, incompatible databases, and a shortage of researchers and participants. These factors make it problematic to translate discoveries, both basic and clinical. It is difficult to translate basic research into clinical studies, and clinical studies into medical practice and the health care system. The Clinical Research Roundtable (CRR)[9] at the IOM was initiated due to these concerns. They suggest that these obstacles can be removed through cooperation between different stakeholders, such as the federal government and industry. Challenges that clinical research is facing in the U.S. are public participation, information systems, workforce training, and funding. Clinical research requires collaboration and skills of various expertise, nurses, physicians, computer programmers, and others. A shortage of skilled personnel may develop in 2005. In 2001, less than four percent of competing grants awarded by the NIH, were awarded to researchers aged 35 years old or younger (Sung et. al, 2003). Furthermore, the infrastructure in clinical research needs to be improved as well as securing stable funding in order to make discoveries benefiting the U.S. population. Since researchers get money for the discoveries, not the translation, the researchers as soon as they make the discovery, most likely will start on a new project in order to get an award and thereby an income.

[9] *CRR - Clinical Research Roundtable at the Institute of Medicine, a group initiated in spring 2000 as a result from the concern of the lack of translation of clinical research.*

7 References

AAAS (2003) "AAAS Report XXVII Research & Development FY 2004", American Association for the Advancement of Science

AAAS (2002) "Senate Completes NIH Doubling Plan, Boosts Bioterrorism R&D", AAAS R&D Funding Update July 24, 2002, American Association for the Advancement of Science

AAMC (1997) "Academic Medicine – Institutions, Programs, & Issues", Association of American Medical Colleges

Eiseman, E., Koizumi, K. & Fossum, D. (2002) "Federal Investment in R&D", Science and Technology Policy Institute, RAND, Prepared for the President's Council of Advisors on Science and Technology

FASEB (2001) US Investment in Biomedical Research 2001, Federation of American Societies for Experimental Biology

Grand Challenges in Global Health (2003) "Bill & Melinda Gates Foundation announces $200…" Press Release January 26, 2003

HHMI (2003) "About HHMI, HHMI: An Introduction", available at http://www.hhmi.org/about/index.html, accessed April 10, 2003, The Howard Hughes Medical Institute

Kaiser, Jocelyn (2003) "A Low-Stress Scheme for Overhauling NIH's Structure", SCIENCE, Vol. 301, No. 5633 (2003)

Korn, D. et al. (2002) "The NIH Budget in the 'Postdoubling' Era", SCIENCE Vol 296, May 24, 2002

Lawrence, Steven (2001) "The Foundation Center's 2001 Health Funding Update", The Foundation Center

NAS (2003) "Organizational Changes Needed at NIH to Pursue more Innovative, Crosscutting, and Strategic Research, Greater Resources, Authority, and Flexibility should Be Given to NIH Director", News Release July 29, 2003, The National Academy of Science

NAS (2002) "Organizational Structure of the National Institute of Health", Background Paper for the NAS Committee on the Organizational Structure of the NIH, The National Academy of Science

NIH (2003a) "Setting Research Priorities at the National Institutes of Health", available at http://www.nih.gov/about/researchpriorities.htm, accessed January 20, 2003, The National Institutes of Health

NIH (2003b) “Award Trends”, available at: http://grants1.nih.gov/grants/award/-trends/avgawdsrgcurrcon9702.htm & http://grants1.nih.gov/grants/award/ trends/distbud02.htm; accessed May 25, 2003, The National Institutes of Health

NIH (2003c) “An Overview”, available at http://www.nih.gov/about/-NIHoverview.html, accessed January 20, 2003, The National Institutes of Health

NIH (2003d) “The NIH Roadmap”, available at http://nihroadmap.nih.gov, accessed October 8, 2003, The National Institutes of Health

NRC (2000) “Addressing the Nation's Changing Need for Biomedical and Behavioral Scientists”, National Research Council

NSF (2002a) “Science and Engineering Indicators 2002”, National Science Foundation

NSF (2002b) “Federal Academic Science and Engineering Obligations Increased 10 percent in FY 2000”, Infobrief, NSF 02-310, National Science Foundation

Research America (2002) “2001 Investment in U.S. Health Research, Less than 6 ¢ of each health dollar goes to research”, available at http://www.researchame-rica.org/advocacy/, accessed February 10, 2003

Sung et. al. (2003) “Central Challenges Facing the National Clinical Research Enterprise”, Special Communication from the American Medical Association

The Foundation Center (2003) “Foundation Growth and Giving Estimates 2002 Preview”, Foundations Today Series 2003 Edition

The Scientist (1998) “Venture Capital for Biomedical Research the Strategic Role of the Private Foundations”, The Scientist 2(2): 9, January 25, 1998

European Commission Delegation (2003) U.S. S/T/E Highlights, Monthly Account of Selected Secience/Technology/Education Developments, November 2003, European Commission Delegation in Washington D.C.

Washington Fax (2003) “News Story from AAAS Annual Meeting in Denver” Washington FAX February 25, 2003

Zemlo, T., Garrison, H., Partridge, N. & Ley, T. (2000) “The Physician-Scientist: Career Issues and Challenges at the year 2000”, Life Sciences Forum 2000, FASEB Journal 2000:14:221-230

8 Interviews and Discussions

Ehrenfeld, E. & Fisher, S. (2003) Interview with Dr. Ellie Ehrenfeld & Dr. Susan Fisher, February 6, 2003, The Center for Scientific Review, The National Institutes of Health

Greenberg, J. (2002) Interview with Dr. Judith Greenberg, December 18, 2002, The National Institute of General Medicines, The National Institutes of Health

Kalt, M. (2003) Interview with Dr. Marvin Kalt, February 21, 2003, The National Cancer Institute, The National Institutes of Health

Kirschstein, R. (2002) Interview with Dr. Ruth Kirschstein, November 8, 2002, The National Institutes of Health

Korn, D. (2003) Interview with Dr. David Korn, June 9, 2003, Association of American Medical Colleges

Ramm, L. (2003) Interview with Dr. Louise Ramm, February 13, 2003, The National Center for Research Resources, The National Institutes of Health

Rickles, F. (2003) Interview with Dr. Frederick Rickles, February 27, 2003, Health and Scientific Affairs, George Washington University

9 Appendix – The NIH Institutes and Centers

National Cancer Institute (NCI) – Established in 1937. Budget: 4.1 billion dollars.

National Eye Institute (NEI) – Established in 1968. Budget: 580 million dollars.

National Heart, Lung, and Blood Institute (NHLBI) – Established in 1948.
Budget: 2.6 billion dollars.

National Human Genome Research Institute (NHGRI) – Established in 1989.
Budget: 428 million dollars.

National Institute on Aging (NIA) – Established in 1974. Budget: 891 million dollars.

National Institute on Alcohol Abuse and Alcoholism (NIAAA) – Established in 1970. Budget: 383 million dollars.

National Institute of Allergy and Infectious Diseases (NIAID) – Established in 1948. Budget: 2.5 billion dollars.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) – Established in 1986. Budget: 447 million dollars.

National Institute of Biomedical Imaging and Bioengineering (NBIB) – Established in 2000. Budget: 262 million dollars.

National Institute of Child Health and Human Development (NICHD) – Established in 1962. Budget: 1.1 billion dollars.

National Institute on Deafness and Other Communication Disorders (NIDCD) – Established in 1988. Budget: 341 million dollars.

National Institute of Dental and Craniofacial Research (NIDCR) – Established in 1948. Budget: 342 million dollars.

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) – Established in 1948. Budget: 1.6 million dollars.

National Institute on Drug Abuse (NIDA) – Established in 1973.
Budget: 892 million dollars.

National Institute of Environmental Health Sciences (NIEHS) – Established in 1969. Budget: 644 million dollars.

National Institute of General Medical Sciences (NIGMS) – Established in 1962. Budget: 1.7 billion dollars.

National Institute of Mental Health (NIMH) – Established in 1949.
Budget: 1.2 billion dollars.

National Institute of Neurological Disorders and Stroke (NINDS) – Established in 1950. Budget: 1.3 billion dollars.

National Institute of Nursing Research (NINR) – Established in 1986.
Budget: 120 million dollars.

National Library of Medicine (NLM) – Established in 1956.
Budget: 274 million dollars.

Center for Information Technology (CIT) - Established in 1964.

Center for Scientific Review (CSR) - Established in 1946.

John E. Fogarty International Center (FIC) – Established in 1968. Budget: 56 million dollars.

National Center for Complementary and Alternative Medicine (NCCAM) – Established in 1992. Budget: 104 million dollars.

National Center on Minority Health and Health Disparities (NCMHD) – Established in 1993. Budget: 157 million dollars.

National Center for Research Resources (NCRR) – Established in 1962.
Budget: 985 million dollars.

Warren Grant Magnuson Clinical Center (CC) - Established in 1953.

10 Sammanfattning

USA investerar mer i de medicinska vetenskaperna än något annat land i världen. Stöd från stat, industri och allmänhet har ökat signifikant sedan efterkrigstiden. Under 2001 investerades cirka 82 miljarder dollar på hälsoforskning (inklusive t.ex. medicinsk forskning, bioteknik och biologi). Summan idag uppskattas till cirka 100 miljarder dollar. Dessa stora investeringar är en bidragande faktor till den amerikanska framgången på detta område.

Denna rapport fokuserar på den medicinska forskningens struktur och finansiering i USA med en översikt över forskningssystem och forskningspolitik. Universitetsforskning och den roll som olika typer av finansiering spelar för forskningen på universiteten inkluderas. National Institutes of Health (NIH) spelar en avgörande roll när det gäller finansiering av den biomedicinska forskningen i USA varför NIH ägnas särskild uppmärksamhet i rapporten.

Mer forskningsmedel till den medicinska forskningen

- Den medicinska forskningens struktur och organisation tog form efter andra världskriget, när stat och allmänhet accepterade tanken att federala investeringar i biomedicinsk grundforskning skulle gagna människors hälsa. Den största delen av forskningen genomförs på universitet och högskolor över hela USA. NIH är den federala regeringens viktigaste institution när det gäller att stödja biomedicinsk grundforskning.
- I och med utgången av 2003 kommer NIH-budgeten att ha fördubblats. Budgeten har ökat från 13,6 miljarder dollar 1998 till 27,2 miljarder dollar under 2003, en årlig ökning med 15 procent under de senaste fem åren.
- Den federala regeringen är den medicinska forskningens största finansieringskälla i USA. Under 2002 uppskattades det totala federala FoU-stödet (forskning och utveckling) till 103 miljarder dollar, av vilka 24,7 miljarder dollar lades på FoU inom hälso- och sjukvård.
- Utvecklingen av den privata industrins finansiering har accelererat under de senaste årtiondena och har passerat den federala regeringens investeringar. Industrin stödjer mer än hälften av all medicinsk FoU i USA. Statens andel är cirka en tredjedel. Övervägande delen av industrins finansiering går emellertid till utveckling, inte till forskning. Den federala regeringen förblir den största finansiären av biomedicinsk grundforskning. Den svenska staten bidrar med cirka 25 procent av finansieringen till medicinsk FoU och den svenska industrin med cirka 50 procent.
- Industrin i USA, d.v.s. läkemedels- och bioteknikföretagen, lägger grovt räknat 46 miljarder dollar per år på FoU.

- I USA har det länge funnits privata finansiärer och medicinsk forskning har varit en stor, viktig mottagare. Av alla bidrag via stiftelser går cirka 20 procent till medicinsk forskning.

NIH:s dominerande roll

- Genom fördubblingen av NIH:s budget har NIH kunnat stödja fler forskare. Ingen annan civil federal myndighet har sett sin budget öka lika mycket.
- NIH stödjer både grundforskning och klinisk forskning som genomförs internt och externt. National Cancer Institute (NCI) får den största delen av budgeten, cirka 4 miljarder dollar under 2002.
- NIH består av 27 institut och center och ligger i Bethesda, Maryland, där den mesta interna forskningen bedrivs. Den interna forskningen får cirka 10 procent av NIH-budgeten. NIH har cirka 18 000 heltidsanställda, av vilka 4 000 har doktorsgrad, antingen yrkesinriktad (”professional doctorate”) eller forskningsinriktad doktorsgrad.
- Den externa forskningen, som får cirka 80 procent av budgeten, äger främst rum på universitet och högskolor. Av den externa budgeten går 60 procent till medicinska fakulteter och undervisningssjukhus. NIH är också den största finansieringskällan av medicinsk forskning på universitet och högskolor.
- NIH:s organisation är decentraliserad och instituten är olikartade vad gäller uppgift, storlek och aktiviteter. De liknar varandra i organisation och det sätt de stödjer forskningen på. NIH-chefens kontor ansvarar för fastställande av policies, planering och koordinering av program och aktiviteter på NIH.
- Totalt omkring 65 000 anslagsansökningar granskas årligen. Cirka 45 000 ansökningar granskas och värderas av Center for Scientific Review och resten av instituten och centren. Instituten fattar beslut om vilka forskare som får bidrag och bidragens storlek. Cirka en tredjedel av alla granskade förslag godkänns.
- Under 2002 finansierade NIH 49 700 anslag värda 19 miljarder dollar. Den genomsnittliga kostnaden för ett forskningsanslag under 2002 var 384 000 dollar. I Sverige ges Vetenskapsrådets anslag till enskilda forskare med en genomsnittlig summa om 360 000 kronor (cirka 42 000 dollar), vilket endast delvis täcker forskningsprojektet. Endast ett litet antal sökande får anslag om 1 miljon kronor.
- Ett NIH-anslag avser normalt fyra år. Därför är en stor del av varje instituts budget redan upptagen av pågående projekt. Cirka 25 procent av den årliga budgeten läggs på nya forskningsprojekt.
- NIH-chefen, Dr. Elias Zerhouni, tillkännagav nyligen sin färdplan (road-map) för NIH-forskningen. Färdplanen har skapats för att möta de utma-

ningar NIH och forskarvärlden står inför idag och som ett enskilt institut inte kan klara av på egen hand. Färdplanen föreslår initiativ som interdisciplinär forskning, högriskforskning och utmärkelser till innovatörer samt offentlig-privata partnerskap.

Universitetens roll i den medicinska forskningen

- Efter andra världskriget blev universitet och högskolor i första hand de främsta utförarna av den medicinska forskningen och forskarutbildningen.
- Av alla FoU-kostnader vid universitet och högskolor spenderas cirka 60 procent inom livsvetenskaperna. Dessa uppgick till 19 miljarder dollar under 2001 och 53 procent av dessa investeringar, d.v.s. 10 miljarder dollar, gick till finansiering av den medicinska forskningen.
- Den federala regeringen är utan jämförelse den största finansieringskällan, följd av institutionella fonder. Federalt stöd under 2001 till livsvetenskaperna uppskattas till 11 miljarder dollar, av vilka 6 miljarder dollar stödde de medicinska vetenskaperna. NIH är den viktigaste federala myndigheten för universitet och högskolor, eftersom den bidrar med cirka 85 procent av all livsvetenskaplig forskning. Halva NIH:s budget går till 20 medicinska fakulteter.
- Statliga och privata medicinska fakulteter konkurrerar om forskningsfinansieringen. Generellt får statliga fakulteter mer stöd från den federala regeringen än privata fakulteter. Det är emellertid viktigt att komma ihåg att det finns många fler statliga fakulteter än privata. I genomsnitt (per fakultet) får de privata medicinska fakulteterna mer NIH-pengar än de statliga fakulteterna.
- Det är mycket dyrt att genomgå en läkarutbildning i USA och efter avlagd examen har många studenter stora skulder. Genomsnittsskulden uppskattas till 104 000 dollar under 2002. Det påverkar många läkares intresse och möjligheter att utföra forskning, eftersom forskning är både tidsödande och inkomsten tenderar att ligga lägre än de högst betalda medicinska specialiteterna.
- Den federala regeringen betalar indirekta kostnader (overhead) i de flesta fall. Indirekta kostnader utgör i genomsnitt cirka 30 procent av de totala externa forskningsprojektmedlen och detta förhållande har varit konstant i cirka 15 år. Beloppet varierar mellan institutioner och regioner i USA och omförhandlas vart tredje år. Statliga universitet erhåller vanligtvis lägre belopp än privata universitet, eftersom de får medel från delstaterna, vilket inte gäller privata skolor.

- Eftersom den medicinska forskningen fått ökade forskningsmedel har antalet akademiker också ökat. Antalet biomedicinska Ph.D. har ökat i USA under senare år men antalet läkare som forskar har inte ökat i samma takt. Detta har blivit ett problem för forskarvärlden i USA.
- Den genomsnittliga tid det tar att avlägga en Ph.D.-examen har ökat och är för närvarande cirka sex eller sju år. För en generation sedan tog det fyra år.
- De tillgängliga befattningarna inom den akademiska världen idag är inte desamma som för ett par decennier sedan. Nästan alla Ph.D. 1975 var fast anställda eller s.k. ”tenure-track”-fakultetsmedlemmar. Endast cirka 10 procent innehade post-doc befattningar. År 1997 innehade 18 procent en post-doc befattning och 55 procent var fast anställda eller hade en ”tenure-track”-anställning.
- Anställningsvillkoren för unga forskare är ofta hårda med låg lön och få förmåner. Forskningslaboratorier vill inte anställa forskare på permanent basis på grund av osäkerheten vad gäller extern finansiering. På universiteten har institutionerna en årsbudget och ett fast antal fakultetsbefattningar. Antalet forskarstuderande som avlägger examen varje år överstiger på ett markant sätt antalet vakanta fakultetsbefattningar. Antalet äldre fakultetsmedlemmar är stort eftersom det inte finns någon obligatorisk pensionsålder enligt amerikansk lag.

Policyfrågor inom den medicinska forskningen i USA

- Policyfrågor inom den biomedicinska forskningen handlar om nivån på den framtida finansieringen, NIH:s organisationsstruktur, bristen på läkare som forskar, den utmaning som ligger i att främja den multidisciplinära forskningen samt omvandlingen av vetenskapliga upptäckter till hälsofördelar för befolkningen.

Det är svårt att göra jämförelser mellan USA och Sverige på grund av storlek, kultur och tradition. Det finns likheter men också skillnader. Starkt stöd från frivilligorganisationer, patientpåtryckningsgrupper och andra forskningsrelaterade intressegrupper och organisationer har bidragit till den federala regeringens stora investeringar samt privata bidrag. Detta har lett till stora framgångar och framstående medicinskt forskningsarbete i USA. Den medicinska forskarvärlden i USA står emellertid inför utmaningar precis som många andra länder.

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