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KEYNOTE ADDRESS

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INTRODUCTION

I thank you all and especially Al Owens for inviting me to join you today -- for two reasons. First, you represent a most important and highly productive component of the nation's biomedical research enterprise. Thus, it is a welcome opportunity to talk with you about the Administration's science and technology policy. The second reason is the fact that I continue to reside in Baltimore, about three miles from here, an hour and one-half from Washington. For reasons I shall subsequently note, we have a daily senior staff meeting at 8:15 a.m. You have today saved me from one more crack of dawn departure for Washington. Now if any of you have access to a corporate jet--perhaps we might meet quietly after the meeting.

When I asked to be relieved of my decanal duties after fourteen years, I had anticipated a year's sabbatical and a full-time return to personal interests in health policy and in vaccine development, application and research. I looked forward to a life without arcane wrangles over indirect costs, agonizing discussions over policies dealing with misconduct in science and such miscellaneous matters as the proper care and feeding of animals. I did not seek an office in the White House and when I was asked to explore such an opportunity, I quietly declined, albeit politely, assuming that there was some mix-up in somebody's mailing list. Eventually, I was persuaded that the White House staff actually believed they had the right name and thus brought me into contact with a truly remarkable man -- the President's Science Adviser, Dr. Allan Bromley -- a physicist from Yale, who has a clear sense as to the importance of science to America and to its future.

I will confirm frankly that I knew little of Science and Technology Policy and apart from Jim Wyngaarden who had served for six months as Associate Director for Life Sciences, I was quite at a loss to identify anyone close who had held this position. As it turns out no one, in fact, has ever held that position.

Thus, a bit of history.

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The Office of the Science Advisor, as I am sure you know, extends back to Vannevar Bush in World War II. It expanded under the Kennedy Administration only to be abolished during the Nixon years. OSTP was created by Congress in 1976. It flourished briefly under the able leadership of Frank Press during the Carter Administration and then again began to shrink in size and influence, especially during the latter years of the Reagan Administration. By 1988, its staff was down to some 15 persons and it was little known or heard from. A major transformation occurred in 1988 coincident with a broad commitment by the Bush Administration to the advancement of science and the improvement of education. For the first time in history, the President's Science Advisor was named Assistant to the President -- one of the small coterie of senior staff, which includes Gov. Sununu, General Scowcroft, the Director of OMB, and the Chairman of the Council of Economic Advisers. The OSTP staff has expanded to 40. Four Associate Directors have been appointed and confirmed by the Senate -- each technically qualified in his own fields of respectively, industrial technology, engineering and physical sciences, international science policy and my own area of life sciences.

Senior White House staff meet daily at 7:30 a.m.; our senior OSTP staff meets at 8:15 a.m. If there are issues to be resolved, there is access almost immediately at the highest levels. Our staff, although expanded in size, is still modest in number. The challenges are numerous and daunting and many of the issues I had thought to leave behind -- such as indirect costs -- are with me again but now cast in a national agenda.

Two basic themes provide policy and program development. The first is the belief that the future prosperity and well-being of America depends heavily on its ability to sustain a leadership position in science. To sustain such a position requires, in turn, a strong and effective educational structure. The second theme is the belief that more effective, longer-term planning is required across government along with a need for Federal funds to be more heavily concentrated in investments for the future and less in current consumption.

For purposes of planning for the future and less in current consumption, a Federal Coordinating Council has been created, comprised of senior cabinet and subcabinet officials and chaired by Dr. Bromley. This year major new directions emerged from that initiative and were announced in January -- high performance computing and communication, and math and science education. Two are expected this year in materials science and biotechnology. This, of course, has substantial relevance to biomedical research.

Biomedical research is, of course, far broader than biotechnology alone and I need not affirm to you that the opportunities for progress have never been greater.

However, if advances are to occur expeditiously -- and if they are to occur in the United States -- this country must have a healthy and stable biomedical research community. We do not believe that the system today is as healthy as it should be. We do not believe that the system today is as healthy as it should be. This morning,

I should like to touch briefly on certain of the issues and initiatives and leave time for questions which you might have -- or observations.

First, and perhaps most important to you, is the NIH budget. The fact is that it doubled in current dollars from 1982 to 1990, and has increased approximately 40 percent in purchasing power. For Fiscal Year 1992, the President proposed an increase of \$500 million in the NIH budget, to reach a grand total of \$8.8 billion, up 6 percent over 1991. Because of the way this increase is structured, funding for research project grants would go up 9 percent to a total of \$4.5 billion. Overall, 22,000 research project grants would be funded, an all-time high.

This increase is all the more significant in that it comes under the first year of the new budget agreement, in which real growth in the domestic discretionary budget is essentially limited to the rate of inflation. Cuts, therefore, had to be made in other programs to accommodate increases in research and development, even though many of these other programs have very strong constituencies.

Yet, as you are all fully aware, there are signs of stress in the system. Established investigators are concerned about funding, and young people are finding it difficult to become established in biomedical research careers. The problems troubling individual investigators are not limited to NIH. At NSF, the so-called "success rate" -- or percent of approved grant applications that were actually funded - fell below 30 percent in Fiscal Year 1988, a year before it happened at NIH.

For some directorates, and for some groups of applicants -- such as young investigators -- the success rate is appreciably smaller.

The discouragement among faculty and students caused by such low success rates could not come at a worse time. By the mid-1990s the number of young investigators coming through the educational pipeline is expected to drop as college-age populations continue to decline. At the same time, the demand for young clinical investigators as well as Ph.D.'s will swell, as the generation trained during the 1960s reaches retirement and as undergraduate enrollments again begin to increase.

Several analyses have predicted that severe shortages of other scientists and engineers will develop by the turn of the century. The actions we take today will do much to lessen or exacerbate those shortages.

There are a number of interacting reasons for the low award rates of the last few years. First is the extension of the duration of grants beginning in the mid-1980s. That change was sorely needed. By extending the length of awards, as the research community advised at that time, NIH endeavored to reduce the pressures of preparing submissions for frequent renewals.

At the same time, the average size of investigator-initiated grants had to be increased -- reflecting the increasing complexity of science and the equipment needed to support it.

Both of these changes resulted in a reduced pool of money available for new and competing proposals.

There are other points, however, which need to be made because they greatly influence how the situation is viewed. While it is true that the number of grant applications has increased, rising about 30 percent over the past 10 years -- the actions of the research community have served to inflate that number. For one thing, part of the growth in the number of grant applications has been due to resubmissions of amended applications. The resubmission rate has increased from a historical rate of about 8 percent to 30 to 35 percent. Also, the number of multiple applications submitted by investigators has increased. Currently about 10 to 12 percent of researchers are submitting more than one application in a fiscal year, compared to a historical rate of about 3 percent.

Current practice also raises troubling questions about the ability of the peer review system to choose among research projects. When study sections approve 95 percent or more of the applications -- compared to a corresponding figure only a few years ago of less than 70 percent -- one has to wonder about the stringency of judgment.

An interagency group under the Federal Coordinating Council for Science, Engineering and Technology has been established to consider many of these issues. It is named the Working Group on the Structure of the Support of Science. Its initial task is that of obtaining reliable statistical data and evolving more effective indices

for policy purposes than the currently used "success rates," which for many reasons are difficult to interpret and are not comparable year to year.

Clearly, more resources are needed and the prospects look good for additional support in FY 92 -- increases which are especially significant give the constraints of the budget agreement. Obviously, we would like to have more for biomedical research but how much more and for what. The argument which has been advanced that there are "x" number of scientists who are not adequately funded is not today a very persuasive argument. The response, quite simply, has been -- perhaps there are too many scientists. Likewise, the argument that provision must be made for so many new and competing grants is an argument which is no longer very compelling. The response has been -- let us cut the grants into smaller pieces.

We need to build a more solid rationale based at least in part on priority needs and anticipated accomplishments -- (I am not suggesting the declaration of a Second War on Cancer). As indicators or bench marks for investments which should be made, might it not make more sense to relate research investment to health care expenditure?

Should we look to appraise the magnitude of our own investments in terms of what other are investing? In the Administration and in Congress there is a growing recognition that we are underinvesting as a nation in our science and technology base as a whole. The United States now spends about 1.8 percent of its GNP on nondefense research and development. West Germany spends about 2.6 percent, and

Japan spends about 2.8 percent. This is no question but that support for research and development is one of the most important investments we can make in our national future, and if we do not make those investments, we place both our future economic prosperity and our national well-being at risk.

This is a message that the President's Council of Advisors on Science and Technology has brought directly to the President and his top advisors.

It is a message relevant to biomedical research and your help in conveying to Congress and to the public the opportunities and needs is welcomed.