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Raising NIH Appropriations Is High Priority, House Subcommittee Chairman Says

Rep. John Porter (R-IL) said Congress would attempt to give NIH more than the 2.6 percent increase requested in the Clinton Administration's budget proposal for fiscal 1998.

At a hearing of the House Labor, HHS & Education Appropriations

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In Brief

HHS Finds Fisher, Wickerham, Redmond Did Not Commit Scientific Misconduct

The HHS Office of Research Integrity has found no scientific misconduct on the part of Bernard Fisher, Lawrence Wickerham and Carol Redmond, three officials at the National Surgical Adjuvant Breast & Bowel Project.

"ORI has not made a finding of scientific misconduct on the part of your client," the office's acting director Chris Pascal wrote in letters to the attorneys who represent the three scientists. The letters were dated Feb. 28 and released March 3.

"The ORI process is over," said Robert Charrow, Fisher's attorney. "Now Dr. Fisher would like to know what government office he can go to to get his good name back."

"[The finding] exonerates me from claims which had no basis in fact," Fisher said to **The Cancer Letter**. "I didn't publish any falsified data, and what I did publish was acceptable. That's what ORI is saying. It took them two years and nine months to come to a conclusion that should have been known long before."

Attorneys for the three scientists and the ORI are expected to begin negotiations over the wording of a notice that would appear in the Federal Register, sources said. The government is required to publish such notices on request from respondents. Similarly, the three scientists have not decided whether to release the ORI report of the investigation, sources said.

The ORI case focused on the question of whether NSABP officials acted improperly when they cited fraudulent data submitted by a Canadian researcher. The controversy, which was played out at two Congressional hearings, led to Fisher's dismissal as the NSABP principal investigator and his loss of chairmanship of the group.

The controversy is not over. Fisher's suit against the government and the University of Pittsburgh is scheduled to go to trial at the U.S. District Court for the Western District of Pennsylvania April 7.

In Congress

"Professional Judgment" Budgets Help NIH, NCI Make Case For Additional Funds

(Continued from page 1)

Subcommittee last week, Porter, the subcommittee chairman, said the President's NIH budget "does not match the rhetoric of his speeches."

"I sincerely hope that we can do much better," Porter said at the Feb. 26 hearing.

The hearing appeared to set the stage for another good year for biomedical research, several observers said. The political climate could hardly be better for NIH, these observers said.

Porter's counterpart in the Senate, Arlen Specter (R-PA), has pledged at least a 7.5 percent increase for NIH. Another Senate measure, Resolution 15, seeks to double medical research funding over the next five years.

As recent hearings in the House and Senate indicate, by proposing a less than spectacular increase for NIH, the President has given the Republican-controlled Congress a viable political issue.

The mood on the Hill is all the more favorable for biomedical research because in recent years NIH has been extraordinarily effective at presenting its story. One fundamental element of the NIH case is the promise to apply the new understanding of genes to improving the health of Americans.

Thus, after NIH Director Harold Varmus delivered his prepared remarks, Porter asked the kind of question most government officials only dream of hearing from appropriators: How much money can you use?

The NIH professional judgment budget, which summarizes the scientific opportunities for fiscal 1998 was $13.88 billion, about $800 million more than the President's final proposal, Varmus replied.

Asked to comment on the increase proposed by Specter, Varmus said the money could be spent usefully. "We could have over $500 million extra under the proposal made by Sen. Specter, compared to the President's request," Varmus said. "Obviously, with that money we could afford a large number of additional grants that would otherwise not be funded."

Varmus said NIH has established a list of new efforts that could be undertaken with additional funds, an approach that first appeared in the NCI Bypass Budget.

"I have tried to look at [additional projects] in the context of an inflationary increase, and increases of 5 percent, 7 percent, and 9 percent," Varmus said. "It's not as though we would not do genetics research with one budget, but would with another; but in general, things would go more slowly."

It appears that controversies at NIH have been so few this year that Porter in effect invited Varmus to give a lengthy lecture on the implications of the recent sheep cloning experiment in Scotland.

"This was the longest answer ever not interrupted by a member of Congress," Porter said after Varmus completed the 20-minute response.

NCI Director Richard Klausner was given a similarly courteous treatment. While much of Porter's questioning centered on the recent controversy over mammography for women between the ages of 40 and 49, the hearing essentially gave Klausner an opportunity to clarify his position and discuss the Institute's plans for making a statement on mammography.

The excerpted text of Varmus's and Klausner's testimony follows:

Professional Judgment Budget

PORTER: I am very disappointed that the President's NIH budget is below the rate of biomedical inflation. I sincerely hope that we can

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do much better.

I would caution everybody in this room that it will not be easy to craft a bill with the kind of increases NIH deserves and that NIH has had for the last few years, given the competing demands of education and other priorities. We must have a [Labor, HHS] allocation with enough room to address all of these priorities.

VARMUS: We recognize that restraints upon the federal budget restrict our ability to pursue every inspiration.

But we believe that the increase requested by the President is built upon a very firm appropriation we've received due to the generosity of the Congress and the Administration over the last few years. [The proposed budget] will allow us to maintain our momentum and achieve the largest number of grants in the history of NIH, 27,000 grants total.

PORTER: The President... has mentioned [biomedical research] very prominently both in his [nomination] acceptance speech and in his State of the Union speech this year. And yet, the budgetary increase that the President suggests is 2.6 percent. I believe that is below the rate of biomedical inflation. I would like to ask you, What was the budget you developed within NIH?

VARMUS: We had a professional judgment budget that was in the range of $13.88 billion. We were allowed $12.865 billion by HHS. The numbers returned to us by the Office of Management and Budget were $12.667 billion. [The NIH budget in fiscal 1997 is $12.754 billion.]

PORTER: So OMB initially suggested a cut from last year's appropriation. A cut in nominal terms, as well as real terms.

VARMUS: That is correct.

PORTER: And what happened then?

VARMUS: There were series of discussions involving OMB, and the White House, and the Department, and NIH, and the final agreement was the budget request of $13.078 billion.

PORTER: I realize that you and the NIH have to be good soldiers in all of this, but our job is to determine priorities for the country and where our money could best be spent. If your professional judgment budget is $13.88 billion, that means that you believe that you can wisely spend that amount of money in the next fiscal year.

I would like you to give us some idea of what has to be foregone between $13.88 billion you suggest in your professional judgment budget and that $13.078 that is suggested by the OMB and the President.

VARMUS: Let me first point out that we make that professional judgment budget in the intellectual framework where we don't worry about other demands on the budget process.

That is the starting point in the dialogue. We need to compromise with the realities of balancing the budget, and meeting other demands of the economy. It's very difficult to say that there is one thing we cannot do. Because, obviously, we are going to continue to work on all fronts with a budget that is below our professional judgment.

But what will happen is that some projects will not get funded, and many things that could go quickly would go less quickly. In some areas, it is possible to say that certain predictable milestones will be met less quickly. For example, in a process like sequencing of the human genome we can say that, given a certain amount of money and equipment and personnel, we can do the sequencing so much more quickly.

We can make very clear predictions about how many less nucleotide sequences will be determined. In other areas of less predictable discovery-type science, we simply have to say that we would fund fewer grants.

PORTER: We are very concerned that we maintain the momentum that NIH has had, that we don't lose young scientists because they can't get their promising projects funded and become discouraged. Our job is to choose priorities.

We may end up seeing this a little differently than the President. I sincerely hope that we do, because I believe that this is among the best money we ever spend; that it pays for itself many times over; that there is so much promising science there, that to delay and put on hold NIH is unwise policy. And I believe that this Congress can put NIH in a high priority within the context of bringing the budget into balance.

Klausner on Mammography

Following Klausner's prepared remarks, Porter asked the NCI director to clarify his position for mammographic screening for women in their forties.

PORTER: I want to begin by discussing the ongoing controversy about mammography guidelines for women in their forties.

NCI initially recommended mammography for this age group, and your predecessor later withdrew those guidelines. You convened a consensus development conference on the subject in light of recent findings. That group concluded that the evidence was not strong enough to recommend guidelines, and that this should be an individual choice of a woman and her doctor.

The press reports that the conference was acrimonious and even raucous. The impression given in the popular press was that you disagreed with the findings of the consensus conference. Some groups charge that you are now changing your mind and supporting the findings.

I would like to know not only your personal views on this, but the course of events in the recent past, and what plans there are in the future to address this very serious issue.

KLAUSNER: This is a very important, very confusing, and, as we have seen, a very contentious issue.

It is the NCI responsibility to speak clearly about the evidence that we have, to provide guidance to women and their physicians about decision-making, guidance that's based upon a clear and balanced description of evidence.

The National Cancer Advisory Board [has] a subcommittee now [that] will be working with all due speed in order to provide guidance for us, so we could as quickly as possible communicate a clear message about what information women and their physicians should use in terms of making decisions about when to begin screening mammography.

The question is not whether to do screening mammography. The controversy is about when.

We will be coming out with what we believe will be clear statements that will provide guidance so that individuals and physicians can make decisions about this difficult issue.

The [NIH] consensus panel, in looking at all the latest data, said that in their opinion a single uniform recommendation for women in their forties to begin screening was not warranted by the data. I think that is not an unreasonable position to take.

I said that I agreed with the sentiment of that conclusion.

My concern was simply the wording, the balance and the tone in the [consensus panel's] draft report.

I want to make sure that if we are to say that women and their physicians need to be informed to make an educated decision, I want to make sure that we provide the most balanced and clear and least confusing answer to the questions of evidence, the questions of the evidence of benefit, the questions about limitations, and the questions of risk.

And that was where some of the confusion about who was agreeing and disagreeing [arose]. I thought the [panel's] conclusion was defensible. I was concerned that the draft report—and it is still a draft report—did not have the clarity and the balance about the evidence about the benefits versus the limitations [of mammographic screening] to actually allow the women and their physicians to actually make the decisions that they were recommended.

Perhaps I can try to spend a few minutes trying to clarify why this is such a complicated, contentious and difficult problem.

Let me just say that whatever guidance NCI provides must be based upon available evidence. Many of us want extremely clear-cut yes-or-no, black-and-white answers to difficult problems.

We cannot and should not produce certainty or say that there is certainty where there is none. So where are we? Why is this so complicated?

There is complete agreement from the data that's available that women 50 and above should have regular screening mammography. There is wide agreement that women below the age of 40 probably should not be recommended to have regular mammography. So we are left with 40 to 49. What happens? How do we know?

One, we look for data. There have been eight randomized clinical trials around the world over the past 30 years that have looked at over 180,000 women who were invited to the trials to begin screening at some time during their forties.

The average age of the mammograms that were received during their studies was 48. It was sometime during their forties.

None of those studies alone had convincing statistically significant data. When one performs meta-analysis, I think there is general agreement that there is a 15 to 17 percent reduction in mortality for beginning screening mammography at some time in the forties.

The data do not address 40, or 40-and-three-months, or 45. And, of course, one of the problems with the controversy is the way we frame the question.

Nothing sudden happens to a woman when she

turns 50. And, certainly, nothing sudden happens to all women when they turn either 40, or 45, or 50.

By asking for a yes/no, black/white question: at this birthday, suddenly there is benefit, we get into a very confusing and contentious argument that evidence and data couldn't directly address, because, in fact, it does not fit anything we know about the biology of risk of breast cancer or the performance of mammography.

So there is going to be uncertainty.

There will always be some period in which you graduate from where there does not seem to be a benefit that outweighs the limitations and the risk to a period where it clearly does.

I think to argue overly about trying to come up with a precise age for all women will keep us in an argument that does not move us beyond an unanswerable question to one that provides useful guidance to women.

One size won't fit all, and I think the guidance that we will come up with will be based upon the evidence, and hopefully will be very useful and clear.

I think we can strive for clarity even when there is not certainty.

PORTER: Correct me if I am wrong, if this consensus panel had said—and you agreed—that women should all be screened beginning at the age of 40, then wouldn't that become a guideline that would become widely adopted, particularly in the Medicaid program?

When you say that this is an issue that has to be determined on a case-by-case basis, aren't you really saying that poor women won't necessarily get screening that might detect their cancer early and perhaps save their lives?

KLAUSNER: The difference between a technique being capable of detecting cancer and that translating into a benefit is something we try to determine by doing studies, so that we actually make our decisions based on evidence.

My feeling is, if there is evidence that supports benefit in the forties, but that that evidence would support the decision—for some women it may make sense earlier in the forties, for some women it may make sense later in the forties—I think that then we can provide that guidance to make sure that those decisions are supported.

This is the type of issues that we will be grappling with over the next couple of weeks to months, so the position of NCI is clear, but does not go beyond what we are comfortable that the evidence actually tells us.

PORTER: You are giving a scientific view, and this issue has tremendous public health consequences.

Women over 50 will get regular mammography. Those under 50 in public programs probably will get nothing.

What you are saying that, perhaps in their forties, they need this additional prevention. But if the guidelines don't provide for it, you can be sure that the funding won't be forthcoming for poor people.

A wealthy individual can go to their individual doctor, and the doctor may well say, sure, you're forty, but we think you need this.

KLAUSNER: Again, I don't want to prejudge what the guidance will be. I think that would be unfair for the NCAB process. We are aware of all these issues. We want to provide guidance that will be clear and will be helpful.

Bill Would Require Medicare To Reimburse Costs Of Trials

Sens. Jay Rockefeller (D-WV) and Connie Mack (R-FL) last week reintroduced a bill to require Medicare to establish a demonstration project that would reimburse routine patient care costs for cancer patients enrolled in clinical trials.

"Our legislation is an effort to give Medicare beneficiaries the security and decency of knowing that if they are diagnosed with cancer, their treatment options will be determined by whatever therapy they and their doctor decide will give them the best shot of beating the disease," said Rockefeller, introducing the bill Feb. 27.

"These life and death decisions should not be guided by what may and may not be paid for by the Medicare program," he said.

Applies To NIH, FDA And Other Trials

Rockefeller and Mack sponsored an identical bill last year. However, at that time, the co-sponsors said their intent was to pressure the Health Care Financing Administration and NCI to come to an agreement that would establish a demonstration project.

Now, the sponsors' intent is to seek enactment of the legislation, Rockefeller said in his floor remarks.

The bill, S 381, applies to clinical trials approved by NIH, its centers and cooperative groups, FDA, the Department of Veterans Affairs, the Department of Defense, and several non-governmental research entities that meet NIH peer review guidelines.

This definition of clinical trials was used during the healthcare reform debates four years ago.

However, last year, negotiations over the demonstration project bogged down as both HCFA and NCI sought to narrow the definition of eligible trials.

NCI expressed additional reservations about having to determine eligibility for the demonstration project.

These objections notwithstanding, Rockefeller and Mack stood by their broad definition of eligible trials.

Co-Sponsors Of Rockefeller-Mack Bill

The bill is co-sponsored by Sens. Bill Frist (R-TN), Daniel P. Moynihan (D-NY), Edward Kennedy (D-MA), Spencer Abraham (R-MI), J. Robert Kerrey (D-NE), Larry Craig (R-ID), Paul Wellstone (D-MN), Thad Cochran (R-MS), Barbara Mikulski (D-MD), Ben Nighthorse Campbell (R-CO), Patrick Leahy (D-VT), James Jeffords (R-VT), Kay Bailey Hutchinson (R-TX), Ernest Hollings (D-SC), Lauch Faircloth (R-NC), and Jeff Bingaman (D-NM).

A similar bill is expected to be introduced by Rep. Nancy Johnson (R-CT).

The advocacy groups and professional societies supporting the measure include the eight-member Cancer Leadership Council, the National Breast Cancer Coalition, the American Cancer Society, the American Society of Clinical Oncology, the American Society of Hematology, the American Society of Pediatric Hematology/Oncology, the Association of American Cancer Institutes, the Association of Community Cancer Centers, the Cancer Research Foundation of America, the International Breast Cancer Research Foundation, the Leukemia Society of America, the National Childhood Cancer Foundation, the National Coalition for Cancer Research, the Oncology Nursing Society, the Prostate Cancer Support Group Network and the Society of Surgical Oncology.

Other supporters of the bill include three Nobel laureates in physiology and medicine, Michael Brown (1984), Alfred Gilman (1994) and Joseph Goldstein (1985).

NCI Extramural Programs

NCAB Approves Guidelines For Cancer Center Grants

Advisors to NCI have approved the Institute's revision of the requirements for Cancer Center Support Grants.

The National Cancer Advisory Board voted unanimously to approve new guidelines on an interim basis for the review of CCSGs over the next year or two.

The 36-page document describing the NCI Cancer Centers Program and CCSG policies will be used by cancer centers seeking renewal of their support grants as well as institutions applying for the grants for the first time.

Reflects "Spirit" Of Review Group's Report

The new guidelines were written in response to a report by an advisory group formed last year to study the Cancer Centers Program.

The report of the Cancer Centers Review Group urged NCI to give centers more flexibility on use of the grant funds, decrease the paperwork for centers reapplying for the grants, and conduct more rigorous scientific review of the CCSG (**The Cancer Letter**, Oct. 18, 1996).

"The document retains the spirit of what we intended," said Joseph Simone, executive director of the Huntsman Cancer Care Program at the University of Utah, and chairman of the review panel.

"How the reviews take place will be the determining factor," Simone said to the NCI Board of Scientific Advisors on March 3. "I think this is a good start."

Last December, NCI officials said most of the changes suggested by the review group's report would be implemented (**The Cancer Letter**, Dec. 13, 1996).

NCI officials decided not to take the report's advice on restricting the amount of the increase that a center can request upon renewal of the grant. The report recommended a $500,000 cap on the increase.

Robert Wittes, director of the NCI Division of Cancer Treatment, Diagnosis and Centers, had instead proposed a cap on the size of the total award request. However, the guidelines approved by the NCAB do not include a cap on CCSG renewals. The

document places a cap of $850,000 on the amount that a "first-time" CCSG recipient can receive.

Also contrary to the group's recommendation, the designation of centers will not be condensed from three—clinical, basic, and comprehensive—to two—comprehensive and all others.

Some NCAB members had said they were concerned that removing the "clinical" designation would harm efforts to support clinical research. The new guidelines include three types of centers: comprehensive, clinical and "unmodified."

In addition, centers with CCSGs will not be called "cancer research centers," as requested by the report, due to concerns about the effect of the word "research" on the ability of centers to work with health insurers.

To Develop Public Outreach Database

The new guidelines will remove "unfunded mandates," or requirements that NCI had placed on centers to conduct programs for which no funding was provided. Most of these requirements were for outreach and educational activities that reviewers said they found difficult to effectively peer review.

Instead, NCI will ask comprehensive cancer centers to submit information to the Institute for a public database that would be available on the Internet. Also, the Institute will develop specific grant initiatives to fund research in outreach and education, Wittes said to the NCAB Cancer Centers Subcommittee at its meeting Feb. 24.

NCI also will develop a program announcement to invite the submission of planning grants to support institutions that are trying to build their research efforts to compete for a CCSG. However, the standards for funding these grants will be higher than in previous years, Wittes said.

According to the introduction to the guidelines, "NCI anticipates that the greater flexibility inherent in the present CCSG guidelines will result in the funding of new centers with a greater variety of scientific agendas."

The Cancer Centers Review Group "has had a fundamental influence on NCI's rethinking of what an NCI-sponsored cancer should be, how it should be reviewed, and how it should relate to other centers and to the NCI."

The Cancer Centers Program will make copies of the new guidelines available. The program may be reached at tel: 301-496-8537.

Director's Advisory Committee To Make Advice "Kosher"

NCI has created an Advisory Committee to the Director to oversee the work of the advisory groups Richard Klausner has formed—and continues to form—since his appointment as the Institute's director in August 1995.

"The Advisory Committee to the Director will provide a mechanism for oversight and integration of various planning and advisory groups serving the broad programmatic and institutional objectives of the NCI," according to a statement provided to the committee at its first meeting March 3.

"This is a mechanism to make all of the stuff we are doing and would like to do kosher," Klausner said.

The working groups examining NCI programs and priorities now will be free to provide their advice as a group to the Institute because the panels will report to the new ACD, Klausner said.

The Federal Advisory Committee Act of 1972 places requirements on the formation and use of committees advising government agencies. Agencies must file charters describing the purpose and membership of committees. The Act requires that meetings of federal advisory committees be open to the public and announced in the Federal Register, except in issues of national security, personnel matters, and confidential business information.

The Act defines "advisory committee" as "any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof which is established by statute or reorganization plan, or ... established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal government..."

Precedent exists on the NIH campus for the new advisory committee: The NIH director meets regularly with an Advisory Committee to the Director, NIH.

Advisory Groups Examining NCI

Klausner said the groups that will have an "official home" at the new ACD, NCI, include:

- "Review groups" comprised of non-federal, external advisors charged with examining NCI programs. The groups formed to date include Cancer

Centers, Clinical Trials, Prevention, and Cancer Control. A group on Developmental Therapeutics will begin meeting soon, Klausner said. NCI officials also at times have called these "program review groups."

•"Working groups," described by NCI as "think tanks" that will hold a "free flowing forum type of discussion" for about a year to identify high-priority and promising scientific opportunities. Membership of these groups included external advisors and NCI staff. The groups formed to date include the high-priority "investment opportunities" described in the NCI Bypass Budget: Developmental Diagnostics, Cancer Genetics, Detection Technologies, and Preclinical Models, as well as a working group on AIDS Malignancies.

NCI plans to form a working group on the need for greater investment in investigator-initiated research, the fifth "opportunity" listed in the Bypass Budget, Klausner said. He said he would ask the working group to rewrite this section of the Bypass Budget.

•"Progress review groups" will be formed to define the national research agenda for cancers in particular disease sites. Breast cancer and prostate cancer will be the first sites for which the Institute is preparing to form progress review groups, Klausner said.

Membership Of ACD

Besides Klausner, who serves as chairman, other members of the ACD and the NCI advisory groups they represent are: Martin Abeloff (Board of Scientific Counselors—Clinical Subcommittee), Johns Hopkins Oncology Center; Joan Brugge (Board of Scientific Advisors), Ariad Pharmaceuticals Inc.; Waun Ki Hong (BSA), M.D. Anderson Cancer Center; David Livingston (BSA), Dana-Farber Cancer Institute; Barbara Rimer (National Cancer Advisory Board), Duke University Medical Center; and Matthew Scharff (BSC—Basic Sciences Subcommittee). Amy Langer, executive director of the National Association of Breast Cancer Organizations, and a member of the BSA, will serve as the patient representative on the committee.

Ex officio members are: Edward Harlow, NCI associate director for science policy; Alan Rabson, NCI deputy director; and Marvin Kalt, director, NCI Division of Extramural Activities. Executive secretary is Susan Waldrop, assistant director for program coordination, Office of Science Policy.

BSA, BSC Approve Concept For NCI Scholars Program

Advisors to NCI have approved in concept a new program designed to train young scientists in the NCI intramural research program and then help them launch careers outside of the government.

Two NCI advisory groups, the Board of Scientific Advisors and the Board of Scientific Counselors, approved the set-aside of up to $5.1 million over the next six years to fund five or six awards to individuals selected for the training program. Approval of both boards was necessary since the grants will be funded from both the intramural and extramural programs.

Following is the excerpted text of the concept statement:

NCI Scholars Program. Program director: Vincent Cairoli, Cancer Training Branch.

The purpose of the NCI Scholars Program is to provide to outstanding new research investigators the opportunity to develop their first independent cancer research programs in the supportive and uniquely interactive intramural environment of NCI and to facilitate their successful transition to an extramural environment.

The program is designed for promising new investigators in basic, clinical or population-based biomedical research who have demonstrated outstanding scientific abilities during their training, to enable them to establish their first independent research program. NCI Scholars will independently design and pursue research projects in their area of interest for which they would be provided with facilities, operating budget, salary and personnel. NCI Scholars will be responsible for all aspects of their research program, including the progress of the research and the management of allocated resources. Each scholar will be affiliated with a Lab/Branch within the NCI intramural program for no more than four years. Any time during the first three years of the program, successful scholars may be eligible for non-competing extramural transition funding of up to two years through a K03 Career Transition Award. The maximum total period of combined support at NCI and the extramural institution as an NCI Scholar will be six years, no more than two of which can be in the extramural setting.

The requested level of funding will be up to $900,000 per year in direct costs for up to four years for the Intramural Support Phase. For the Extramural Support Phase, a total of up to $750,000 per year in direct costs for up to two years is requested to provide support for salaries and minimal operating expenses. Final allocations of funds will depend on the excellence of the proposals.