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The New NCI: Structure, Procedures, Advisory Boards To Change, Klausner Says

NCI advisors this week got their first official look at "The New NCI" that is rapidly emerging under the directorship of Richard Klausner.

In his first presentation before the National Cancer Advisory Board, Klausner outlined his plans for restructuring and revitalizing the Institute, noting that some of the changes—particularly the change in the ethos of the Institute—have already taken place.

In his remarks at the NCAB meeting Sept. 12, Klausner provided
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In Brief

Deisseroth Leaves M.D. Anderson To Head Yale's Oncology, Gene Therapy Programs

ALBERT DEISSEROTH has joined the Yale Cancer Center as head of the center's oncology and gene therapy programs. Deisseroth, formerly chairman of the hematology department at M.D. Anderson Cancer Center, will serve as a consultant to M.D. Anderson while five gene therapy protocols are transferred to Yale, according to Vincent DeVita Jr., director of the Yale Cancer Center. "Dr. Deisseroth's expertise in this fast-growing field will enable the Yale Cancer Center to offer new treatments to patients who have poor prognoses for long-term survival from their advanced cancer," DeVita said. Deisseroth joined M.D. Anderson in 1987. . . .

DURHAM, NC, City of Medicine Awards will be presented next month to three medical researchers: Vincent DeVita Jr., director of the Yale Cancer Center; P. Roy Vagelos, former chairman and CEO of Merck & Co. Inc.; and Paul Zamecnik, principal scientist of Worcester Foundation for Experimental Biology. The awards were established by the city of Durham to recognize medical scientists and organizations that have made significant contributions to medicine. . . . BRIDGET CULHANE has been promoted to deputy executive director of Oncology Nursing Society Professional Affairs. She has served as the society's director of education since 1989. In the newly created position, Culhane will assist the executive director on ONS professional and administrative duties. . . . ONCOLOGY NURSING Certification Corp. announced that 219 nurses (86%) passed the first Advanced Oncology Nursing Certification Examination, administered last April to 256 nurses. Advanced certification is open to nurses who have an RN license, a master's degree or higher in nursing, a minimum of 30 months experience and a minimum of 2,000 hours of oncology nursing practice. In addition, 339 nurses (82%) passed the

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Klausner Revamping NCI Administration, Budget, Ethos

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additional details on the proposals he presented to NCI staff last month (*The Cancer Letter*, Aug. 11) and gave the board a glimpse of his views on issues he had not previously addressed at public meetings.

"Our goal is to decrease the intramural budget and transfer that money into the research project grant pool," said Klausner, adding that the money will be directed to investigator-initiated research grants.

At the same time, the Institute's intramural resources should be revamped to serve both the intramural and extramural scientists, Klausner said. Thus, the Frederick Cancer Research & Development Center should be less a resource for the NCI intramural program, and become a national resource for cancer research, he said.

Addressing other issues that could stir controversy, Klausner said NCI should radically change its planning process, including the process of drafting of the annual Bypass Budget. Klausner said the document's traditionally weighty format should be abandoned in favor of a brief, focused and readable discussion of scientific opportunities (story, page 8).

Klausner invited NCAB members to observe what he described as the new mood of the Institute. "All of you should, if you have a chance, walk around NCI," Klausner said. "The feeling of change is very clear."

"An Institution of Science"

Klausner said that since his appointment as NCI director Aug. 1, he has met with many organizations and individuals involved in cancer research and cancer

care. "I've taken from these meetings a great desire on the part of virtually everyone for change," he said. "I've tried to articulate my vision of what we are and what we are not, where we want to head and how we want to get there."

NCI must articulate a "clear and consistent vision of priorities, principles and processes," Klausner said. The Institute needs to design a planning process that would be open to the cancer research and advocacy communities, he said.

"As an institution we must take a proactive approach," Klausner said. "We can no longer hunker down in defense of posture, lurching from crisis to crisis. Rather, we've got to move forward with the ultimate protection of our own convictions and the integrity of our processes."

"We are an institution of science, and all of our structures and processes must serve the science," Klausner said. "As an institution of science, we must model the habits and values of science, which include open discussion and dialogue."

"Most importantly, if we are an institution of science, decisions must be made that appeal to evidence and not to authority," he said. "We must be a meritocracy. We must strive for excellence. And we must rely on a clear process of accountability."

NCI's Role: Knowledge Broker

Asked by NCAB member Robert Day how he would handle controversies similar to the recent debate over breast cancer screening for women under age 50, Klausner said:

"I have real concerns about NCI, which is first and foremost a research institution, becoming a standard of care institution, a regulatory institution, a certifying institution, and in that sense, a policy-making institution," Klausner said. "NCI's essential role in society is to be an honest broker of knowledge that then allows the larger community to take on the issues of standards of care and policies."

"I am wary about NCI losing its ability to be an honest broker of knowledge by taking on regulatory standards," Klausner said. "However, I think NCI has a very important role helping to convene the communities, of making sure information is disseminated, and is responsive to the communities about the areas of knowledge that are not clear, that lead to controversies."

Klausner said he was not diving into the fray of politics when, four days after he took office, he joined

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NIH Director Harold Varmus in writing a letter to the White House urging action on tobacco control, especially for children.

"The reason Dr. Varmus and I wrote to the President was, in the midst of all the discussion and struggles about what to do, we felt it was very clear, as the two scientists directly appointed by him to oversee the health research enterprise, that we clearly articulate the data, the scientific basis, but not to argue for specific regulatory steps," Klausner said.

"Will you state your beliefs, your passions, which are outside of what you can do?" Harold Freeman, chairman of the President's Cancer Panel, asked.

"I have and I will," Klausner said.

Klausner: NCI Reliance on RFAs Is Excessive

Board member Frederick Becker urged Klausner to redirect some percentage of funds from the intramural program to extramural grants.

"If only a small percentage were shifted to the R01 pool, the impact on the extramural community would be extraordinary," Becker said.

Agreeing in principle, Klausner said he plans to shift funds from intramural research to extramural R01 grants. However, Klausner said the decisions on what portion of funds should be shifted are yet to be made.

Klausner said he was uncomfortable with what he saw as NCI's heavy reliance on Requests for Applications and contracts, as opposed to investigator-initiated research. However, he said NCI's grantmaking is only one part of a bigger problem. "The crisis in grants is certainly an issue of there not being enough money," he said.

One logistical problem that plagues the grant review process at NIH is the lack of limits on the number of times an amended grant application can be submitted for review, Klausner said.

The practice overloads NIH staff and leads to a system of "if you amend it enough times, you get funded," he said.

NIH should limit the number of times an application can be amended, Klausner said.

Structural Changes

Klausner said the Institute's new administrative structure is expected to be implemented by Oct. 1.

Under that structure, intramural and extramural research programs will be separated. The separation follows the recommendations of the NCAB Working

Group on NCI Intramural Programs, also known as the Bishop-Calabresi report, Klausner said.

The new structure (see chart, page 5) provides for two intramural divisions:

—Div. of Basic Sciences, headed by acting director George Vande Woude.

—Div. of Clinical Sciences, headed by acting director Philip Pizzo.

The remaining five divisions will be focused on extramural research, though two of them will retain some intramural components. The divisions, which are being assembled from existing administrative units at NCI, are:

—Div. of Cancer Epidemiology and Genetics (formerly Div. of Cancer Etiology). Acting Director, Joseph Fraumeni. The division is expected to have both extramural and intramural components.

—Div. of Cancer Prevention and Control. Director, Peter Greenwald. DCPC will be a "mixed" division with extramural programs and intramural programs, sources said. However, the division's two laboratories are expected to be moved into the new intramural program.

—Div. of Cancer Treatment, Diagnosis and Centers (formerly Div. of Cancer Treatment). Acting Director, Robert Wittes.

—Div. of Cancer Biology (formerly Div. of Cancer Biology, Diagnosis and Centers). No acting director has been named. The division will oversee the Frederick Cancer Research and Development Center.

—Div. of Extramural Activities. Director, Marvin Kalt. The division will continue to oversee grants and contracts management.

Two External Advisory Boards

In addition to changing the divisional structure, NCI is revamping the manner in which it seeks advice from extramural scientists.

The existing structure of four Boards of Scientific Counselors will be replaced by one BSC that will advise the intramural program and one Board of Scientific Advisors that will advise the extramural program.

Members of the existing BSCs will be asked to serve as interim members of the new advisory groups for the next four to six months, Klausner said.

The new BSC for the intramural program will include a basic sciences subcommittee and a clinical sciences subcommittee, Klausner said.

The basic sciences subcommittee will be headed by Edward Harlow, scientific director of the Massachusetts General Hospital Cancer Center and professor of genetics at Harvard Univ. Harlow will spend a sabbatical year at NCI, starting in November, Klausner said.

Martin Abeloff, director of the Johns Hopkins Oncology Center, will head the clinical sciences subcommittee.

"The Board of Scientific Counselors will have the role of being true advisors for intramural activities contained within the divisions that have intramural activities," Klausner said. "Not only do I expect the [BSC] to be involved in overseeing reviews and site visits, but more importantly, I expect them to be integrated into and involved in the planning process of what the intramural program looks like."

NCI will establish a Board of Scientific Advisors that will advise the Institute on extramural programs. David Livingston, director of the Dana-Farber Cancer Institute, will serve as chairman of the advisory group and is expected to spend a one-year sabbatical at NCI, starting Oct. 1, Klausner said.

Klausner said he will ask the BSA to conduct over the next year a comprehensive review of issues including cancer centers, clinical trials, cooperative groups, developmental therapeutics, as well as other issues.

"My goals for these boards are not simply to serve as advocates of different fiefdoms within the Institute, or different divisions, but to oversee the program," Klausner said. "The charge to these boards is not only to oversee reviews and critiques, but to establish menus of projects aimed at proactively determining where we need to go, with all of the major thrusts and mechanisms, goals and issues, that confront NCI."

NCI has submitted the charters for the advisory boards to NIH, and is developing lists of individuals who will be asked to serve.

Two Internal Advisory Boards

Klausner said he has established two advisory boards of NCI scientists working in the intramural and extramural programs. The groups will provide advice and communication from NCI staff to the leadership.

Several recent reports, including the Bishop-Calabresi report and the 1992 Klausner report, have noted that the Institute's administration lacked effective communication with the staff.

"There is no institute that does this, but as I have been saying for years, all institutes should," Klausner said.

The Intramural Advisory Board, chaired by Claude Klee, chief of the Laboratory of Biochemistry, will consist of scientists working in the intramural laboratories.

The Extramural Advisory Board, chaired by Faye Austin, director of the Extramural Research Program in the Div. of Cancer Biology, Diagnosis and Centers, will consist of scientists and managers in the extramural programs.

"The function of these boards is to advise the directors of the divisions, the deputy director, and to advise me on whatever issues they feel are important to the smooth and effective running of their programs," Klausner said. "These individuals will provide an open forum for communication from the entire community to the leadership that does not depend on the need to go through hierarchical structures or chains of command."

The chairmen of the boards will sit on the NCI Executive Committee.

Administrators As "Folk Heroes"

NCI has divided its existing Office of Administrative Management into two offices, to provide separate administration of the *intramural* and extramural programs, Klausner said.

Philip Amoroso, who has headed the Office of Administrative Management, will head the new Office of Extramural Management.

The new Office of Intramural Management will be headed by Maryann Guerra, formerly of the National Heart, Lung and Blood Institute.

"I've given them their job description, which is to become folk heroes to the members of this institution," Klausner said. "Administration must serve the science, and that has not been the case before."

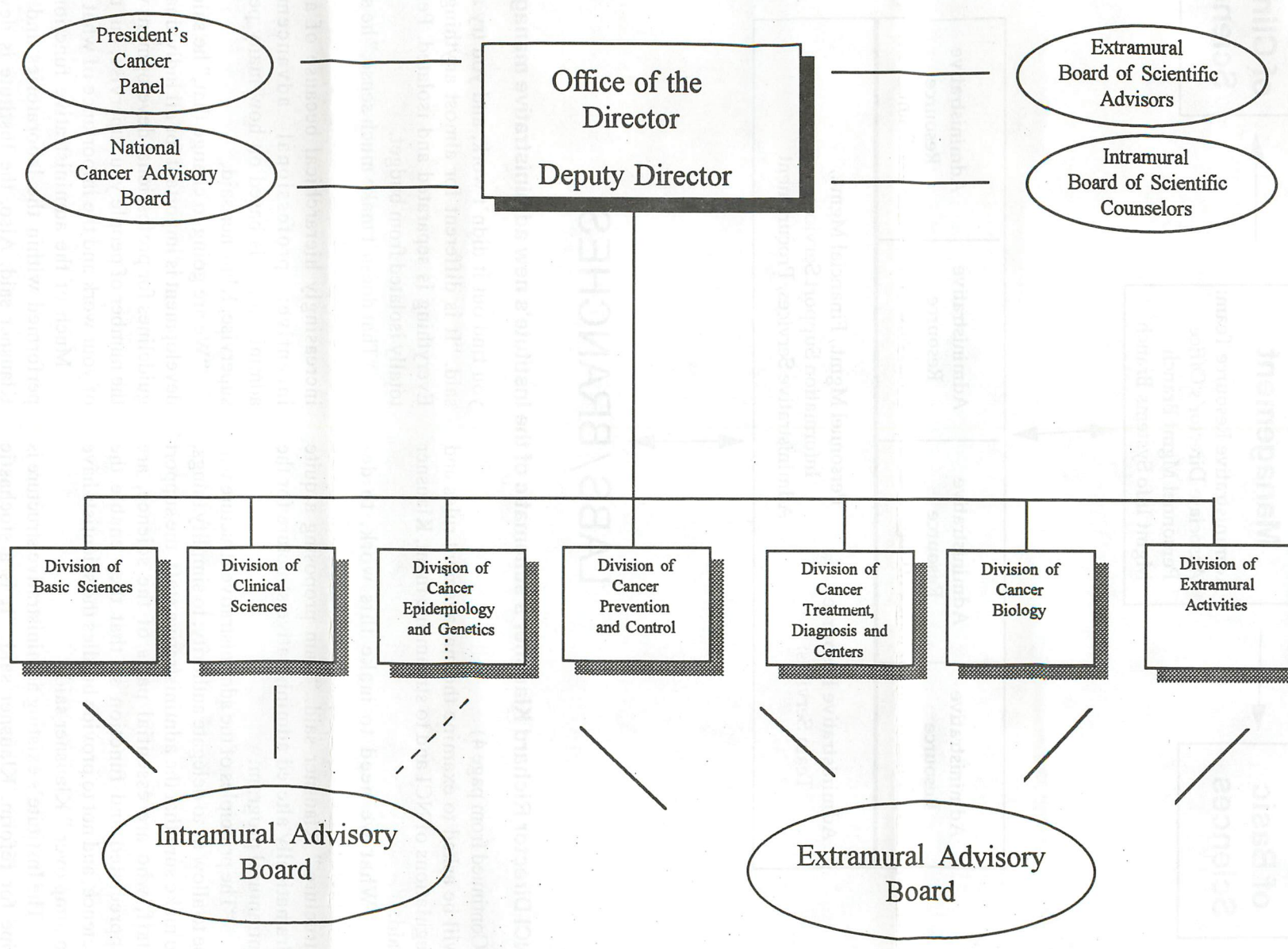
Authority for the management of laboratories and training programs will be delegated to the scientists who are running the programs.

"HHS Secretary Donna Shalala will be announcing a whole new set of delegations of authority that [NIH Director] Harold Varmus asked for, and I asked for, as part of the condition of accepting this job," Klausner said.

The intramural and extramural advisory boards

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National Cancer Institute



job will require acting as the interface between the labs and administration.

Administrative Resource Teams

In another change, the Institute will form "administrative resource teams" to help labs with personnel and financial management, information and administrative support, procurement and contracts administration, Klausner said.

"Some number of labs and branches will turn to a particular team, and the goal of that team is to make things happen, or to tell them in a clear way why that can't happen," Klausner said.

The administrative teams will report to Guerra's office, but will be reviewed by Guerra and the scientists that they serve, he said.

"I think that with this approach there will be greater opportunity and flexibility for individuals to advance and change their job and not be stuck in a particular track," Klausner said.

Intramural Program Funding

Klausner said he agreed with the conclusion of the Bishop-Calabresi report that the percentage of the NCI budget that is spent on intramural research is too high. Estimates of that spending have ranged from 18 percent to 25 percent of NCI's budget.

However, he said he was not yet able to say how much NCI should spend on the intramural program. The Bishop-Calabresi report also declined to name a target percentage.

Part of the problem, Klausner said, is that NCI officials don't have the data for a comprehensive accounting of intramural spending. NCI staff are gathering this information, Klausner said.

"We are working with the division directors to establish in detail the critical demographics of the intramural program," Klausner said. "This includes how many principal investigators there are and how many people each of them have and in what sort of positions. What the groups look like and what they do, how much space is assigned to each group. And, what does the budget look like."

Simpler Structure

NCI plans to simplify the internal scientific structure of the Institute, and improve communication between intramural laboratories, Klausner said. As of Oct. 1, each laboratory will have its own budget.

"There is no place that should be better at

integrating a very strong basic, clinical and population-based approach to cancer research than here in the intramural program," he said. "There has been too little communication and interaction. I promise that will change."

In early November, Klausner will hold a retreat with NCI senior staff to look at Institute demographics, budget, and program reviews.

"We will come up with a plan of where we go in terms of restructuring the organization and allocation of resources within the intramural program," he said.

Klausner said he plans to appoint an ombudsman for the intramural program whose job will be to oversee career development at the Institute.

"I feel the intramural program always has, and must, provide an extraordinary opportunity for young people to begin their careers with the extraordinary freedom and resources that are provided by the intramural program," he said.

Review of scientists will be based not only on quality of science, but on leadership and management. "The position of laboratory chief is not a position of power, but of responsibility," Klausner said. "We will explicitly review issues of mentorship and career development."

Frederick: A "National Resource Center"

Klausner said he is committed to supporting a strong program at the NCI Frederick Cancer Research and Development Center.

"I feel very strongly that it would be a terrible thing to walk away from Frederick," Klausner said to the NCAB. "However, we need to take a very hard look at Frederick in terms of the opportunities it provides us."

Klausner said he would like to see Frederick "become a place that is neither intramural nor extramural, but both." The center could serve as a national resource for cancer research, he said.

"Frederick should not just be a large service center for the intramural program," Klausner said. "We talk a lot about translational research, but in many ways, we are unprepared to do the types of translational research we talk about because of some fundamental intellectual infrastructure that [needs to be developed]."

Some of these needs include research in informatics, complex genetics, animal models, developmental therapeutics, and developmental diagnostics, Klausner said.

Bypass Budget To Get Slim, Trim Look Under Klausner

As part of the reform of NCI and its planning processes, NCI Director Richard Klausner said he wants to abolish the current format of the annual Bypass Budget.

The Bypass Budget, a document that allows the NCI director to appraise the US President of the scientific opportunities in cancer research, is an important symbol of the special status of the National Cancer Program.

Its symbolic importance notwithstanding, in recent years the document has been criticized by cancer specialists, politicians and policymakers as unwieldy, unfocused and uninviting.

At his first appearance before the National Cancer Advisory Board Sept. 12, Klausner added to the torrent of criticism:

"It would not be a product I would be proud of, because it is not very helpful," he said to the NCAB Planning and Budget Subcommittee.

"It represents a failure of planning," Klausner continued. "It's like the Brooklyn phone directory. Everything is in there. I don't think anyone uses it."

Funding Request Unrealistic

The most recent Bypass Budget takes 615 pages to describe how the Institute could spend \$3.6 billion in fiscal 1996. The Institute's current appropriation is about \$2 billion.

Considering the political climate, asking for \$1.6 billion more is unrealistic, Klausner said. Worse yet, the request could make NCI look insensitive or not credible to members of Congress.

"Congress is concerned about NIH demonstrating financial stewardship," he said.

The Bypass Budget should be a part of the Institute's planning process, and should provide a list of six to 10 priorities for new funding, Klausner said.

"We need to make it clear why we are asking for an increased investment, and the dangers and delays of not having additional funding," he said. "It should be readable, slick, 40 to 50 pages.

"It should say what we could do and what might happen if we don't do it," Klausner said. "It should state our real accomplishments and not the fake accomplishments," he said.

Klausner listed some potential priority areas:

- Increased funding for R01 grants.

- New funding for animal models.
- New funding for information banks and tissue banks.

Reaction from the NCAB Planning and Budget Subcommittee was laudatory. "It's music to all of us," said Ellen Sigal, chairman of the subcommittee. "I commend you. We fought long and hard for this."

"This is what we have been talking about for a while and it has been frustrating," NCAB member Deborah Mayer said.

Sondik To Lead Strategic Planning

Under Klausner's reorganization plan for NCI, strategic planning, including the compilation of the NCI Bypass Budget, will be coordinated by the new office of associate director for strategic planning. Edward Sondik, formerly the Institute's acting director, was appointed to the new position.

The document will be redesigned by the Bypass Budget Planning Group composed of Klausner, Sondik, Deputy Director Alan Rabson, the division directors, the chairmen of the new Board of Scientific Advisors and Board of Scientific Counselors, two members of the NCAB, and NCI budget officers.

Plans for the revamped document are expected to be submitted to the NCAB at its meeting in November.

In Brief

Foundation Awards Grants

(Continued from page 1)

Generalist Oncology Nursing Certification Examination, administered last April to 411 nurses. Of those who passed, 160 are newly certified, 114 renewed their credential and 65 were repeating the examination. According to ONCC, there are now 15,336 oncology certified nurses. For information contact: ONCC, 501 Holiday Dr., Pittsburgh, PA 15220-2749, tel: 412/921-8597. . . . **W.M. KECK FOUNDATION** has awarded five grants totaling \$3.45 million for medical programs: Univ. of Utah Institute of Human Genetics, \$1 million; Univ. of California, Berkeley, \$750,000 for immunology and genetics; Whitehead Institute for Biomedical Research, \$750,000 for an x-ray crystallography suite; Univ. of Colorado at Boulder, \$500,000 for research in mammalian biology; and the National Academy of Science, \$450,000 for a study by the Institute of Medicine on substance abuse research. .