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Klausner To Revamp NCI Budget Process To Make Categories Mean What They Say

NCI officials have begun a detailed review of the Institute's fiscal expenditures as the next step in the reorganization led by Director Richard Klausner.

Having completed the structural reorganization of the Institute's divisions, labs, and branches, the NCI leadership has been gathering fiscal

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In Brief

Weicker Joins Tobacco Company Board; Hatfield To Leave Senate Next Year

LOWELL WEICKER JR., a former US senator and governor of Connecticut, who has long been regarded as an advocate of medical research, has been elected to the Board of Directors of UST, a producer of smokeless tobacco products, the company said. Weicker received the Albert Lasker Public Service Award in 1988 for his work on behalf of medical research. He is also the former head of Research!America, a biomedical research advocacy group. UST produces smokeless tobacco products including Copenhagen and Skoal. . . . **SEN. MARK HATFIELD** (R-OR) said he would not seek another term next year. Hatfield, chairman of the Senate Appropriations Committee, is author of a proposal to increase taxes on tobacco products to establish a trust fund for biomedical research. . . . **NATIONAL COALITION** for Cancer Survivorship as put forth recommendations which will become a declaration of principles of quality cancer care. A vote to move forward on formalizing the proposed declaration of principles was the culmination of a three-day national meeting on cancer survivorship hosted in Washington last month by NCCS, that included cancer survivors, their families, oncologists, nurses, social workers, patient advocates and public health officials. NCCS expects to publish the formal declaration of principles and official white papers early next year. . . . **AMERICAN ASSOCIATION** of Cancer Education elected new officers at its annual meeting held last month in Tampa, FL. They are: President, **Ajit Sachdeva**, Dept. of Surgery, Medical College of Pennsylvania; president-elect and program chair, **Joseph O'Donnell**, associate dean, Dartmouth Medical School; secretary, **Robert Chamberlain**, Dept. of Epidemiology, M.D. Anderson Cancer Center; and treasurer, **Charles Kupchella**, provost, Southeast Missouri State Univ. Former President **John Currie**, of Dartmouth Medical School, has become

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NCI Fiscal Review Examining Every Grant, Contract Category

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data on personnel, grants and contracts, Klausner said to the National Cancer Advisory Board last week.

"I feel strongly that at this time, when we are starting anew, we need to get our budgetary and fiscal house in order," Klausner said to the NCAB at a meeting Nov. 28. "We have spent the last three months intensely beginning to review each and every program, mechanism and approach of this Institute."

The fiscal review is likely to result in the reduction of funds for contracts and intramural research, and increased funds for extramural research, particularly investigator-initiated research project grants, NCI sources said.

The reorganization is expected to include the following:

- NCI has proposed shifting funds within budgetary categories to reflect how the funds are actually being used. The proposal requires approval from NIH, HHS and Congress, Klausner said.
- NCI plans to move about $5 million from intramural AIDS research and contracts to extramural research by the close-out of fiscal 1995.
- The NCI Executive Committee plans to review every grant and contract mechanism used by the Institute to determine whether the funding under each mechanism has scientific merit.

Klausner said that in a matter of days the Executive Committee would begin examining every contract funded by the Institute.

"I very much want to see each contract justified scientifically," Klausner said. "I want to know how long it has been in existence; I want to know whether it is the most efficient mechanism."

Gathering The Data

In his remarks to the NCAB, Klausner said major organizational changes have reshaped the Institute since September, when he last met with the board.

NCI has a new divisional structure, a reconfigured Executive Committee, and new internal advisory boards. Reviews are underway of several major programs, including the intramural research program. Chairmen of the two new external advisory boards have been appointed, and the first meetings of the boards are expected to be held early next year.

"Since becomming director, my first priority was to articulate where we are going, how we are going to get there, and who is going to help lead the institution," Klausner said to the NCAB.

Detailed examination of NCI's spending is the next step, Klausner said. The Institute's staff has been collecting the information needed to make fiscal changes, but the process has not been straighforward, he said.

"Just getting the fundamental demographics of this Institute of how many people, where, how much money, and how that money is distributed—which I believe is essential if I am going to oversee where we go—continues to take an extraordinary amount of time," he said.

"It took a full three months of extraordinary amount of effort to find out exactly how much money was spent by exactly how many people, where, and what categories" in the intramural program, he said. "I found out the Institute has eight different personnel systems that it used to track the different divisions' employees."

The "best estimate" of the percentage of the NCI budget spent on intramural research is 18.7%, Klausner said.

As NCI reviews all of the programs, the NCAB will be informed of the effect on budget allocations, Klausner said.

In the process of gathering the fiscal data on the Institute, Klausner said he realized that some funds were inappropriately classified.

For example, the salaries of extramural grants administrators were listed in the intramural program, rather than the research management and support category, he said. Some funds were charged to intramural research rather than contracts, or cancer

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control rather than the NCI director's office.

"What I have had to do is sit down and look exactly at what is being done in every program, in every mechanism," Klausner said. "That forced me to recognize that there needs to be a major reprogramming of funds so that we begin with a description of our budget that accurately reflects where the money is being spent."

Klausner said he has proposed "a significant number of changes" to reflect the amounts spent in every budget category. The specific proposals could not be discussed at the NCAB meeting because the plan requires the approval of NIH, HHS and Congress, he said.

The reclassification plan probably will not be released for about two months, sources said.

Intramural AIDS Funds Redirected

The manner in which NCI funds AIDS research is getting particularly intense scrutiny, Klausner said.

NCI Deputy Director Alan Rabson is working with the NIH Office of AIDS Research and the National Institute on Allergy and Infectious Disease to define the work that should be funded by NCI with AIDS research money, Klausner said.

"We have already reprogrammed money from the intramural program to the extramural program to address the issue of imbalance of distrubution of AIDS funding," Klausner said to the NCAB.

About $2 million has been reprogrammed officially, but by the time NCI closes its books on FY1995, up to $5 million will have been moved from intramural AIDS research and contracts to extramural research, sources said to **The Cancer Letter**.

Under the new schema, NCI is taking the lead on AIDS-related malignancies. The Institute has funded an *AIDS Malignancy Consortium* and an AIDS malignancy tissue bank.

Research in AIDS malignancies will be overseen by a newly formed working group headed by Ellen Feigal of the Div. of Cancer Treatment, Diagnosis and Centers.

Newly Reconstituted Executive Committee

The recently expanded NCI Executive Committee has taken the lead in charting the fiscal reorganization, Klausner said.

Prior to Klausner's arrival, the committee consisted of the NCI director, deputy director, division directors, and the director of administrative management. Staff members were sometimes asked to present information, but were not involved in deliberations.

Acting on the advice of the Bishop-Calabresi report and his own 1992 report on the functioning of the NIH intramural program, Klausner opened the committee to the participation of two key NCI staff members and four advisors from outside the Institute (see list of Executive Committee members, page 5).

The NCI staff added to the Executive Committee are intramural scientist Claude Klee, chairman of the Intramural Advisory Board, and extramural administrator Faye Austin, chairman of the Extramural Advisory Board. Their role is to act as liaison to the NCI staff.

"I think they have clearly gotten the message that the staff now is empowered to speak to the administration and that the administration is empowered to listen," Klausner said.

The changes double the size of the Executive Committee, from nine to 18 members.

"I gather from [NCI Deputy Director] Alan Rabson, who is my memory, that the Executive Committee has changed quite dramatically, not the least of which is because of the opening up of the institution and our decision-making processes to people other than division directors, institute directors and deputy directors," Klausner said to the NCAB.

The reorganization has improved communication among NCI leadership, Klasuner said. "The breakdown of what I perceived initially as fiefdoms within the Institute has allowed the Executive Committee to openly discuss all of the funding and mechanism issues without regard to any preconceived notion about entitlements," he said. "That has allowed us to begin to make profound changes and to reformulate priorities about how we use our funding mechanisms."

Planning For FY96: Fewer RFAs

The FY1996 budget impasse on Capitol Hill has left NCI operating under a continuing resolution until Dec. 15.

"The fluidity of the situation has made planning and rebudgeting extremely difficult," Klausner said . "We simply don't know what budget we are going to be operating under."

If no budget agreement is reached between Congress and the White House by Dec. 15, NCI and other government agencies could face another

shutdown. Another possible scenario is a succession of continuing resolutions that would fund NCI through the fiscal year.

"Given the uncertainty of these times, we feel that we must take a fairly conservative approach in terms of planning in all areas, including intramural research and contracts," Klausner said.

In November, operating under the first continuing resolution that delivered a 5% cut to the NIH budget, the Institutes decided that noncompeting (type 5) grants would not receive the expected 4% annual increase.

Klausner provided the NCAB with two budgetary scenarios for NCI grants funding:

—If NIH decides to provide the 4% increase to noncompeting grants, NCI would be able to fund 2,251 noncompeting grants and 793 competing grants. The research project grant success rate would be 19%, and the R01 percentile would be 17.

—If NIH does not provide the increase to noncompeting grants, NCI would be able to fund 2,251 noncompeting grants and 928 competing grants. The RPG success rate would be 23% and the R01 percentile 21.

In FY95, the R01 percentile was 15 and the success rate was 21%.

These scenarios include a significant drop in the number of grants funded through Requests for Applications, Klausner said. "I think the Institute was overusing [RFAs]," Klausner said. "This overly directed funds away from investigator-initiated research."

RFAs solicit grant applications in specific research areas selected by the Institute. The grants compete for a specific amount of funds set aside by the Institute, and are reviewed through special NCI committees, rather than NIH study sections.

Last year, NCI spent about $50 million to fund 126 competing grants through RFAs. In FY96, NCI expects to spend about $11 million to $15 million to fund about 59 grants through RFAs, Klausner said.

The funds not spent through RFAs will become available for investigator-initiated research, Klausner said.

The decision was questioned by one NCAB member. "The RFA mechanism is one mechanism the Institute has used to correct the failure of clinical research to be funded through NIH study sections," said Sydney Salmon, director of the Arizona Cancer Center.

"The RFAs we have been questioning—many of them were not clinically oriented," Klausner said. In the past, there was a perception among NCI staff that, "if you get a workshop, you get an RFA," he said.

"Not that I don't want to use the RFA mechanism, but I want to use it in context," Klausner said. "The number of RFAs that program directors have been willing to bring before me have dropped."

In other developments discussed at NCAB:

—Two NCI officials were named to develop a strategic plan for privatizing the Institute's information services.

The strategies are being developed by Susan Hubbard, director of the International Cancer Information Center, and Paul Van Nevel, director of the Office of Cancer Communication.

Recently, NCI announced its plans to privatize the Journal of the National Cancer Institute (**The Cancer Letter**, Dec.1).

Klausner said he plans to present new privatization initiatives at the next NCAB meeting in February.

—NCI has completed development of a protocol for a study of the BRCA1 mutation in the Ashkenazi Jewish popultion.

Under the Paperwork Reduction Act, the protocol requires approval from the Office of Management and Budget, Klausner said.

NCI expects to complete the study by next summer.

The study would enroll about 5,000 men and women in the Washington metropolitan area to establish the incidence of the mutation in persons of East European Jewish descent.

—NCI will expand support of the Cancer Genetics Consortium, which consists of 11 institutions funded by NCI, the National Center for Human Genome Research, the Nursing Institute and the National Institute of Mental Health. The consortium is studying issues of counseling and psychological effects of the diagnosis of predisposition to cancer based upon molecular and genetic tests.

"We need to be ready as an institution to deal with the next phase of these sorts of studies," Klausner said. "That is, the types of designs of clinical trials, be they for prevention, surveillance, diagnosis, therapy, stratification studies in terms of response to therapy, based upon these rapidly

accruing numbers of accessable cancer predisposition mutations."

Robert Wittes, director of the Div. of Cancer Treatment, Diagnosis and Centers, will establish a task force to work with NCHGR and the consortium "to plan the infrastructure for moving to these sorts of clinical trials," Klausner said.

—NCI is preparing a new Bypass budget that is expected to be ready by next spring's appropriations hearings in Congress (**The Cancer Letter**, Sept. 15). The Bypass budget will include "new and extraordinary and immediate opportunities for investment based upon scientific advances," Klausner said. "There is an extraordinary responsiveness that I have gotten to this from both the Administration as well as the Congress."

NCI Executive Committee Membership Listed

Following is a list of the current membership of the NCI Executive Committee:

NCI Director Richard Klausner

Deputy Director Alan Rabson

Philip Amoruso, associate director, extramural management

MaryAnn Guerra, associate director, intramural management

Edward Sondik, associate director, strategic planning

Division Directors:

—Faye Austin, Div. of Cancer Biology

—Joseph Fraumeni, Div. of Cancer Etiology and Genetics

—Peter Greenwald, Div. of Cancer Prevention & Control

—Marvin Kalt, Div. of Extramural Activities

—Philip Pizzo, Div. of Clinical Sciences

—George Vande Woude, Div. of Basic Sciences

—Robert Wittes, Div. of Cancer Treatment, Diagnosis & Centers

Internal Advisors:

—Claude Klee, chairman, Intramural Advisory Board

—Faye Austin, chairman, Extramural Advisory Board

External Advisors:

—Martin Abeloff, Johns Hopkins Oncology Center, and co-chairman for clinical sciences of the NCI Board of Scientific Counselors.

—Edward Harlow, Massachusetts General Hospital, and co-chairman for basic sciences of the NCI Board of Scientific Counselors.

—David Livingston, Dana-Farber Cancer Institute, and chairman of the NCI Board of Scientific Advisors.

—Alfred Knudson, Fox Chase Cancer Center, a special advisor to the NCI Div. of Cancer Epidemiology and Genetics.

Executive secretary, Iris Schneider

Tamoxifen Use Limit 5 Years, NCI Recommends In Letter

NCI last week recommended that the use of the drug tamoxifen be limited to five years.

The recommendation, contained in a letter mailed to 22,000 oncologists in the US, follows a decision by the National Surgical Adjuvant Breast and Bowel Project to stop a trial of tamoxifen as an adjuvant therapy for breast cancer.

The trial, protocol B-14, which compared five years to 10 years of tamoxifen (Nolvadex) after surgery in women with node-negative, estrogen receptor-positive breast cancer, found no additional benefit for women taking the antiestrogen for more than five years.

The incidence of second primary tumors in the two groups was slightly higher in the 10-year group, but the difference was not statistically significant, NCI and NSABP officials said.

"There was a time when many people believed that tamoxifen should be given for the life of the patient, because it was thought to be a cytostatic agent, and, obviously, the information from the NSABP protocol B-14 refutes that belief," said Norman Wolmark, chairman of NSABP.

"Whatever effect is going to be achieved is achieved with five years of treatment, and that positive effect could last a lifetime," Wolmark said to **The Cancer Letter**.

Wolmark and NCI officials said results of the B-14 trial should have no impact on the Breast Cancer Prevention Trial, which tests tamoxifen in healthy women at high risk of developing breast cancer.

"These findings don't change any of the risk-benefit information for the Breast Cancer Prevention Trial," Wolmark said. "All of this underscores the wisdom of having selected five years of treatment for the Prevention Trial."

NCI officials said the new information from B-14 has been presented to the Endpoint Review Safety Monitoring and Advisory Committee for the BCPT, after which the committee unanimously approved the continuation of the prevention study.

"This new information does not affect the overall risk/benefit profile seen for five years of tamoxifen use and supports our continued evaluation of this drug as a possible preventive agent in the context of a well designed clinical trial," said Leslie Ford, the NCI official who coordinates BCPT.

"Only by successfully completing this trial will we be able to determine the true worth of tamoxifen for the prevention of breast cancer, heart disease and bone fracture," Ford said.

BCPT has enrolled almost 12 000 women and needs another 4,000 to reach its accrual goal, NCI officials said.

The B-14 trial was halted after the study's Data and Safety Monitoring Committee found that the results indicated the lack of additional benefit for tamoxifen beyond five years.

The data also suggested the possibility that using the drug beyond five years could be harmful, documents said.

The B-14 trial followed 1,172 patients who were node-negative and estrogen receptor-positive and had already been on tamoxifen for five years without suffering a relapse. The patients were randomized a second time to receive five more years of a 20 milligram daily dose of tamoxifen or a placebo.

After four years of follow-up, 92% of the group that received five years of tamoxifen and then took the placebo were alive and free of disease. By comparison, 86% of the group scheduled to receive 10 years of tamoxifen were disease-free.

"The difference at an interim analysis does not represent statistically significant evidence of a detrimental effect, but it does make it very unlikely that continuation of tamoxifen would produce an actual clinical benefit," NCI said in a letter to US oncologists.

The B-14 results were consistent with a Scottish trial that also rerandomized women who had been on tamoxifen for five years with no recurrence of breast cancer to continue the drug or to discontinue its use.

The results of the first five yeas of the study, reported in 1987, showed a significant survival benefit for adjuvant tamoxifen. In addition there were cardiovascular benefits. Other studies have shown a benefit in maintaining bone density which may lead to a reduction in bone fractures, NCI officials said.

In the Scottish trial, 70% of women who had stopped taking tamoxifen after five years were alive and free of disease. In the group that continued treatment beyond five years, 62% of patients were alive and disease-free.

"The results of the Scottish trial are less definitive," said Jeff Abrams, an official with the NCI Div. of Cancer Treatment, Diagnosis, and Centers. "It is smaller than the NSABP trial and is not double-blinded, but the trend in results favoring five years of treatment supports our recommendation to stop adjuvant tamoxifen therapy at five years."

In women with an initial breast cancer, tamoxifen use of up to five years has been shown to reduce the risk of developing cancer in the opposite breast by approximately 40%, NCI officials said.

Clinical trials have also shown that tamoxifen can increase the risk of uterine cancers two to three times that of the general population, a risk similar to that seen in postmenopausal women taking estrogen replacement therapy, NCI officials said.

Although more endometrial cancers occurred in the women continuing the drug beyond five years, the numbers were small and the difference not statistically significant, NCI officials said.

According to the NCI letter to physicians, the occurrence of second primary tumors diagnosed after re-randomization included 11 contralateral breast cancers, six of which occurred in the 10-year tamoxifen group; eight endometrial cancers, six of which occurred in the 10-year group; and 21 other primary cancers, 12 of which occurred in the 10-year group.

"The findings from this trial should serve as very fertile ground for basic research," Wolmark said. "I think all of this raises a good question as to why 10 years of tamoxifen is not superior to five."

"If we hadn't done that trial, there would be total chaos relative to the duration of treatment of tamoxifen," said Bernard Fisher, former chairman of NSABP who is now the group's scientific director.

"From that standpoint, I think it's good news. It shows that the scientific process through clinical trials works," Fisher said to **The Cancer Letter**.

The analysis excluded the data from St. Luc Hospital in Montreal, the institution that employs former NSABP investigator Roger Poisson, who was found guilty of submitting falsified data to the

cooperative group. Altogether, 66 patients (5.6%) were enrolled at St. Luc.

The deletion of the St. Luc patients did not alter the conclusions, NCI officials said.

NEJM Papers Reaffirm Results Of NSABP Lumpectomy Trial

A series of papers in the New England Journal of Medicine last week reaffirmed the results of a landmark trial comparing mastectomy with lumpectomy with and without breast irradiation.

One of the papers, submitted by the National Surgical Adjuvant Breast and Bowel Project, found that the results of the lumpectomy study, protocol B-06, were not affected by fraudulent data submitted by St. Luc Hospital in Montreal.

Another paper, an overview of an NCI audit of NSABP data, said the NSABP data were accurate and apparently not marred by any additional incidents of fraud. Altogether, NCI auditors were able to verify 97.5% of the 7770 data points that were audited.

One remaining area of controversy was the adequacy of informed consent procedures. Commenting on the NSABP paper and the NCI audit, biostatistician John Bailar noted problems with the informed consent status of roughly a third of the 1,554 patients whose files were audited by NCI.

"To find that large numbers of investigators treat consent so casually is disheartening," Bailar wrote.

However, Bailar wrote, the B-06 study withstood the scrutiny of the audit. "The evidence is now persuasive that reducing the scope of surgical intervention for early breast cancer, within the limits carefully defined in these papers, has little or no effect on survival, at least in the short and midterm," Bailar wrote.

Bernard Fisher, who was toppled from his post as chairman of the cooperative group in the midst of controversy over the reliability of the data and the adequacy of NSABP auditing procedures, said the NEJM publications demonstrate that last year's events amounted to a "tempest in a teapot."

"These publications should remove any questions or doubts from the minds of the patients and physicians about the validity of the B-06 study," Fisher, the lead author on the NSABP paper who serves as the cooperative group's scientific director, said to **The Cancer Letter**.

"The NCI audit demonstrated the fantastic credibility of the NSABP database," Fisher said. "The auditors did not find any new fraud, and less than 1% of the data were considered to be discrepant.

"The quality of the data demonstrates that there was nothing to be worried about.
The safeguards incorporated in the design of the B-06 study prevented any single investigator or institution from affecting the findings or overall conclusions of the study."

Fisher said Bailar and the NCI auditors were not familiar with the informed consent practices in B-06.

To begin with, the structure of the NCI audit prevented the auditors from locating all consent forms, Fisher said. Indeed, the NCI paper states that auditors "did not attempt to clarify consent issues beyond noting the nature of consent (written vs. oral) and the date of consent relative to the definitive surgery."

"Institutions were not asked to provide additional information, as they were for other missing or ambiguous items," the NCI paper states.

Some of the informed consent problems noted in the audit were not problems at all, Fisher said. In fact, an entire category of patients was improperly classified by the auditors, he said.

From the start of B-06, women who had excisional biopsies performed as part of the diagnostic procedure and subsequently were randomized to the lumpectomy arm were not required to have additional surgery to the breast and therefore signed the consent forms following the surgery, but prior to the node dissection.

"These women signed the consent forms [for the trial], but the time of consent came after they had lumpectomies, which were really excisional biopsies," Fisher said. "This was a medical, ethical, scientific issue which escaped Bailar's understanding."

The NSABP paper analyzed the 12-year results of B-06 with and without the data from St. Luc. Patients were divided into three cohorts. The first included 2,105 patients who were analyzed according to the intent-to-treat principle.

The second consisted of 1,851 patients who agreed to be followed, and excluded six patients from St. Luc whose biopsy dates were falsified, refused assigned treatment and patients whose nodal status was unknown.

The third consisted of the patients of the second cohort minus 322 eligible patients from St. Luc.

Regardless of the cohort, the study found no significant difference in overall survival and disease free survival between patients who received

mastectomy and patients treated by lumpectomy and lumpectomy followed by irradiation.

The NCI auditors examined the data on 1,554 of the 1,809 randomized patients from institutions other than St. Luc. The patients were enrolled at 37 clinical sites in North America. Eligibility status was completely verified for 1,429 patients, or 94.8%.

Written informed consent was documented for 1,098 patients before surgery and 210 patients after surgery. No date appeared on the signed forms of 137 patients. Informed consent status was not verified for 71 patients, and could not be determined for another 38.

In Brief

AACE Names New Officers; ODAC Meeting Scaled Down

(Continued from page 1)

chairman of the Advisory Committee. The Margaret Hay Edwards Medal for Achievement in Cancer Education was awarded to **Daisilee Berry**, of Univ. of Arkansas Cancer Research Center. **Martin Abeloff**, director of the Johns Hopkins Oncology Center, was the 43rd Samuel C. Harvey Memorial Lecturer. Abstract forms for the 50th annual meeting of the association, scheduled for Oct. 17-20, 1996, and membership information, may be obtained from Robert Chamberlain, fax: 713/792-0807. . . . **FDA ONCOLOGIC** Drugs Advisory Committee has changed its plans and will not discuss cancer initiatives that it was scheduled to discuss at its next meeting Dec. 14 (**The Cancer Letter**, Dec. 1). The committee will review a New Drug Application and a Product License Application.

Program Announcement

PA-96-008

Title: **Epidemiology Of Lung Cancer: Interdisciplinary Studies**

NCI and the National Institute of Environmental Health Sciences invite investigator-initiated research project grant (R01) applications for innovative interdisciplinary studies to better understand the etiology of adenocarcinoma and small cell carcinoma of the lung and the means of prevention.

Inquiries: The PA may be obtained electronically through the NIH Grant Line (data line 301-402-2221) and the NIH gopher (gopher.nih.gov) and by mail and email from: A.R. Patel, Division of Cancer Epidemiology and Genetics, NCI, 6130 Executive Blvd Suite 535, MSC 7395, Bethesda, MD 20892-7395, tel: 301/496-9600, fax: 301/402-4279, email: Jasonc@epndce.nci.nih.gov

Or, Gwen Collman, Chemical Exposures and Molecular Biology Branch, NIEHS, PO Box 12233, Research Triangle Park, NC 27709, tel: 919/541-4980, fax: 919/541-2843, email: collman@niehs.nih.gov

ORI Finds Misconduct In Cases Of Two Researchers

The Office of Research Integrity has made final findings of scientific misconduct in the following cases:

--Nicholas Lorenzo, Mayo Foundation: ORI found that Lorenzo, formerly of the Mayo Foundation, committed scientific misconduct by falsifying and fabricating data incorporated in an abstract submitted for presentation at a professional meeting; the research was supported by a Public Health Service grant. The abstract was withdrawn prior to publication.

Lorenzo has entered into a Voluntary Exclusion Agreement with ORI in which he has accepted ORI's finding and has agreed to exclude himself voluntarily, for three years from any federal contracts and from PHS advisory positions.

The exclusion does not apply to Lorenzo's future training or practice of clinical medicine whether as a medical student, resident, fellow, or licensed practitioner unless that practice involves research or research training.

--Weishu Weiser, Harvard Medical School: ORI found that Weiser, formerly of the Harvard Medical School at Brigham and Women's Hospital, committed scientific misconduct by falsifying data in biomedical research supported by two PHS grants.

Weiser has entered into a Voluntary Exclusion Agreement with ORI in which she has accepted ORI's finding and has agreed to exclude herself voluntarily, for three years from any federal contracts and from PHS advisory positions.

She has agreed to submit a letter to the Journal of Immunology and to the Proceedings of the National Academy of Sciences to retract the articles entitled "Human recombinant migration inhibitory factor activates human macrophages to kill Leishmania donovani" (Journal of Immunology 147:2006-2011, 1991), "Recombinant migration inhibitory factor induces nitric oxide synthase in murine macrophages" (Journal of Immunology 150:1908-1912, 1993), and "Recombinant human migration inhibitory factor has adjuvant activity" (Proceedings of the National Academy of Sciences 89:8049-8052, 1992).