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FAX

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After Furlough, Blizzard, NCI Struggles To Clear Backlog And Resume Business

After a three-week furlough followed by a four-day blizzard, many NCI officials are finding that the piles of papers on their desks have grown as high as the snowbanks along Rockville Pike.

"I used to know where everything was on my desk," said Tony Mead, a branch chief in the NCI Developmental Therapeutics Program, on his
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In Brief

UK Scientist Receives Pezcoller Award; Yale Appoints Associate Director For Trials

PAUL NURSE, director of research and head of the Cell Cycle Laboratory, Imperial Cancer Research Fund, London, was selected as winner of the 1995 Pezcoller Award for Oncology for his seminal contributions to the understanding of the molecular mechanisms of control of cell progression through the cell cycle. The award of ECU 100,000, worth about \$120,000 in US dollars, is given every other year by the Alessio Pezcoller Foundation, of Trento, Italy, to recognize meritorious contributions to medical research. The foundation also sponsors scientific symposia, a scientific journal, and seminars in oncology for Italian clinicians. . . . **LEE PHILIP SCHACTER** was named to the newly created position of associate director for clinical trials, Yale Cancer Center. Schacter was director of the clinical cancer research program at Bristol-Myers Squibb Co. . . . **JOHN COFFIN**, an American Cancer Society Research Professor at Tufts University School of Medicine, was named to the National Board of Trustees of the Leukemia Society of America. . . . **KENNETH TREVETT**, general counsel for Dana-Farber Cancer Institute for the past six years, announced he is leaving the center to enter private law practice. Trevett will specialize in technology transfer, professional conduct, and general health care law. . . . **ROBERT OZOLS**, senior vice president, medical oncology, Fox Chase Cancer Center, was chosen as one of 50 "most positive" physicians in America by Positive Medicine, a Philadelphia-based organization. Ozols was the only medical oncologist to be honored by the group, which will publish profiles of the physicians in a book to be distributed to US medical schools. . . . **NATIONAL RACE** for the Cure will donate \$650,000 to more than a dozen Washington, DC, area hospitals and research centers at a ceremony Jan. 22. The proceeds from last year's race will fund breast cancer research and provide screenings for low income women.

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NCI Employees Return To Overflowing "In" Boxes

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first day back at work in a month. "We are trying to find out what's in the 'In' box, what's on the voice mail, what's on the e-mail."

The backlog notwithstanding, Mead said he was glad to be back at his desk. "We're going to be digging out of a pile for some time, but we're in better shape than the agencies that aren't funded," he said.

The furlough ended when Congress approved the NIH appropriation for fiscal 1996 on Jan. 5. About 24 hours later, a blizzard brought Washington to a standstill, and federal offices were closed once again.

"There's a feeling of great euphoria here—people have missed working, and they are glad to be back," said NCI Deputy Director Alan Rabson. "But there are a lot of problems, a lot of things that need to be done."

Robert Wittes, acting director of the Division of Cancer Treatment, Diagnosis and Centers, said it could take months to restore the Institute to its normal functioning. "It was a terrible four weeks," Wittes said. "Most things slowed to a crawl, and everything is being delayed."

Wittes said the furloughs hit extramural administration particularly hard, as most extramural staff members were classified as "nonessential," and were told to stay home.

"The government's distinction between 'essential' and 'nonessential' employees is arbitrary and nonsensical," Wittes said. "The essential functions of this place, the services, came to a halt."

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Grant Payments To Resume

Investigators who were expecting to receive grant payments in December or January should begin receiving checks soon, NIH officials said.

At the time the furlough began, NIH said about 1,000 non-competing grants had not been awarded. Another 750 to 1,000 new and competing awards had not been processed.

While NIH officials chip away at the backlog, they will also have to contend with their normal work schedule that requires the processing of an additional 2,000 awards that start Feb. 1.

"We will begin to process grant awards and ensure that competing continuations get priority so that we do not interrupt ongoing work," Wendy Baldwin, NIH deputy director for extramural research, wrote in a letter posted on the NIH Internet home page Jan. 5. "Institutes that were unable to issue funding letters (sent in advance of the notice of grant award) will be issuing them as quickly as possible to ensure the research community is advised of our plans for the support of new and continuing research."

Review Meetings Delayed

According to Baldwin, NIH officials took the following actions to clear the backlog:

—The Jan. 10 deadline for National Research Service Awards research training grants was extended to Jan. 19.

—The Feb. 1 deadline for regular research applications is still in effect.

—NIH will pay the annual 4% increase to continuing grants. Non-competing grants that have been awarded will receive retroactive adjustments.

—Initial scientific review meetings that were scheduled between Dec. 15 and mid-February will be rescheduled.

Advisory councils scheduled to meet this month may not be able to complete all grant and contract actions because of the inability of NIH staff to reproduce material for the meetings, Baldwin wrote. Thus, there may be delays in resolving rebuttals to reviews.

An estimated 10,000 grants are scheduled to be reviewed in the January cycle with 2,000 awards that would be made in the spring, Baldwin wrote. These are "potentially at risk" of being delayed if council actions are not completed.

The furlough disrupted the publication of the NIH Guide to Grants and Contracts, a publication that lists

new grant and contract programs. In addition, the publication's staff has moved to a new building.

"Getting the Guide back in publication and adjusting receipt dates for RFAs and RFPs will be a high priority for my office," Baldwin wrote.

NCI: Dealing With The Backlog

In the aftermath of the shutdown, NCI officials said they could offer little information on the resumption of grant and contract payments.

"We have no clear picture yet about anything," Marvin Kalt, director of the Division of Extramural Activities, said. "NIH is trying to figure out how to get restarted."

"Right now we are trying to make sure people get paid, and assessing where we are," said Philip Amoroso, associate director of the NCI Office of Extramural Management. "We are looking at the budget."

Leo Buscher, chief of the NCI Grants Administration Branch, said the branch planned to issue award notices for non-competing grant renewals this week. "We have a huge backlog, and we are trying to get them out as quickly as possible," he said.

Investigators who were supposed to receive new awards in December or January probably felt the impact of the shutdown most acutely, Buscher said.

Grantees who received awards in fiscal 1995 were able to withdraw their funds from the NIH payment management system, which continued to operate during the furlough, Buscher said.

"The interesting thing I found during the furlough was that some grantees who called us said they didn't know we were part of the federal government," Buscher said. "We need to communicate better what NIH is."

Keeping Emergencies Under Control

In the Cancer Therapy Evaluation Program, all protocol review was suspended during the furlough, said David Parkinson, acting associate director of the program.

Staff members handled emergency business, including reports on adverse drug reactions and emergency shipments of drugs to patients on Group C protocols.

"We were able to keep the safety things under control," Parkinson said. "We have not been able to move ahead with INDs, protocols, and protocol amendments."

Award checks were scheduled to be sent this month to four of the cooperative groups—the Pediatric Oncology Group, the Children's Cancer Group, the Southwest Oncology Group and the Radiation Therapy Oncology Group.

"It is clear that had the impasse continued, it would have interrupted funding of clinical trials," Parkinson said.

Several cancer centers were scheduled to receive their core grant payments Dec. 1, said Margaret Holmes, chief of the Cancer Centers Branch.

"I don't know the status of those grants right now," Holmes said. "The centers are being patient about it."

Site visits for a few of the centers are likely to be postponed until the next grant round, she said.

The Community Clinical Oncology Program had completed the current round of CCOP reviews the day before the shutdown, said Leslie Ford, chief of the Community Oncology and Rehabilitation Branch. However, summary statements did not get mailed, Ford said.

In addition, some CCOPs were scheduled to receive supplements for accrual to prevention trials last month. Those payments have been delayed.

Mead, chief of the DTP Grants and Contracts Operations Branch, said NIH grants administrators were instructed not to speculate with grantees about grant paylines.

Checks will be sent as quickly as possible, he said.

"There is nothing we can be specific about," Mead said. "We tell them to look at the NIH home page. I can't even ask anyone higher up—they are all in meetings up to their eyebrows."

Mead said many DTP grantees are expecting checks, and many grant applicants need to receive the summary statements from grant reviews in order to amend their applications in time for Feb. 1 and March 1 deadlines.

"It's just a matter of how fast we can get everything out," Mead said.

"We Lost A Lot of Momentum"

Faye Austin, acting director of the Division of Cancer Biology, said she and another senior administrative official were the division's only staff members designated to work during the furlough.

"Absolutely nothing got out of the programs," Austin said. "I am sure there are summary statements that have been sitting here a month. Applicants

weren't able to get information."

Program administrators generally work on three grant rounds at one time: the grants that are about to be paid, grants under review, and applications that are coming in, Austin said.

"There are going to be delays at many points in the cycle," she said.

Getting the normal functions of NCI back on track will take priority over the Institute's restructuring efforts, Austin and others said.

Austin said she had to cancel the January meeting of the Extramural Advisory Board, which she chairs. The board of NCI staff members is one of two internal advisory groups recently created by NCI Director Richard Klausner.

"We have lost a lot of momentum, a lot of creativity and vitality," Austin said. "It's hard to go back and say, 'Where was I, what were the issues?' We had dedicated people who wanted to come in, but we had to tell them not to."

JNCI Skips An Issue, Returns Papers

The Journal of the National Cancer Institute will skip publication of its Feb. 7 issue, the third issue of 1996. Articles submitted in recent weeks will be returned to the authors, with a letter advising researchers to submit their papers elsewhere.

"We could not field enough of the staff to keep it going," said Julianne Chappell, the journal's managing editor. "We've never been late with an issue or missed an issue. This is a kind of failure. It's very gut-wrenching for our staff."

The pipeline of articles to be reviewed, edited, and prepared for publication was "flooded and stuck," Chappell said.

Normally, three articles per week are selected for review.

Though the issue could have been published late, it would have affected the journal's response time for the rest of the year, Chappell said.

"The only thing we could do to save our responsiveness was to cancel an issue of journal and turn back papers," she said.

Chappell advised authors to submit the articles to other journals. Re-submission to JNCI would increase the backlog—and the likelihood of a rejection, she said.

The journal was able to meet publication deadlines in December and for the first two issues in January because the staff anticipated the furloughs and completed some work ahead of time, Chappell said.

Judge Hears Arguments In Database Flagging Case

A federal judge is expected to rule within a month whether NCI and other HHS agencies violated the rights of the clinical trialist Bernard Fisher by placing "scientific misconduct" labels on the abstracts of his articles in the CancerLit and Medline databases.

At a hearing Wednesday before Judge Ricardo Urbina of the US District Court for the District of Columbia, attorneys for Fisher maintained that the government had violated the federal law which requires government agencies to maintain accurate "systems of records" on individuals.

While Fisher's side has prepared a voluminous case based on depositions and documents obtained through discovery, the government presented a case based entirely on legal arguments, contending that the literature databases do not fit under the definition of records in the Privacy Act.

"We believe the Privacy Act does not apply to the databases," Richard Friedman, an attorney with the HHS Office of General Counsel said at the hearing. "Our argument is that the pieces of information [in the databases] are not about the plaintiff."

Rather than referring to an individual, the database entries refer to the materials they annotate, he said. Even the address on each entry is not used as the author's address, Friedman said. "It's an address to get more information on the article."

Last spring, Urbina granted a preliminary injunction sought by Fisher, ordering the removal of flags from the databases (**The Cancer Letter**, March 24, 1995). Now, Fisher seeks a permanent injunction, a public apology and an assurance that similar flagging would not occur in the future. If Urbina grants these motions, a separate proceeding would determine the damages due to Fisher (**The Cancer Letter**, Oct. 20, 1995).

"Their argument is that a database entry is not a record on Dr. Fisher," said Stuart Newberger, an attorney with Crowell & Moring, the Washington firm that represents Fisher. "What they are saying is that as a matter of law they can do it again."

Newberger said HHS and NIH officials decided to blame Fisher for the scandal involving fraudulent data submitted by a Montreal surgeon to a breast cancer trial run by Fisher's cooperative group.

To accomplish this, the government launched a scientific misconduct investigation of Fisher and

proceeded to flag his publications in the databases, Newberger said.

Rules that generally apply were ignored in the Fisher case, his lawyers contend. Thus, the start of a scientific misconduct investigation—always a confidential matter—was announced by Philip Lee, HHS Undersecretary for Health, in an interview with *The New York Times*.

Similarly, then-NCI Director Samuel Broder announced the misconduct investigation at a meeting of the National Surgical Breast & Bowel Project, the group Fisher ran until the start of the scandal.

When NIH officials proceeded with the annotation of Fisher's articles, they placed labels on the basis of the titles of the articles, without reading the text. Thus, articles that included editorials and award speeches by Fisher were flagged "scientific misconduct," Newberger said.

"[The databases] are created to help people find out about a scientist's work," Newberger said. "And they contain an address, so Dr. Fisher could be contacted."

Newberger said many of Fisher's co-authors could have Privacy Act claims against the government. "I am not trying to drum up a class action case, but many people may have an action here," he said.

HHS: Flags Not Meant To Point To Fisher

Responding to Newberger, HHS attorney Friedman defended virtually every aspect of the flagging.

"The words 'scientific misconduct' [in the flags] were never meant to communicate that Dr. Fisher himself committed scientific misconduct," Friedman said.

In fact, the flags were not intended to identify the perpetrator. According to Friedman, the flags were to be interpreted in the following manner: "Somebody's scientific misconduct has affected this article. We are reanalyzing the data. Watch this space.

"It was still a statement about the article," Friedman said. "There is no evidence that anyone has read it any other way."

Friedman acknowledged one error on the part of an official of the HHS Office of Research Integrity who placed a "scientific misconduct" flag on a paper by Fisher that included no data from the trials in question.

Friedman said Dorothy Macfarlane, the ORI official responsible for deciding which papers to flag,

read only the titles of the papers in question.

"Perhaps she should have done more and read the articles themselves," he said. However, Friedman said Macfarlane did not act arbitrarily. "The titles in medical literature are generally more informative than the titles of legal articles," he said.

Defending Macfarlane's decision to flag several of Fisher's speeches and editorials, Friedman said, "Any general piece by Dr. Fisher is based on the totality of the NSABP product."

The opinions set forth by Fisher could have been based on fraudulent entries submitted by Roger Poisson, a surgeon at St. Luc Hospital in Montreal.

"There is a linkage here," Friedman said of Macfarlane's decision to flag. "It's a judgment call."

Friedman further argued that HHS Undersecretary Lee and NCI Director Broder did not violate the Privacy Act when they stated publicly that ORI had begun a misconduct investigation of Fisher.

Fisher's lawyers have not demonstrated that Lee and Broder had revealed information obtained from ORI records, Friedman said. "Information that is lodged in an employee's mind does not refer to a disclosure from a system of records," Friedman said. "There has to be a retrieval from the system."

A series of papers published in the *New England Journal of Medicine* last month reaffirmed the results of the NSABP trial comparing mastectomy with lumpectomy, with and without radiation (**The Cancer Letter**, Dec. 8, 1995). The controversy over the fraudulent data submitted to that trial led to Fisher's removal as chairman of NSABP.

Supreme Court Rejects Appeal Of Ruling On AZT Patents

The Supreme Court, rejecting an appeal by two generic drug manufacturers, let stand a ruling that said the former Burroughs Wellcome Co. is entitled to five patents for AZT.

The court, without comment on Jan. 16, turned away the argument that the company should not receive exclusive patents because NIH researchers tested the drug for activity against AIDS.

Burroughs Wellcome was acquired by Glaxo last year, creating Glaxo Wellcome Inc., based in Research Triangle Park, NC.

Barr Laboratories, based in Pomona, NY, and Novopharm, based in Ontario, each sought federal permission to sell generic versions of AZT. Burroughs sued both companies, alleging patent infringement.

Cancer Meetings Listed For February, March

February

Gene Therapy for Hematopoietic Stem Cells in Genetic Disease and Cancer—Feb. 4-10, Taos, NM. Contact Keystone Symposia, tel: 303/262-1230.

International Congress on Anti-Cancer Treatment—Feb. 6-9, Paris, France. Contact Prof. David Khayat, SOMPS, Hopital de la Pitie-Salpetriere, 47 Bd de l'Hopital, 75651 Paris CEDEX 13 France.

Clinical Advances in the Treatment of Genitourinary Tumors—Feb. 8-10, Houston, TX. Contact M.D. Anderson Cancer Center, Pam Hamre, Conference Services, tel: 713/792-2222.

Radiation Therapy Oncology Group Semi-Annual Meeting—Feb. 8-11, New Orleans, LA. Contact Nancy Smith, RTOG, tel: 215/574-3205, fax: 215/928-0153, e-mail: nsmith@acr.org.

American Association for the Advancement of Science, Annual Meeting and Science Innovation Exposition—Feb. 8-13, Baltimore, MD. Contact AAAS, tel: 202/326-6440.

Society of Gynecologic Oncologists Annual Meeting—Feb. 11-14, New Orleans, LA. Contact Wang Associates, 212/685-1900.

Multidisciplinary Symposium on Breast Disease—Feb. 15-18, Amelia Island, FL. Contact Univ. of Florida, tel: 904/549-3158.

Cancer Information Exchange Conference—Feb. 15-18, Amelia Island, FL. Contact Adina Cook, Columbus CCOP, tel: 614/443-2267.

Molecular Regulation of Platelet Production—Feb. 16-22, Taos, NM. Contact Keystone Symposia, tel: 303/262-1230.

Clinical Hematology and Oncology—Feb. 19-22, La Jolla, CA. Contact Scripps Clinic, tel: 619/554-6310.

National Cancer Advisory Board—Feb. 26-28, NIH Building 31 Conference Rm 10, Bethesda, MD.

March

Proteases and Protease Inhibitors—March 1-5, Panama City, FL. Contact AACR, tel: 215/440-9300, fax: 215/440-9313.

National Comprehensive Cancer Network First Annual Conference: Practice Guidelines—March 3-6, Fort Lauderdale, FL. Contact Jack Gentile, conference coordinator, 516/424-8900, ext. 813.

Recent Advances In Paget's Disease of Bone

and Related Bone Diseases—March 9, Natcher Building, Bethesda, MD. Contact The Paget Foundation, tel: 212/229-1582, fax: 212/229-1502.

NCI-EORTC Symposium on New Drugs in Cancer Therapy—March 12-15, Amsterdam, The Netherlands. Contact (in the US) Technical Resources Inc., tel: 800/883-MEET, fax: 301/770-6343. Non-US, contact VU Conference Service, Amsterdam, tel: 31-20-444-5790.

International Conference on the Adjuvant Therapy of Cancer—March 13-16, Scottsdale, AZ. Contact Arizona Cancer Center, tel: 520/626-2276, fax: 520/626-2284, e-mail: meetings@azcc.arizona.edu.

Association of Community Cancer Centers Annual Meeting—March 13-16, Washington, DC. Contact David Walls, tel: 301/984-9496.

American Society of Preventive Oncology—March 20-23, Bethesda, MD. Contact Dr. Richard Love, tel: 608/263-7066 or Judy Bowser, tel: 303/938-1045.

Society of Surgical Oncology Annual Meeting—March 21-24, Atlanta, GA. Contact SSO, tel: 708/427-1400, fax: 708/427-1294.

Investigational Approaches and Opportunities for Preventing Prostate Cancer—March 31-April 2, Annapolis, MD. Contact Judith Karp, NCI, tel: 301/496-3505, Dr. Andrew Chiarodo, tel: 301/496-8528, or Dr. Otis Brawley, tel: 301/496-8541.

April

UNC Lineberger Comprehensive Cancer Center Annual Symposium—April 1-2, Chapel Hill, NC. Contact Sarah Rimmer, tel: 919/966-3036.

National Cancer Pain Initiative Convention—April 11-14, Houston, TX. Contact Pam Hamre, conference services, tel: 713/792-2222.

Hereditary Predisposition to Cancer—April 12, Memphis, TN. Contact Univ. of Tennessee, Memphis, tel: 901/448-6354.

American Cancer Society National Conference on Cancer Prevention and Early Detection—April 18-20, Washington, DC. Contact Andy Cannon, tel: 404/329-7606.

American Association for Cancer Research Annual Meeting—April 20-24, Washington, DC. Contact AACR, tel: 215/440-9300.

International Congress on Breast Disease of the Senologic International Society—April 28-May 2, Houston, TX. Contact Conference Services, tel: 713/792-2222.