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FDA Advisors Ok Marketing Of Taxotere As Treatment For Advanced Breast Cancer

An FDA advisory group this week recommended marketing approval of Taxotere for the treatment of locally advanced or metastatic breast cancer that has progressed or relapsed during anthracycline-based therapy.

The Oncologic Drugs Advisory Committee voted 6-0, with one abstention, to recommend approval of Taxotere (docetaxel), sponsored by Rhone-Poulenc Rorer Inc. of Collegeville, PA and Paris, France.

The Oct. 17 recommendation was based on the results of three phase2 studies involving 134 breast cancer patients with anthracycline-resistant disease.

(Continued to page 2)

In Brief

Goldman Named Director, Albert Einstein Cancer Center; Wiernik Resumes Post

DAVID GOLDMAN was named director of the Albert Einstein Cancer Center, an affiliate of the Montefiore Medical Center. Goldman replaces **Mathew Sharp**, who held the job for five years. Also at Albert Einstein, **Peter Wiernik** returned to his former job as the cancer center's associate director for clinical research (**The Cancer Letter,** Nov. 5 & Nov. 12, 1993). Wiernik takes over after **Janice Dutcher**, who held the job for two years. . . . **I. CRAIG HENDERSON** has left the position of director, clinical cancer programs, Univ. of California, San Francisco, to become CEO at SEQUUS Pharmaceuticals of Menlo Park, CA. Henderson *will continue to be director* for the NCI breast cancer SPORE and will retain a faculty appointment at UCSF. Interim director of clinical cancer programs is **Joe Gray**, director of the Div. of Molecular Cytometry. . . . **JOSEPH ROSENBLATT** was named head, medical oncology, and associate director for clinical research, Univ. of Rochester Cancer Center. Rosenblatt was associate professor of medicine, director of the gene therapy program, and associate director of the AIDS Institute at Univ. of California, Los Angeles. . . . **PEGGY YASEM**, secretary in the NCI Div. of Cancer Etiology director's office for the past 27 years, has retired from NCI to take a position as secretary at the Institute for Human Virology being formed by NCI scientists Robert Gallo and William Blattner. . . . **JEFFERSON CANCER CENTER** has received an NCI core grant of $1.2 million, becoming one of four NCI-supported cancer centers in Pennsylvania. **Carlo Croce** is director of the center; clinical director is **Robert Comis**.

ODAC Chairman Critical Of Taxotere Indication, Dose

(Continued from page 1)

Taxotere, made from needles and twigs of the European yew, stops cancer cell division by promoting the assembly and blocking the disassembly of microtubules.

"Narrow Indication" Criticized

Committee Chairman Paul Bunn abstained from the vote on approval. "I feel we could have approved Taxotere for a wider indication if we had the data," said Bunn, director of the Univ. of Colorado Cancer Center. "The dose is too high and the indication is too narrow."

The recommended dosage of Taxotere is 100 mg/m^2 administered by infusion over one hour, repeated every three weeks.

Bunn said he was disappointed that Rhone-Poulenc could not verify the quality of data in a Japanese study that apparently demonstrated a better safety profile for Taxotere at a dose of 60 mg/m^2, with response rates similar to those seen in the company's US and European studies.

"All of us hope this information can be verified," Bunn said. "I personally think dose is a big issue."

Rhone-Poulenc officials said their non-randomized studies demonstrated that the 100 mg/m^2 dose of Taxotere produced a higher response rate than a dose of 75 mg/m^2.

A randomized phase 3 trial comparing the two dosage levels of Taxotere began last week, company officials said.

In addition, a randomized phase 3 trial comparing Taxotere and its competitor, Taxol (paclitaxel, Bristol-Myers Squibb), is beginning.

FDA reviewer Julie Beitz said the agency also wants to see the Japanese data. "We would like to give patients and physicians an option of dosages, as was done with Taxol," she said.

RPR: Benefits Outweigh Risks

Gabriel Hortobagyi, chief of breast and gynecologic medical oncology at M.D. Anderson Cancer Center, presented the phase 2 data to the committee on behalf of Rhone-Poulenc.

The studies used a strict definition of anthracycline resistance, Hortobagyi said. A patient with advanced disease must have experienced tumor growth, or a patient on adjuvant therapy must have experienced a relapse.

"Taxotere is highly effective at shrinking tumors and improving symptoms in these patients, who have very few treatment options available," Hortobagyi said. "The benefits of Taxotere are clear, and efficacy and safety results are consistent and reproducible in this group of patients."

The three studies, at M.D. Anderson, the Univ. of Texas Health Science Center at San Antonio, and in Europe, demonstrated an overall response rate on an intent-to-treat basis of 41 percent (20 of 134 patients). There were two complete responders.

Median duration of response was six months, median time to progression was four months, and median survival was 10 months. One-year survival was seen in 43% of the patients.

In addition, most symptomatic patients improved or maintained their performance status while taking Taxotere, Hortobagyi said.

Most patients experienced improvement or no change in pain while on the drug.

Daniel Von Hoff, director of the Cancer Therapy and Research Center's Institute for Drug Development and professor at Univ. of Texas Health Science Center in San Antonio, said safety data showed that patients with liver problems had a higher incidence of drug-related toxicities.

Three of the 134 patients, or 2.2%, died due to drug-related toxicities. Two of the patients had abnormal liver function. The rates of febrile neutropenia, thrombocytopenia, and stomatitis were greater in those patients than in patients with normal liver function.

The company recommended that physicians

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exclude from Taxotere treatment any patient with SGOT and/or SGPT > 1.5 x ULN and alkaline phosphatase > 2.5 x ULN.

The company also recommended that patients receive a premedication regimen of corticosteroids to delay the onset and reduce the incidence and severity of fluid retention.

"For treatment of patients with anthracycline-resistant breast cancer with normal liver function, the safety profile of Taxotere is predictable and manageable," Von Hoff said.

Second Bid For Approval

Rhone-Poulenc's presentation to ODAC this week was its second bid for approval of Taxotere. The company submitted a New Drug Application to FDA *in July 1994*.

ODAC reviewed the drug last December and voted against approval for metastatic breast cancer, citing the drug's serious side effects. At that time, the committee voted against approval of Taxotere for non-small cell lung cancer, saying clinical trials did not demonstrate the drug's efficacy.

The company will continue to seek FDA approval of Taxotere for lung cancer, a spokesman said. "We are still actively pursuing approval for lung cancer in the US and other countries," Bob Pearson, a spokesman for Rhone-Poulenc, said to **The Cancer Letter**. "The activity we are seeing is significant in relation to other available agents."

Taxotere is approved in Canada, Mexico, South Africa, Uruguay, and Brazil, and has been recommended for approval in Australia, for the treatment of patients with advanced breast cancer and non-small cell lung cancer in whom initial therapy has failed.

Two Other Breast Cancer Therapies

ODAC also recommended marketing approval for two other drugs for advanced breast cancer.

The commmittee recommended approval of Fareston (toremifene, Orion Corp.) for treatment of advanced breast cancer in postmenopausal women, and Arimidex (anastrozole, Zeneca Pharmaceuticals) as a selective aromatase inhibitor for the treatment of postmenopausal women with advanced breast cancer who develop progressive disease while receiving tamoxifen.

Additional articles on the ODAC meeting will be published in the October issue of The Clinical Cancer Letter.

Role of Former NCI Director Examined

Fisher Moves For Judgment In Suit Over Database Flags

Attorneys for breast cancer researcher Bernard Fisher filed a motion Monday seeking a summary judgment in a suit claiming that the government violated the law when NIH databases marked Fisher's articles with statements that included the words "scientific misconduct."

The motion, brought under the Privacy Act, seeks permanent removal of the flags, a public apology to Fisher and creation of a "system of records" for the databases.

The document, filed in the US District Court for the District of Columbia, also requests a separate proceeding to determine the amount of the damages.

The Privacy Act requires government agencies to maintain accurate records and prohibits capricious dissemination of personal information. The law establishes a minimum award of $1,000 per violation of the Act.

If every flag that appeared on database entries and journal citations is found to be a violation, damages could reach into millions of dollars, Fisher's attorneys say.

Documents and depositions filed in the suit offer a wealth of new material on the crisis that began in March 1994, when the Chicago Tribune broke the story about fraud in lumpectomy trial conducted by the National Surgical Adjuvant Breast & Bowel Project, the copperative group Fisher headed.

The motion asserts that former NCI Director Samuel Broder, a defendant in the suit, in effect "scapegoated" Fisher by compelling the HHS Office of Research Integrity to start a scientific misconduct investigation against Fisher. Moreover, the motion asserts, Broder similarly compelled NIH staff to place flags on NSABP articles in the Medline and CancerLit databases.

"These violations are astronomically beyond the scope of any other Privacy Act case," the motion claims. "This is not the typical Privacy Act case in which one or two inaccurate paper records of an individual are disclosed to a limited number of third parties.

"Defendants disseminated these records, which were not merely incomplete and inaccurate, but patently false, misleading, and extraordinarily harmful, around the world to thousands of scientists,

practitioners, patients, and others.

"They did so as part of a deliberate, well-orchestrated plan directed by high-ranking government officials and carried out by the powerful machinery of government," the motion said.

Controversy Revisited

Though NCI fired Fisher as the NSABP principal investigator soon after the controversy began, NCI was sharply criticized at the April 13, 1994, hearing of the Subcommittee on Oversight & Investigations of the House Committee on Energy & Commerce.

The subcommittee, then chaired by Rep. John Dingell (D-MI), scheduled a second hearing for June 15, 1994, and Broder's plan was to initiate the misconduct investigation against Fisher and annotate the databases before that hearing, Fisher's attorneys allege.

The motion, filed by the Washington firm of Crowell & Moring, alleges that Broder's strategy was to shift the blame to Fisher.

"At first, Broder's plan encountered resistance from senior NCI staff," the motion states. "NCI officials told Broder that Dr. Fisher had made unprecedented contributions to the field of cancer research, had a sterling reputation, and should not be `scapegoated...' Broder responded to such officials that Dr. Fisher's world-wide reputation somehow was clouding their judgment, and that anyone who was not with his `program' could resign.

"Determined to proceed with his plan, he forbade NCI staff from defending Dr. Fisher," the motion states.

In excerpted depositions that accompanied the motion, several top NCI officials said they had heard Broder repeatedly state: "My only regret is that I can only fire Bernie Fisher once."

Broder, now the chief scientific officer at Miami-based IVAX Corp., was out of his office and did not return a reporter's call.

Summary judgments can be requested when litigants believe that the facts of the case have been established and only matters of law remain to be resolved.

The US Attorney's office is expected to file an opposing motion, sources said.

Resignation On A Macro

In depositions, several NCI officials said that soon after the NSABP scandal became public, Broder became intolerant of disagreements from his subordinates.

"If you weren't with the program, you knew what you could do," Leslie Ford, chief of the Community Oncology and Rehabilitation Branch, said in a deposition.

Ford said she attempted to defend Fisher early in the controversy, but was admonished by Broder. "[He] never wanted to hear me say that again," Ford said.

Top NCI officials were engaged in virtually non-stop meetings following the outbreak of the NSABP crisis, several officials said. "I was practically a house guest in [Broder's] office for... six to eight months," Bruce Chabner, former director of the NCI Div. of Cancer Treatment, said in a deposition.

At times, the meetings appeared to follow no agenda, several officials said. Frequently, there was anger in the air. "I have found it difficult to identify the subject of Dr. Broder's anger on some occasions, and it was clear that Dr. Broder was angry," Michael Friedman, former director of the Cancer Therapy and Evaluation Program, said in a deposition. "It was not always clear to me with whom he was angry."

On one occasion Broder instructed Friedman to prepare a letter of resignation, Friedman testified.

"[Broder] suggested that I should set up a macro within my computer with my resignation, so I could just punch a button," Friedman said. "I can remember another occasion in which, in requesting certain information from him, ... [Broder] asked me whether I wished to resign at that moment," Friedman said.

In a similar incident, described in a deposition by Peter Greenwald, director of the Div. of Cancer Prevention and Control, Broder had allegedly said, "If you don't like the way NCI is being run, you can resign today, or you can go to the President and ask him to ask for my resignation."

Pressure From Subcommittee?

The motion alleges that NCI and ORI were under pressure from Dingell's staff to launch a misconduct investigation against Fisher.

However, it is unclear whether Dingell's staff members specifically demanded a misconduct investigation.

According to documents, subcommittee staff members first expressed an interest in NSABP in January 1994, two months before the Chicago Tribune story revealed that Montreal surgeon Roger Poisson had been found to submit fraudulent data to NSABP.

At a meeting with officials from NCI and the HHS Office of Research Integrity, Dingell staff members inquired about the aftermath of the Poisson investigation. "Congressional staff... told ORI officials that they `had been too easy on Dr. Fisher,' and repeatedly demanded to know why Dr. Fisher himself had not been charged with scentific misconduct," the motion states.

Ultimately, the investigation of Fisher focused on the question of propriety of the publication of papers that contained data from Poisson's institution, Hospital St. Luc.

One claim about the position of Dingell's staff is made by Dorothy Macfarlane, then acting deputy director of the ORI Div. of Research Investigations.

Asked by Fisher's counsel whether subcommittee staff member Suzanne Hadley ever stated that Fisher had committed scientific misconduct, Macfarlane said, "Dr. Hadley expressed the opinion that publishing falsified and fabricated data would represent misconduct."

Documents do not appear to establish whether Dingell or his staff played any role in the decision to flag NSABP publications in the databases.

And, compounding the mystery, after completing the laborious task of flagging NSABP papers in the databases, NCI and ORI officials did not even mention the flagging at Dingell's second hearing.

Fisher's attorneys have attempted to subpoena Hadley and her former colleague, Peter Stockton. However, the counsel for the House of Representatives has moved to quash the subpoena. Contacted by **The Cancer Letter**, Hadley and Stockton declined to comment on the case.

The Case of Unwitting Complainant

Formally, the misconduct case against Fisher was brought by Ronald Herberman, who at the time was the NSABP interim chairman and principal investigator.

There was, however, one problem: Herberman was never asked whether he would be willing to appear as the complainant. Herberman said he learned about the designation during a deposition by Fisher's attorneys.

Herberman was aware of the fact that a sentence from his plan for restructuring NSABP was used as a basis for launching the misconduct investigation against Fisher (**The Cancer Letter**, May 6, 1994).

The sentence, in Herberman's April 20, 1994, letter to NCI, stated that Fisher had sent letters to editors of journals notifying them that NSABP publications submitted since 1991 contained data from St. Luc Hospital.

"When we submitted the plan to NCI, we certainly had no thought or intention to raise the issue about possible scientific misconduct on the part of Dr. Fisher or others," Herberman, director of the Univ. of Pittsburgh Cancer Institute, said to **The Cancer Letter**. "I was very surprised to learn that I was listed as the complainant when I was deposed in regard to Dr. Fisher's law suit."

Herberman's designation is all the more puzzling because ORI does not require a complainant to initiate an investigation, Fisher's attorneys said.

The Rush To Flag

"After the first Dingell hearing... Broder ordered that all of Dr. Fisher's records containing St. Luc data in all the National Library of Medicine and NCI databases be flagged with annotations," Fisher's motion said.

The objective was to complete the annotations before the second hearing, Fisher's motion said.

"Broder made clear that the 'scientific misconduct' flags had to be placed on all of Dr. Fisher's records before that hearing in order to show that NCI had been responsive to the Congressman's concerns," the motion states.

NCI's International Cancer Information Service conducted a keyword search for "NSABP" and provided ORI's Macfarlane with a complete list of publications from the cooperative group.

In a deposition, Macfarlane said she went through the list, crossing out the articles that appeared to contain no data from St. Luc.

"In most cases it was clear from the title," Macfarlane said in a deposition. "If I wasn't sure, I tried to check in one way or another... One of the methods was to check against a listing of titles of protocols so that I could link a statement in the title of the article with the title of the protocol."

Macfarlane testified that she did not have complete confidence in the list she compiled.

"We were under pressure to complete the task quickly, and we had told NCI that we felt it was their responsibility to identify these, not ORI's responsibility."

Documents indicate that the decision to flag NSABP papers was never subjected to legal review.

When the job was completed, 73 citations were flagged in Medline, and another 13 were placed in

Cancerlit. NCI's Physician Data Query database was modified as well. The job was completed weeks before the June 15 hearing, documents say.

The articles were flagged with the words, "Scientific Misconduct—Data To Be Reanalyzed." The ORI investigation has not been concluded.

"[The] defendants dealt Dr. Fisher the equivalent of a `professional death sentence," the motion said. "Broder's plan to destroy Dr. Fisher's reputation was now fully realized."

Last March, Judge Ricardo Urbina granted a preliminary injunction that included the removal of flags from the databases (**The Cancer Letter**, March 24). However, the records are yet to be completely expunged, the recent motion states.

Scientist Seeks Removal Of NIH License To Use Radioactive Materials

The Nuclear Regulatory Commission last week appointed a panel to evaluate a petition that the radioactive materials license of NIH be suspended or revoked due to the contamination of a pregnant scientist.

The three-member panel will review the petition filed Oct. 10 on behalf of the scientist, Maryann Wenli Ma, who was working as a visiting fellow in the NCI Laboratory of Molecular Pharmacology when she was contaminated last June with phosphorus-32, a radioactive isotope.

"We are taking this petition quite seriously and we will be evaluating it," Joe Gilliland, an NRC public affairs officer, said.

The FBI is conducting a criminal investigation of the incident, in which Ma and 26 other NIH employees were contaminated last June.

NIH Deputy Director Ruth Kirschstein called the contaminations "apparently deliberate acts," and said NIH is cooperating with the FBI and NRC.

Isotope Was Ingested

In the petition filed with NRC, Ma said she was 17 weeks pregnant when she ate food she had left in a closed container in a conference room refrigerator on June 28. Her husband, Bill Wenling Zheng, who works in the same laboratory, discovered that Ma was contaminated when he conducted a routine sweep of the laboratory with a Geiger counter the next day.

Their lawyer, Lynne Bernabei, of Bernabei & Katz, a Washington firm, said NIH routinely violates NRC's radioactive materials handling regulations by leaving the materials in unsecured refrigerators and other unguarded storage sites.

About two weeks after the incident, it was discovered that 26 other employees in Building 37, where the laboratory is located, were exposed to P-32 found in a water cooler.

Ma and Zheng, both from China, were on a two-year fellowship at NCI. They worked with radioactive isotopes, but Ma's intention to declare her pregnancy meant that under federal guidelines she would be shielded from exposures over 0.5 rem.

Ma said when she told her supervisor, senior investigator John Weinstein, of her pregnancy, he asked whether she planned to keep the baby and throughout June tried to persuade the couple to abort the fetus because the maternity would interfere with their research project.

Morris Topf, of Bethesda, an attorney for Weinstein, was quoted in The Washington Post saying Weinstein denies that he urged Ma to abort her pregnancy.

Ma and Zheng were developing a method, called Restriction Display PCR, for displaying more efficiently the existence of expressed genes, the petition said. The method "would have had significant scientific and commercial value, if successful," Ma said in an affidavit.

According to the petition, NIH officials also tried to minimize reports of the dose of radiation Ma received, discounted any risk to Ma or her fetus and interfered with proper treatment when she sought help at a hospital for sharp pains in the liver area and persistent vomiting.

According to the petition, an independent assessment of Ma's radioactive contamination concluded that she was exposed to 9.2 rem, which is 16 times the recommended maximum dose for pregnant women and that the fetus was exposed to 6.4 rem, or 12 times the recommended dose.

At a news conference held by Ma's attorney's last week, a Bethesda community group said it has been concerned for several years about NIH's handling of radioactive material and human pathogens. The North Bethesda Congress of Citizens' Association said it would seek a Congressional investigation into the recent incident.

NRC's Gilliland said the panel will make recommendations to one of the agency's technical

directors, who will issue a "director's decision" whether to take the action requested by the petition.

Kirschstein's Statement

"We at the NIH are deeply concerned at the apparently deliberate acts that led to the contamination of Dr. Ma and 26 other employees by radioactivity," NIH's Kirschstein said in a statement Oct. 10. "We are distressed at the allegations made by Dr. Ma. We believe NIH has provided full and proper assistance to all the employees affected, and because our record with radioactive materials, as documented by the NRC, has been excellent."

Kirschstein said NIH "made every effort" to help Ma and her husband by consulting experts and providing medical care. "According to these experts, *there is no reason to believe* that Dr. Ma has been injured or her pregnancy compromised by the amount of radioactivity to which she was exposed," Kirschstein said.

According to the statement, the NIH Radiation Safety Program was under routine inspection by the NRC regional office at the time of the incident.

NCI Restructuring

Extramural Advisory Board Named, Begins Discussion

Seventeen NCI staff members have been appointed to the Extramural Advisory Board, one of two internal advisory groups created by NCI Director Richard Klausner.

The board's purpose is to enhance communication between NCI extramural program staff and the Institute's leadership, Faye Austin, board chairman and acting director of the Div. of Cancer Biology, said to **The Cancer Letter**.

"We are trying to provide a forum to improve two-way communication between extramural staff and NCI leadership, and to discuss various issues or policies that will affect the functioning of extramural operations," Austin said.

The board was scheduled to meet this week.

Klausner proposed the new Extramural Advisory Board, as well as an Intramural Advisory Board, to fill what he described as communications gap between NCI's top leadership and the staff involved in day-to-day program operations.

Austin said the extramural board will begin to set priorities for addressing the issues extramural staff face in the restructuring of NCI. The board meets once a month, but may meet more often if needed.

According to the board's charter, it will hold forums twice a year to allow all NCI extramural staff the opportunity to discuss issues with the Institute's leadership.

"We want this group to be very interactive and we want to encourage NCI staff to forward their concerns to any of the members," Austin said to **The Cancer Letter**. "In times of change it is especially important to keep lines of communication open so that people can make informed decisions, and so that we can get feedback as soon as possible if changes are having a negative effect."

Since the board is comprised entirely of NCI staff, its meetings are not required to be open to the public.

Following is the membership of the Extramural Advisory Board:

Chair, Faye Austin, deputy director and acting director, Div. of Cancer Biology.

Div. of Cancer Biology: Colette Freeman, Cancer Biology Branch; Kenneth Cremer, Biological Carcinogenesis Branch; David Longfellow, Chemical & Physical Carcinogenesis Branch.

Div. of Cancer Epidemiology and Genetics: Iris Obrams, Extramural Programs Branch.

Div. of Cancer Prevention and Control: Leslie Ford, Community Oncology & Rehabilitation Branch; Sherry Mills, Prevention and Control Branch.

Div. of Cancer Treatment, Diagnosis and Centers: Marianna Bledsoe, Cancer Diagnosis Branch; Diane Bronzert, Clinical Oncology Branch; Brian Kimes, Centers, Training & Resources Program; J.A.R. Mead, Biochemistry and Pharmacology.

Div. of Extramural Activities: Kirt Vener, Review Logistics Branch; David Irwin, Research Programs Review Section; Mary Bell, Research Resources Review Section.

Grants management: Bill Wells, Biology, Prevention & Resources Grant Section; Joan Metcalfe, Grants Administration Branch.

Contracts management: Beverly Wyatt, Treatment Contract Section.

Ex officio: Alan Rabson, NCI deputy director; Marvin Kalt, director, DEA; Philip Amoruso, associate director for extramural management; Stephen Hazen, chief, Extramural Financial Data Branch.

Executive secretary: Susan Waldrop, assistant director for program coordination.

Program Announcements

PA-96-001

Title: **Investigator-Initiated Interactive Research Project Grants**

Application Receipt Dates: Feb. 15, June 15, Oct. 15

The Interactive Research Project Grant (IRPG) program provides support for formal, investigator-initiated, collaborative relationships. The IRPG program was announced in 1993 and revised in 1994. This revision contains the Instructions for Preparing Applications for an IRPG Group that are compatible with the revised PHS 398 (rev. 5/95) application form and supersedes the previous Program Announcements.

An IRPG group consists of the coordinated submission of two or more applications for related research project grants (R01) and, to a limited extent, FIRST awards (R29) that do not require extensive shared physical resources. Although these applications must describe the objectives and scientific importance of the collaboration, each project could be accomplished independently.

The principal investigators may be from one or more institutions. Each application will be reviewed independently for scientific merit and those judged to have substantial merit will be considered for funding both as an independent award and as a component of the proposed IRPG group.

This PA includes a description of NIH policies and procedures for the preparation and review of applications for IRPG groups, including instructions to applicants that supplement the instructions in form PHS 398 (rev. 5/95). In addition to meeting the requirements of form PHS 398, each R29 and R01 application in the IRPG group must contain identical information about the IRPG group in the Research Plan and Consultants/Collaborators Section.

An IRPG group must include a minimum of two independent applications, R01 and R29 or only R01, but not only R29, applications. Applications for both new (Type 1) and competing renewal (Type 2) awards may be submitted as part of an IRPG group.

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 e-mail from: Office of Grants Information, Div. of Research Grants, 6701 Rockledge Dr., Room 3032-MSC 7762, Bethesda, MD 20892-7762, tel: 301/435-0714, fax: 301/435-3963, e-mail: girg@drgpo.drg.nih.gov

PA-96-002

Title: **Human Brain Project: Phase I Feasibility Studies**

Application Receipt Date: Jan. 16, and Oct. 15 thereafter

The purpose of this initiative is to encourage and support investigator-initiated, neuroinformatics research that will lead to new digital tools for all domains of brain and behavioral research.

This program will use the research project grant (R01) and exploratory center grant (P20) mechanisms for supporting neuroinformatics research. In addition, the interactive research project grant (IRPG), which uses the R01 and R29 mechanisms, may be employed. Anticipated maximum annual budgets (direct and indirect costs) at time of award are $230,000 for the R01 mechanism and $1.1 million for the P20 mechanism. Support may be requested for a period of up to five years (foreign R01 grants are limited to three years duration). Because not all of the Federal organizations participating in this initiative support all of these mechanisms, it is important to contact program staff prior to preparing the application.

The previously scheduled receipt date of Oct. 15, 1995 has been rescheduled. The next date for receipt of applications will be Jan. 16, 1996. The application receipt date will revert to Oct. 15 for subsequent rounds (starting with Oct. 15, 1996).

Inquiries: The PA may be obtained electronically through the NIH GOPHER (gopher.nih.gov), by NIMH's FAX4U system (301-443-5158), and from: Michael F. Huerta, Div. of Neuroscience and Behavioral Science, National Institute of Mental Health, Parklawn Building, Room 11-103, Bethesda, MD 20892, tel: 301/443-5625, fax: 301/443-1731, e-mail: mhuerta@helix.nih.gov

Komen Foundation Awards Second Round Of Grants

The Susan G. Komen Breast Cancer Foundation announced its second round of research grants for basic and clinical breast cancer research for 1995.

The second round of grants, which total $1.048 million, marks the first time in the Foundation's history that it has offered two sets of research grants in one year. The second round grant monies will be used for direct costs relating to basic and clinical research projects investigating various aspects of breast cancer.

Komen Foundation 1995 second round grantees for basic breast cancer research are: Michael Andreeff, M.D. Anderson Cancer Center; Andrew Godwin, Fox Chase Cancer Center; Jeffrey Holt, Vanderbilt School of Medicine; Terumi Kohwi-Shigematsu, La Jolla Cancer Research Foundation; Stephen Weiss, Univ. of Michigan Medical Center.

The second round grant recipients for clinical breast cancer research are: Michael Clarke, Univ. of Michigan Medical Center; John Reed, La Jolla Cancer Research Foundation; Jerry Shay, Univ. of Texas Southwestern Medical Center.