THE CANCER LETTER INTERACTIVE

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Wider Use Of Adjuvant Chemotherapy Recommended By NIH Consensus Panel

An expert panel convened by NIH last week recommended wider use of adjuvant chemotherapy for most women with localized breast cancer, hormonal therapy for women whose tumors have estrogen receptors, and radiation therapy for women whose cancer is at high risk for recurrence.

The panel took a conservative view of the use of taxanes in the treatment of localized disease. Last year, FDA approved Taxol (paclitaxel) for the adjuvant treatment of node-positive breast cancer.

The agency's approval was based on the results of a 3,170-patient

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In Brief:

Lame-Duck Session Required To Complete HHS Funding Bill; Nobel Laureates For Gore

UNABLE to reach an agreement with the Clinton Administration over education finance and tax issues, Congress went home for the elections last week without finalizing the appropriations bill that funds NIH. Altogether, seven of the 13 spending bills have been signed by President Clinton, and the Labor, HHS & Education bill is the only piece of legislation that is yet to be sent to the White House. Congress is expected to meet in a lame duck session to complete its work. NIH was expected to get a 15 percent increase. . . . **FIFTY-SEVEN NOBEL PRIZE** winners and more than 750 other prominent U.S. scientists and engineers endorsed Al Gore and Joe Lieberman, praising their plans to increase investment in scientific research, according to a Nov. 2 statement by the Gore campaign (received after **The Cancer Letter's** deadline last week). The first signatories of the letter were physicist **Murray Gell-Mann** and Memorial Sloan-Kettering Cancer Center President **Harold Varmus**. The text of the letter is available at http://www.algore.com/scifg/endorsement.html. . . . **KANSAS CANCER RESEARCHERS** have united to form a Center for Cancer Experimental Therapeutics and successfully competed for a grant from the NIH National Center for Research Resources. The five-year, $9.9 million Center of Biomedical Research Excellence grant will bring together researchers from the University of Kansas-Lawrence, the University of Kansas Medical Center, Kansas State University and Emporia State University. **Gunda Georg**, distinguished professor in medicinal chemistry at KU, is the principal investigator. . . . **CONSTANCE PERCY**, an NCI employee for 30 years, announced her retirement, effective in January, at an Oct. 19 meeting of Principal Investigators on Surveillance, Epidemiology, and End Results

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Taxol Adjuvant Therapy Data "Inconclusive," Panel Says

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randomized trial conducted by the Cancer and Leukemia Group B. After reviewing updated results from that trial, as well as new data from another trial, the NIH panel said the evidence for use of paclitaxel in adjuvant therapy was "inconclusive."

The panel's recommendations emerged from a Consensus Development Conference on Adjuvant Therapy for Breast Cancer held Nov. 1-3 at on the NIH campus in Bethesda, Md. The conference was sponsored by the National Cancer Institute and the NIH Office of Medical Applications of Research.

"Clinical trials over the past 10 years have contributed an enormous amount of new information about adjuvant therapies," said panel chairman Patricia Eifel, professor of radiation oncology at M.D. Anderson Cancer Center.

"Women with breast cancer have more treatment options and a better chance of surviving their disease than ever before," Eifel said. "At the same time, making treatment decisions has become a more complex process for them and their physicians due to a growing list of effective options."

Recommendations Called "Balanced"

Experts contacted this week characterized the panel's recommendations as solid and not likely to cause controversy.

"The recommendations are balanced," said Richard Schilsky, CALGB chairman and associate dean for clinical research at the University of Chicago. "You could say they are a little bland. The panel avoided staking out extreme positions on any issue."

Schilsky said the panel's moderate stance was appropriate. "Most of the data we see in adjuvant therapy demonstrate very small increments of improvement," he said. "If there is a small benefit for some new therapy, compared to a standard, what we'd like to figure out is, who are the women who are likely to benefit? The small differences we see in many of the studies are probably a reflection of the fact that we don't understand the underlying biology very well."

Because of their emphasis on irrefutable results from randomized clinical trials, consensus conference recommendations in cancer treatment are likely to reflect a more conservative approach than what might be encountered in clinical practice in individual cases.

Nevertheless, the panel's statement on taxanes placed it in the highly unusual position of not supporting an FDA-approved indication:

"Taxanes (docetaxel, paclitaxel) have recently been demonstrated to be among the most active agents in the treatment of metastatic breast cancer," the statement said. "As a result, several studies have explored the clinical utility of adding these drugs to standard doxorubicin/cyclophosphamide treatment programs in the adjuvant treatment of node-positive, localized breast cancer. Although a number of such trials have completed accrual and others remain in progress, currently available data are inconclusive and do not permit definitive recommendations regarding the impact of taxanes on either relapse-free or overall survival. There is no evidence to support the use of taxanes in node-negative breast cancer outside the setting of a clinical trial."

Last year, FDA's Oncologic Drugs Advisory Committee voted unanimously to recommend approval of Taxol for sequential administration to doxorubicin-containing therapy for the adjuvant treatment of node-positive breast cancer (**The Cancer Letter**, Sept. 24, 1999).

FDA approved the indication based on data from a CALGB/Intergroup trial in node positive breast cancer patients who received four courses of doxorubicin and cyclophosphamide, followed by either Taxol or no further therapy. Patients who received four courses of Taxol once every three weeks had a

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26 percent reduction in death and a 22 percent reduction in disease recurrence (**Business & Regulatory Report**, November 1999).

"The CALGB data which were the basis for the FDA approval actually do continue to show a statistically significant advantage for the group that got Taxol overall, though the magnitude is smaller than it was a year ago," Schilsky said to **The Cancer Letter**.

Three years after treatment, the disease-free survival rate was 73 percent for the group that received only the standard drugs and 77 percent for the group that also received Taxol, a five percent difference. "The addition of four cycles of paclitaxel after the completion of a standard course of CA [doxorubicin and cyclophosphamide] substantially improves disease-free and overall survival of patients with early breast cancer," said I. Craig Henderson, adjunct professor of medicine, University of California, San Francisco, who presented updated results of the trial.

Martine Piccart, chairman of the Breast International Group and head of the chemotherapy department at Jules Bordet Institute in Brussels, came to the opposite conclusion in a presentation to the consensus panel. "FDA may have made a hasty decision" in approving Taxol for adjuvant therapy, Piccart said. The European Regulatory Agency decided against approval after reviewing the data last year.

"The general view in the scientific community is that a single randomized trial does not constitute sufficient evidence, no matter how compelling the results," Piccart said. "Given that numerous randomized trials of taxanes will be reported in the next few years and that the absolute survival difference reported by the Intergroup trial was modest (2 percent), it would have been more prudent to await corroborative evidence before approving the routine use of adjuvant taxanes."

The consensus panel agreed. "Now we have more data than we had at the time of the ODAC meeting a year ago, and in our opinion, it's not as convincing as it was then," said panel member Robert Mayer, vice chairman for academic affairs in the adult oncology department at Dana-Farber Cancer Institute. The data available from other trials, including one by the National Surgical Adjuvant Breast and Bowel Project, are "extremely preliminary," Mayer said.

Last year, FDA and its advisory committee debated the Intergroup trial's results in subgroups of node-positive breast cancer that are positive or negative for estrogen receptors. The Intergroup trial found that the benefit for Taxol was primarily seen in ER-negative cancers. However, this subset analysis was not planned before the trial began, and therefore not considered solid evidence.

"Though it was a large group of patients, over a thousand ER-negative patients, you can't describe it as more than hypothesis-generating," said Schilsky. "What this study tells us overall is that there are patients who benefit from Taxol in the adjuvant setting and we have to figure out who those patients are."

Several trials in the U.S. and in Europe are using new molecular tumor profiles to try to identify subgroups of patients more likely to benefit from taxanes, clinical investigators said.

The Breast Cancer Cooperative Group of the European Organization for the Research and Treatment of Cancer has begun a trial in locally advanced breast cancer to examine the predictive value of p53 mutations in response to taxanes, Piccart said.

CALGB will use tumor tissue collected from patients on the Intergroup trial to conduct a molecular analysis study, Schilsky said.

Jeffrey Abrams, a senior investigator at NCI and chairman of the consensus conference planning committee, said the NIH panel's position on taxanes was reasonable. "We asked panel members to base their recommendations on the evidence, and the evidence only goes so far," he said to **The Cancer Letter**.

"There are two ways to look at the evidence," Abrams said. "One is the approach taken by Larry Norton [head of the Division of Solid Tumor Oncology at Memorial Sloan-Kettering Cancer Center], who told the panel that since taxanes are reasonably well tolerated, he would prefer to err on the side of giving them, with the hope that they will result in a survival benefit, because he would hate to be in a position in five or 10 years from now of feeling that he had denied women the therapy.

"Another way to look at the evidence is that the NSABP and CALGB studies seemed to show that in women who had positive hormone receptors and positive nodes, paclitaxel didn't seem to provide a benefit," Abrams said. "In both studies, the benefit, if there was one, was in the hormone receptor-negative group. So maybe this is the group that will ultimately benefit from taxanes."

FDA could ask ODAC to review the Taxol approval in light of the new data, Abrams said to **The Cancer Letter**.

"The ODAC decision at the time was reasonable

one, based on the evidence," he said. "The taxanes had shown impressive activity for women with metastatic disease. Given that drug didn't have overwhelming toxicity, the logical progression was to move it into treatment against earlier disease. The data, however, do now show that one trial sometimes isn't enough."

"I don't see any reason for the FDA approval to be jeopardized," Schilsky said. "What has to happen now is the community of physicians and patients need to be aware of the updated information. I'm pretty well convinced that there are women who will benefit from Taxol. I would continue to give it especially to ER-negative patients. That is very much in keeping with the recommendation as expressed in the package insert for Taxol."

Schilsky, who served as chairman of ODAC last year, did not take part in the committee's discussion or voting on Taxol.

High Dose Chemo Not Recommended

The consensus panel also did not support the use of high-dose chemotherapy with peripheral stem cell support outside of clinical trials.

William Peters, director of the Barbara Ann Karmanos Cancer Institute in Detroit, presented an update of CALGB 9082, a randomized trial testing high-dose chemotherapy with stem-cell support for women with 10 or more positive nodes.

When Peters presented the data from the same trial at the annual meeting of the American Society of Clinical Oncology in 1999, the results were considered too early to draw conclusions and there was no statistically significant difference in event-free or overall survival between the high-dose and the intermediate dose groups. The hope was that over time, survival for the high-dose group would increase.

"That has not panned out," Schilsky said. "The data are negative with respect to the benefit from high-dose therapy."

However, the trial demonstrated "excellent outcomes" overall, Schilsky said. "Whether that's because both therapies are good therapies or because the patients were carefully selected and staged, or both, we can say that for women with 10 or more nodes, if we put them through rigorous staging and treat with either regimen, they will have a pretty good outcome. What we don't know is, if we stage them carefully and use less toxic therapy, would they have as good an outcome?"

Five Years of Tamoxifen

In its report, the panel said decisions about the choice of adjuvant therapy should be based on age, tumor size, presence or absence of hormone receptors, presence or absence of cancerous lymph nodes, and other generally accepted factors. New technologies and molecular markers hold potential, but require further study.

Hormonal therapy is recommended for women whose breast tumors contain estrogen receptors, regardless of age, menopausal status, tumor size, or whether the cancer has spread to nearby lymph nodes, the panel said. Five years of tamoxifen is currently the standard adjuvant hormonal therapy. The panel said that data do not support the use of tamoxifen for longer than five years outside of a clinical trial, but that this is an important area for investigation.

The panel recommended chemotherapy with a combination of drugs for most pre- and post-menopausal women regardless of lymph node involvement or estrogen receptor status. Including anthracycline drugs as part of chemotherapy regimens produces a small but statistically significant survival advantage over regimens that do not contain anthracyclines.

Women who have undergone mastectomy and who have four or more cancerous lymph nodes or an advanced primary tumor benefit from post-surgical radiation, the panel concluded. The panel added that it is unclear whether women with one to three cancerous lymph nodes benefit from radiation therapy and that this question should be tested in a randomized clinical trial.

Adjuvant treatments often involve serious side effects such as premature menopause, weight gain, mild memory loss, and fatigue. The panel recommended that selected trials of adjuvant therapy include quality-of-life measures. Long term follow-up of women in these trials is important to fully understand the effects of adjuvant therapies, the panel said.

The panel also endorsed continued development of decision-making tools to help patients and their physicians weigh the risks and benefits of adjuvant treatments.

The panel called for further studies of:

—combined hormonal therapy

—hormonal therapy versus chemotherapy in premenopausal women whose tumors have estrogen receptors

—high dose chemotherapy

—taxanes

—factors that predict the effectiveness of treatments in individual patients

—new drugs, including trastuzumab and bisphosphonates

—radiation techniques that reduce the dose to normal tissue such as the heart and lungs

—the effectiveness and side effects of adjuvant therapies in women older than 70.

NCI's Abrams said the panel members, who are not breast cancer experts, "did a very good job" in writing its report. "Those of us who work in breast cancer were concerned whether the panel would be able to assimilate all the knowledge and make recommendations," he said. "With good presentations and clear discussion, the process demonstrated that people who don't work in the field all the time can come up with good recommendations."

"Few fields have benefited as much from randomized trials as breast cancer," Barnett Kramer, director of the Office of Medical Applications of Research, said in his opening remarks. "It was Bernard Fisher and the NSABP that established the worth of the randomized trial in breast cancer. It is in this rich environment that we now no longer debate whether adjuvant therapy works, but how to refine the regimens. We've come a long way from consensus conferences held in 1985 and 1990."

The NIH Consensus Statement on Adjuvant Therapy for Breast Cancer is available at http://consensus.nih.gov or by calling 888-NIH-CONSENSUS (888-644-2667).

Scientific Misconduct:

U.S. Oncologists To Audit Another Bezwoda Trial

The University of Witwatersrand in Johannesburg has hired two U.S. oncologists to conduct an audit of a frequently cited, influential trial of high-dose chemotherapy as a treatment for metastatic breast cancer.

This is the second effort by U.S. oncologists to scrutinize the trials conducted by Werner Bezwoda, a researcher whose work was influential among proponents of high dose chemotherapy for breast cancer.

This time around, auditors will focus on the study that randomized 90 patients with metastatic disease to either high-dose chemotherapy or a conventional regimen used at the university.

The data from the metastatic trial were published in the Journal of Clinical Oncology (1995; 13:2483-2489). That study, which reported a highly statistically significant advantage for high-dose therapy, continues to be cited in published articles in the medical literature. At last count, the study in question was cited 324 times.

"This study was the only randomized trial reporting results of high-dose therapy extant in the middle 1990s, and it was cited in numerous individual cases as justification for providing such therapy to women with metastatic breast cancer," said Raymond Weiss, a consultant and clinical professor at Georgetown University, the auditor who will be conducting the new audit.

Weiss will be working with Clifford Hudis, chief of the Medical Breast Service at Memorial Sloan-Kettering Cancer Center.

An earlier audit, conducted by Weiss and colleague Roy Beveridge, an oncologist at Inova Fairfax Hospital, led to the discrediting of Bezwoda's trial of high-dose chemotherapy for high-risk primary breast cancer.

The results of the adjuvant trial were reported at a plenary session during 1999 annual conference of the American Society of Clinical Oncology. Inaccuracies in that trial were described by Weiss and Beveridge in an article in the Lancet (Lancet 2000; 355:999-1003).

The ASCO leadership withdrew the paper and retracted the data presented by Bezwoda.

After the audit, which was conducted last January, Bezwoda admitted misrepresentation of the chemotherapy regimen he reported was given to the control patient group. He was discharged from his position as head of Hematology-Oncology at the University of Witwatersrand and is in solo private practice in Johannesburg.

"The impact of this scientific fraud can only be described as monumental because it negated the only 'positive' randomized trial of the five reported at the 1999 ASCO meeting," said Weiss. "It also injected additional controversy into a form of therapy that had already sparked heated arguments among oncologists in the 1990's regarding the efficacy of high-dose chemotherapy for breast cancer."

"With the high-risk study now discredited as fraudulent, the University is investigating the validity of the other major study Bezwoda reported," Weiss said.

George Canellos, editor of JCO, published an

editorial (JCO 2000;18:2353) calling for such an audit of the data published in his journal.

An on-site audit will be performed in the last week of November, with Weiss and Hudis as the two principal auditors. Weiss has been chairman of the CALGB Data Audit Committee for 19 years. Hudis is also a member of this CALGB committee and is an oncologist noted for his expertise in breast cancer.

Geraldine Gill, a Johannesburg pharmacist and independent auditor of pharmaceutical studies, has been hired to assist with the audit. Gill has spent several weeks searching the medical records files of two hospitals where this study was supposed to have been conducted to gather all possible patient records, using the 90-patient enrollment list (with patient names and hospital numbers) provided to the auditors by Bezwoda at the time of the January audit.

The audit will be conducted in the same fashion as the previous one, but Bezwoda will not be involved.

Bezwoda has appealed his dismissal from the University faculty, and this appeal remains in litigation.

Weiss and Hudis said they plan to publish the findings of the audit.

Regulatory Agencies:

FDA, HCFA Form Council On Biomedical Imaging

FDA and the Health Care Financing Administration have formed an Interagency Council on Biomedical Imaging in Oncology.

The council is designed to serve as a sounding board for investigators and manufacturers attempting to take emerging medical imaging technology to market, the agencies said in a recent statement.

The council consists of staff from the FDA, HCFA, and NCI with experience and knowledge concerning the decision-making processes for their agency for medical imaging products. Additional agency staff may be added to the core group on specific matters when needed.

Excerpted text of the announcement by the agencies follows:

The purpose of the council is to provide multi-agency advice that may help guide imaging technology developers in the fight against cancer. The council will provide advice on projects or project proposals brought voluntarily by investigators and technology/device developers in industry and academia. It offers a new, multi-agency perspective to the communication with government agencies that is already available to investigators and companies. The council held its first meeting on July 20.

Why does the nation need this?

In September 1999, NCI and the National Electrical Manufacturer's Association co-sponsored the First NCI-Industry Forum and Workshop on Biomedical Imaging in Oncology. This meeting included senior leadership from industry, FDA, HCFA, NCI, and researchers from academia. We gathered to discuss ways to align investment in imaging technologies with the biomedical opportunities and unmet clinical needs in cancer.

Participants asked NCI to convene meetings between the multiple government agencies and industry to facilitate forward movement of promising technologies into the marketplace. The goal is to bring effective technologies into clinical use so that an impact on the public health can be achieved. The summary of the Forum and Workshop and follow-up comments to that conference can be reviewed on http://dino.nci.nih.gov/dctd/forum.

What will the Interagency Council do?

The three agencies participating in the Interagency Council all have different roles in the development of medical imaging technologies. NCI has created and is expanding a Biomedical Imaging Program. This effort currently funds innovative device and technology development, small animal imaging, in vivo cellular and molecular imaging centers, and a clinical trials imaging network (ACRIN). FDA is responsible for determining the safety and efficacy of specific products proposed for marketing and for monitoring those products while they are on the market. HCFA is responsible, as a federal health insurance provider, for determining coverage and reimbursement for products and services in the marketplace for their beneficiaries. By participating in the council, these three agencies will be able to provide coordinated assistance to sponsors as they go through the development and regulatory processes necessary to bring products to market.

The specific roles envisioned by the participants in the council are as follows:

NCI will provide input on scientific and medical issues, information on the initiatives and research resources available to fund or develop imaging technologies, explain the process for gaining access to such resources, and facilitate future interactions of imaging technology developers with NCI staff or with other NCI-sponsored investigators.

FDA will provide information on the issues that

may need to be addressed to establish that a product is safe and effective, explain its existing guidance and procedures, and facilitate future interactions of imaging technology developers with its regulatory staff. How FDA may interact with sponsors is defined in statutes, regulations, and performance goals, and FDA expects that the council will provide a mechanism to explain to imaging technology developers how to work within existing processes to bring products to market.

HCFA will provide information on its coverage and reimbursement processes, and facilitate future interactions of imaging technology developers with HCFA staff.

The products of the Interagency Council will be:

—Suggestions on the scientific and medical issues related to proposals, and information regarding available resources, potential relevant contacts for investigators within FDA, HCFA, NCI or with other investigators; and

—Written summary of the session, detailing the agenda topic, participants, and proposed plans or advice given or discussed.

Will the Interagency Council maintain confidentiality?

Council meetings will be closed to the public. Information exchanged with the Interagency Council will be held in confidence by the participants, consistent with applicable laws. NCI, FDA, and HCFA are all agencies in the Department of Health and Human Services, and by law are obligated to protect from disclosure trade secrets and confidential commercial information.

Who can present before the Interagency Council?

Any company or academic investigator developing a device or technology relevant to biomedical imaging in cancer who seeks the perspectives of a multi-agency assessment and discussion may present.

What is the process?

The due date for requests was Oct. 9. The council will consider additional calls for requests after the second Interagency Council meeting has taken place on Nov. 20. The council expects to meet about four times each year, if it receives enough requests to do so.

The council may schedule discussion of several similar types of products at a single meeting. Generally, the council will give preference in scheduling meetings to promising new technologies that are viewed as important new developments in cancer imaging.

Request To Present

The requestor should follow a standardized format that the council will make available on the Internet or that can also be completed and sent by hard copy.

Within approximately three working days of receipt of the letter of request, the council coordinator will send a letter acknowledging receipt of the request. Within 30 days, and after consultation with council representatives, the council coordinator will either invite the requestor to a meeting (at the requestor's expense) if it appears that the question or issue would benefit from a multi-agency discussion, or indicate the council's determination that a meeting will not be provided. A letter of invitation will ask the requestor to provide specific questions or issues they want to discuss with the council, and, at the discretion of the requestor, relevant background information and data in a packet not to exceed 25 pages.

If it is not thought that a multi-agency discussion is required or desirable, then a letter will be sent to requestor stating the reason why such a meeting request has been denied. If appropriate, the letter may suggest other viable paths the requestor might pursue.

If the council has already met with requestor before, the council coordinator will determine if this is a new situation that requires a multi-agency discussion. All letters will be kept on file with the council at the NCI.

What the Interagency Council is Not

The Interagency Council is intended to provide research groups with advice on the spectrum of scientific, regulatory, coverage and reimbursement issues that affect the development of imaging devices or technologies.

The council's advice does not replace the legislatively mandated roles and functions of the agencies individually. In particular, the Interagency Council does not approve funding of research and development, and does not make or guarantee FDA regulatory, or HCFA coverage or reimbursement decisions.

A form to request to present to the Interagency Council, in printable PDF format, is available at http://www.cancer.gov/scienceresources/announcements/imageform.pdf.

For further information,contact Ellen Feigal, deputy director, Division of Cancer Treatment and Diagnosis, NCI, 31 Center Dr., Building 31 Room 3A44, Bethesda, MD 20892-2440, tel: 301-496-6711, fax: 301-496-0826, e-mail: ef30d@nih.gov

Funding Opportunities:

NCI Grant Supplements

Minority Supplements to NCI Institutional Clinical Oncology Research Career Development Award K12 Program

The Comprehensive Minority Biomedical Branch of NCI has initiated the Continuing Umbrella of Research Experiences, a strategy for increasing the number of underrepresented populations engaged in basic, clinical and population-based biomedical cancer research (http://deainfo.nci.nih.gov/cmbs/index.htm). NCI Institutional Clinical Oncology Research Career Awardees are invited to participate by submitting administrative supplements for promising minority postdoctoral fellows in cancer research settings. The mechanism will support one selected candidate with up to five years of funding for postdoctoral candidates per project period.

Inquiries: Bobby Rosenfeld, senior program analyst, e-mail: rr63v@nih.gov or Sanya Springfield, chief, Comprehensive Minority Biomedical Branch, Office of Centers, Training and Resources, NCI, 6116 Executive Blvd. Suite 7013 MSC 347, Bethesda, MD 20892, phone 301-496-7344; fax 301-402-4551; e-mail ss165i@nih.gov

NCI Cancer Center P30 Supplements for High School and Undergraduate Research Experience

CMBB has initiated the CURE program for underrepresented populations, beginning with introductory science experiences at the high school student level. NCI-supported Cancer Centers are invited to participate in the initial stages of the CURE program by submitting administrative supplements for placing promising high school and undergraduate students in peer-reviewed funded research programs that form the research base of the cancer center. The maximum period of support is five years.

Inquiries: See preceding entry.

Minority Supplement to the NCI Cancer Education and Career Development Award R25T

CMBB of NCI has initiated the CURE program for underrepresented populations, beginning with introductory science experiences at the high school student level and continuing progressively and selectively to the production of well-trained scientists conducting independent cancer research. The mechanism of support will be an administrative supplement to an active NCI Cancer Education and Career Development R25T grant for one selected candidate with up to five years of funding for predoctoral candidates and three years of funding for postdoctoral candidates per project period.

Inquiries: See preceding entries.

In Brief:

Constance Percy Retires From NCI After 30 Years

(Continued from page 2)

Program contracts. Percy is an expert in nosology, the classification of cancer cases and deaths. At the annual meeting of the International Association of Cancer Registries last weekend, Percy announced the publication of ICD-O-3, the international coding standard for cancer cases. The U.S. will begin coding cases using this standard as of Jan 1. Percy was the lead editor of two earlier versions of the standard that have been in use for the past three decades. A recognized leader in the development of worldwide standards for cancer classification systems, Percy received the most distinguished member of the National Cancer Registry Association award and the North American Association of Central Cancer Registries award for outstanding contribution in the field of cancer registration. She also received two Public Health service awards for superior service and special recognition. Before she came to NCI, Percy had a 20-year career at the American Cancer Society, where she worked as a health statistician and an expert in classification standards for cancer. . . . **VANDERBILT-INGRAM CANCER CENTER** presented the Frances Williams Preston Award for Breast Cancer Awareness to **Susan Caro**, director of the center's Family Cancer Risk Service. Caro, a nurse specialist in the center's breast service, started the center's cancer risk assessment counseling service on a part-time basis more than 10 years ago. Caro is a member of the Susan G. Komen Foundation board and serves as its co-chair for education. She was honored earlier this month with Komen's Local Hero Award. . . . . **SUSAN ELLMANN FEINMAN**, 70, a microbiologist and an author who retired in 1993 as a contract proposal review administrator at NCI, died of ovarian cancer Nov. 2 in Rockville, Md. Feinman also was the author of three technical books about antibiotic resistance, allergic sensitization and toxicity to chemicals, and women's careers and health. She worked at the Alcohol, Drug Abuse and Mental Health Agency, FDA, and the Consumer Product Safety Commission before joining the Institute in 1990. . . . **MARJORY WEISS**, 82, an NCI biomathematician who retired in 1978 after 21 years with the Institute, died of cancer Nov. 2 at her home in Bethesda. She was a graduate of the University of Michigan and did graduate work in mathematics at American University.

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AGENDA UPDATE

City of Hope National Medical Center
Los Angeles, California

Dana-Farber Cancer Institute
Boston, Massachusetts

Fox Chase Cancer Center
Philadelphia, Pennsylvania

Johns Hopkins Oncology Center
Baltimore, Maryland

Huntsman Cancer Institute at the University of Utah
Salt Lake City, Utah

Fred Hutchinson Cancer Research Center
Seattle, Washington

James Cancer Hospital and Solove Research Institute at the Ohio State University
Columbus, Ohio

Robert H. Lurie Comprehensive Cancer Center of Northwestern University
Chicago, Illinois

Memorial Sloan-Kettering Cancer Center
New York, New York

H. Lee Moffitt Cancer Center and Research Institute at the University of South Florida
Tampa, Florida

Roswell Park Cancer Institute
Buffalo, New York

St. Jude Children's Research Hospital
Memphis, Tennessee

Stanford Hospital and Clinics
Stanford, California

UCSF Comprehensive Cancer Center
San Francisco, California

University of Alabama at Birmingham Comprehensive Cancer Center
Birmingham, Alabama

University of Michigan Comprehensive Cancer Center
Ann Arbor, Michigan

UNMC/Eppley Cancer Center at the University of Nebraska Medical Center
Omaha, Nebraska

University of Texas M. D. Anderson Cancer Center
Houston, Texas

6TH ANNUAL CONFERENCE

February 28 – March 4, 2001

Practice Guidelines and Outcomes Data in Oncology

*PRELIMINARY AGENDA

Wednesday, February 28

Join us as we kick off the conference with a welcome reception from 7:00–9:00 PM.

Thursday, March 1

- Welcome from William T. McGivney, PhD, CEO of the NCCN.
- Rodger J. Winn, MD, Chairman of the NCCN Guidelines Steering Committee, will follow with an overview of the guidelines development process.
- Guideline updates to be presented include breast cancer, multiple myeloma, lung cancer, and sarcoma.

Friday, March 2

- Roundtable discussion, "Patient Information and Specimens: Issues of Privacy, Confidentiality, and Ownership."
- NCCN Outcomes Database: Sessions will discuss current updates of the breast database and directions in lymphoma and pain, and new initiatives in extending the database to the community level.
- Panel discussions on the application of NCCN guidelines and pricing models in the marketplace, new directions in pain management, and a HCFA update.

Saturday, March 3

- Session on the NCCN Symptoms Assessment Project
- Supportive care guideline updates will be highlighted including fever and neutropenia, distress management, and palliative care.
- Update of the NCCN Non-Hodgkin's Lymphoma Pathway
- Oncology Business Update

Sunday, March 4

- Update of the NCCN Chronic Myelogenous Leukemia Guidelines
- Discussion of the appropriateness of bone marrow transplant by NCCN transplant experts in hematologic and solid tumors.
- NCCN Melanoma Guidelines
- 12:15 PM: Departures according to individual itineraries

*Speakers will include NCCN guideline chairpersons and panel members, as well as other experts from the NCCN and the oncology arena.

Conference Chairmen

Rodger J. Winn, MD
Chairman, Adult Guidelines Steering Committee, NCCN

William T. McGivney, PhD
Chief Executive Officer, NCCN

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REGISTER ONLINE AT WWW.NCCN.ORG or FAX THIS REGISTRATION FORM TO 215-413-3953

❑ Please register me for the National Comprehensive Cancer Network's Sixth Annual Conference.

Name as you would like it to appear on your badge: (Please Print)

Degree(s)

Affiliation

Address

City State ZIP

Business Phone Number

Fax Number

Email Address

CONFERENCE REGISTRATION FEE

	Until 1/15/01	After 1/15/01
❑ Non-NCCN Member	$375	$425
❑ NCCN Member	$325	$425
❑ Federal Employee	$325	$425

(Please check one of the boxes above)

METHOD OF PAYMENT

(Registration fee and 1-night hotel deposit required)

❑ Check Enclosed ❑ VISA ❑ Mastercard ❑ AmEx

- If you will be sending a check, please make checks payable to **CoMed Communications, Inc.,** and mail to address listed below. For credit card payments, all billing information is required.

Signature

Cardholder's Name

Billing Address

City State ZIP

CC Account Number

CC Expiration Date

(Your credit card will be charged by CoMed Communications, Inc.)

HOTEL RESERVATIONS

The Marriott Harbor Beach Resort, Fort Lauderdale, Florida

Reserve a ❑ Single ❑ Double room for the following nights:

❑ Wednesday, 2/28/01 ❑ Thursday, 3/1/01

❑ Friday, 3/2/01 ❑ Saturday, 3/3/01

Be sure to check the nights you will be staying.

❑ Check here if you have any special accommodation or dietary needs.

Indicate what those needs are:

❑ Check here if you want to be contacted regarding air fares.

Please return this form to CoMed Communications, Inc.

Fax: 215-413-3953

Phone: 215-592-1363, ext. 1441

Mail: NCCN Conference
c/o CoMed Communications, Inc.
210 West Washington Square, 8th Floor, Philadelphia, PA 19106

Or, register online at **www.nccn.org**

CONFERENCE INFORMATION

REGISTRATION

For those who register by January 15, 2001, the fee is $375, except as noted in the next paragraph. After January 15, 2001, the registration fee will be $425 for all. The registration fee includes all conference materials, breakfasts, lunches, and arrival cocktail buffet the evening of February 28. In addition, the program workbook will be supplied at the conference.

All registrants from NCCN member institutions and their satellite cancer centers are eligible for a reduced registration fee of $325 if registered no later than January 15, 2001. For federal government employees, the registration fee will be discounted to $325 if they register and pay by January 15, 2001. Registration and payment after January 15, 2001 will be $425 for all.

ACCOMMODATIONS

The conference will be held at the Marriott Harbor Beach Resort in Fort Lauderdale, Florida. A limited number of rooms at a discounted rate have been arranged for registrants of the NCCN conference.The special rate is $309 per night, single or double occupancy, plus tax. At the time of reservation, a 1-night deposit is required by a credit card as a guarantee for all reserved nights. Because space is limited at the Marriott, a block of rooms at the Sheraton Yankee Clipper and the Radisson has also been reserved for conference registrants.

Please contact CoMed Communications, Inc., the NCCN Conference Secretariat, at 215-592-1363, extension 1441. World Travel, Inc., the official travel service of the NCCN Conference, will also work with federal employees to reserve rooms at nearby hotels accepting the maximal level of government housing allowance.

AIRLINE TRAVEL ARRANGEMENTS

World Travel, Inc. is the official travel agency for the NCCN Conference. Special discounts have been negotiated for conference attendees. World Travel, Inc. has the ability to search all carriers and offer a variety of discounts to ensure the lowest fare is obtained. Note: Registrants reserving 60 days in advance will receive additional discounts.

To take advantage of the services, discounts, and low fares offered by World Travel, Inc., please call 1-800-867-2970 Monday through Friday from 8:30 AM to 5:30 PM Eastern Time. Identify yourself as an NCCN conference attendee.

CANCELLATION POLICY

HOTEL: Owing to hotel requirements for guarantees of conference space, the demand for hotel rooms, and the special discount room rate, all cancellations of rooms (whether for all nights or some nights) must be received in writing by January 31, 2001. **After January 31, 2001, you will be responsible for reserved and unused room nights.**

REGISTRATION: A substitute attendee may be sent in place of the original registrant. A $50 administration fee will be charged for all cancellations received before January 31, 2001. After January 31, 2001, the registration fee is nonrefundable.

This registration form may be photocopied for your colleagues.

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