THE



PO Box 9905 Washington DC 20016 Telephone 202-362-1809

Is More Better? ASCO Plenary Session **Opens Debate On High-Dose Chemotherapy**

ATLANTA—There was something for everyone at the eagerly awaited discussion of the results of bone marrow transplant trials in breast cancer:

Opponents of high-dose chemotherapy were given one of the most visible platforms in the world-the plenary session of the American Society of Clinical Oncology annual meeting-from which to pronounce the demise of the controversial procedure.

Proponents of stem cell transplantation were far from capitulation. Taking their turn at the dias, they called for additional studies and a re-(Continued to page 2)

In Brief:

Blumberg To Direct NASA Astrobiology Institute: Hopkins To Get \$20M Donation

BARUCH BLUMBERG, Nobel laureate and scientist at Fox Chase Cancer Center, will direct the NASA Astrobiology Institute at NASA Ames Research Center, Moffett Field, CA. He will continue his work on cancer prevention at Fox Chase, the center said. The Institute, established last July, is an interdisciplinary virtual research center managed by NASA to search for the origins of life on Earth and in the universe. . . . JOHNS HOPKINS Oncology Center has received pledges of \$20

million from two donors for its new 10-story cancer research building. The Bunting Family and the Jacob and Hilda Blaustein Foundation each pledged \$10 million for the new building, scheduled to open next January. ... QUEEN NOOR of Jordan will be the honorary chair of the national Coalition for Cancer Survivorship's "Rays of Hope" annual candlelight vigil, scheduled for Sept. 25, in Washington, the NCCS said. Last year, Noor spoke at The March: Coming Together to Conquer Cancer. Noor's husband, King Hussein, died earlier this year of cancer. Contact NCCS for information on the Rays of Hope event, 888-650-9127, or http:// www.cansearch.org. . . . MARY LOU SMITH has joined the Coalition of National Cancer Cooperative Groups as director of government, patient, and payer relations. Smith was previously at the Blue Cross and Blue Shield organization in Chicago. She is a member of the patient representative committee of the Eastern Cooperative Oncology Group. .

. . "WIRED FOR HEALTH and Well-Being: The Emergence of Interactive Health Communication," is the title of a recently issued report by the Science Panel on Interactive Communication and Health, an (Continued to page 8)

Vol. 25 No. 21 May 28, 1999

© Copyright 1999 The Cancer Letter Inc. All rights reserved. Price \$275 Per Year

Clinical Trials: Oncologists, Insurance Executive, Comment On The Results **Of Transplant Trials** ... Page 6

OPRR Reinstates **Duke Medical Center's** License To Conduct Human Studies

... Page 7

Funding Opportunities: **HHS To Fund Studies On Organ Donation** ... Page 8

Leukemia Society Offers Scholar Awards; **Armstrong Foundation** Seeks Grant Proposals ... Page 8



Round Two Begins In Debate Over High-Dose Therapy

(Continued from page 1)

examination of existing definitions of high-dose therapy.

Three out of four phase III trials of high-dose chemotherapy/stem cell transplants presented at the plenary session reported no advantage for the experimental procedure in the treatment of breast cancer.

At first glace, these results appear to have dealt a crushing blow to oncologists who subscribe to the more-is-better school of treatment, as well as to hospitals that established stem cell transplant units in the past decade.

"There will be a change in the assumption that transplant is superior," Edward Stadtmauer, principal investigator on one of the studies, said in a press conference. "I think it's equal. Conventional dose chemotherapy is an O.K. thing to do."

The results also appear to vindicate oncologists who never were comfortable with the high-dose approach. According to that school, if cancer can't be eradicated entirely from the patient, perhaps it can be treated as a chronic disease, with less toxic therapies. The four-day ASCO meeting provided information on many new agents and potential approaches for taking that route.

"We need to figure out how to use the newer



Member, Newsletter Publishers Association World Wide Web: http:// www.cancerletter.com

Editor & Publisher: Kirsten Boyd Goldberg Editor: Paul Goldberg

Editorial: 202-362-1809 Fax: 202-362-1681 PO Box 9905, Washington DC 20016

E-mail: kirsten@cancerletter.com or paul@cancerletter.com

Customer Service: 800-513-7042 PO Box 40724, Nashville TN 37204-0724

Subscription \$275 per year worldwide. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc. Other than "fair use" as specified by U.S. copyright law, none of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, mechanical, photocopying, facsimile, or otherwise) without prior written permission of the publisher. Violators risk criminal penalties and \$100,000 damages. **Founded Dec. 21, 1973 by Jerry D. Boyd** agents better," Robert Comis, chairman of the Eastern Cooperative Oncology Group, said to **The Cancer Letter**. "At the ASCO meeting, we had the followup data on the Herceptin trials, really exciting data, establishing a new paradigm for treatment, and everyone is hung up on bone marrow transplants. The idea of moving on is important."

Not so fast, said two of the discussants at the ASCO plenary session May 17.

The statistical power of a subset of complete responders in one trial wasn't adequate, said plenary session discussant Robert Livingston, of the University of Washington. Another trial in that subset may be indicated, he said. The small South African study, the only positive trial reported, took a different treatment approach that resulted in a survival advantage for patients who received transplants.

The South African approach eliminates lowerdose induction chemotherapy, and uses a high-dose regimen up-front. In his comments, Livingston proposed a larger trial of that approach.

Karen Antman, another discussant, said the studies warrant a new look at the definitions. What dose "high-dose" really mean? asked Antman, of Columbia University. Does it mean cumulative dose, sequential dose, peak dose? Antman invoked Winston Churchill's 1941 statement: "Now is not the end. It is not even the beginning of the end, but it is, perhaps, the end of the beginning."

Watching from the sidelines, the insurers are unlikely to get absorbed in the semantics. "Any insurance company that refused to cover [transplants] outside of trials, based on these results, would be justified, in my opinion," said Arthur Levin, vice president for technology and clinical practice assessment at Prudential HeathCare, of Roseland, NJ.

However, policies are not going to change overnight, Levin said. "We are not rushing to alter our coverage decisions based on the ASCO meeting," he said. "None of these studies have been published in journals yet. We are going to wait until they are published, wait and see what the editorials and letters say."

In other words, round two has begun.

The Importance Of The Randomized Trial

The transplant trials clearly demonstrated why randomized trials are the gold standard for testing the effectiveness of new therapies.

Phase II studies in the 1980s produced what



appeared to be dramatic treatment benefits for highdose chemotherapy, compared to historical data on results from standard therapies.

In a critique of the phase III trials, presented at the ASCO plenary session, Gabriel Hortobagyi, of the University of Texas M.D. Anderson Cancer Center, recalled that a study by the Cancer and Leukemia Group B, presented by principal investigator William Peters at the ASCO meeting in 1990, demonstrated substantial differences favoring high-dose chemotherapy over historical controls after just one year. The earlier trial suggested a 30 percent absolute difference favoring high-dose therapy after two years, and a 40 percent absolute difference by three years, Hortobagyi said.

"It was this promise of a dramatic treatment benefit that drove the rapid growth and expansion of this field in the past decade," Hortobagyi said.

"We and others have published about the pitfalls of comparing the results of single-arm phase II trials of high-dose chemotherapy with historical control groups," Hortobagyi said. "The dangers of such comparisons include the highly selected nature of patients entered in clinical trials of high-dose chemotherapy and stage migration resulting from extensive metastatic evaluation."

Hortobagyi minced no words in his critique. "Based on the available evidence, I have to conclude today that high-dose adjuvant chemotherapy has not fulfilled the expectations," he said. "The predominance of evidence suggest that high-dose chemotherapy provides little or no added therapeutic benefit to standard adjuvant programs. Furthermore, the toxicity of these regimens is still considerably higher than that of conventional adjuvant regimens."

ASCO released abstracts of the plenary session presentations in April (**The Cancer Letter**, April 16). The abstracts are available at <u>http://</u><u>www.conference-cast.com/asco/plenary frame.htm</u>. Audio of the plenary session presentations may be heard and the speakers' slides may be viewed on ASCO's "Virtual Meeting" section, at <u>http://</u> <u>www.conference-cast.com/asco/lecture frame.htm</u>.

The following is a summary of the results of the four trials from the plenary session presentations:

Abstract 1, The Philadelphia Intergroup Study (PBT-1): The study enrolled 553 patients with metastatic breast cancer who were assigned either conventional dose CAF or CMF for four to six cycles. Patients were taken off study if the disease was stable or progressive. There were 296 patients with documented complete or partial responses; 199 went on to randomization.

Patients were randomized to either autologous stem cell transplant or CMF maintenance therapy for up to two years. If assigned to the transplant group, patients underwent bone marrow harvest, followed by GM-CSF stimulated peripheral stem cell harvest, followed by high-dose carboplatin, thiotepa and cytoxan, stem cell transplant (the CTCB or STAMP V regimen), and then GM-CSF stimulated marrow recovery.

The trial was designed with an 85 percent power to detect a doubling in median survival from transplant versus CMF. There was no significant difference in survival between the two groups. The median survival was 24 months for transplant and 26 months for CMF. The three-year survival was 32 percent for transplant and 38 percent for CMF.

There was no difference in time to progression between the two groups. The median time to progression was 9.6 months for transplant and 9 months for CMF. The three-year progression-free survival was 6 percent for transplant and 12 percent for CMF.

"There was no significant benefit for transplant observed in any stratified subgroup, response, hormone receptor status, age, dominant metastatic site," Stadtmauer, the principal investigator, said.

"This largest randomized trial of bone marrow transplant in metastatic breast cancer demonstrates no improvement in overall survival with transplant, no improvement in time to progression or progressionfree survival with transplant, no substantial difference in lethal toxicity," Stadtmauer said. "Non-lethal serious toxicities were greater in the transplant arm, particularly hematologic, infection, nausea and diarrhea."

"Obviously from the survival curves, these results will not change with more follow-up in this study," he said.

Abstract 2, Preliminary results of CALGB 9082/SWOG9114/NCIC MA-13: The trial enrolled 884 patients with primary breast cancer that had spread to 10 or more lymph nodes. All patients were initially treated with four cycles of CAF.

Following induction therapy, 785 patients randomized to receive either cyclophosphamide, cisplatin and BCNU with bone marrow and peripheral blood stem cell support, or intermediate-dose chemotherapy using CPB at the highest doses possible with out transplant but using G-CSF support.



All patients received radiation therapy to the chest, and tamoxifen was prescribed for women whose tumors were hormone-receptor positive or unknown.

The trial requires an additional two years of follow-up for adequate power to detect differences between the groups. Principal investigator William Peters, of the Karmanos Cancer Institute, presented data based on a first cohort of 341 participants who have been followed for a minimum of three years. However, there is no significant difference in either event-free or overall survival between the randomized groups.

There were 126 relapses on the intermediate dose arm and 85 relapses on the high dose arm. Fewer relapse numbers were seen in each age group and in each early time interval examined, Peters said.

There were 31 deaths related to therapy in the high dose arm, a rate of 7.4 percent. There was also a trend toward higher transplant mortality with advancing age.

"The overall outcomes in this patient population for both arms currently appear better than any previously observed in randomized trials within the CALGB in this patient population involving 10 or more nodes," Peters concluded. "More effective treatment, better patient selection, consolidation with combined alkylating agents, local-regional radiation therapy, hormonal therapy, may all have played a role contributing to the value of these treatment programs."

"Further follow-up is required before final disease-free or overall survival conclusions can be drawn," he said.

Abstract 3, The Scandinavian Breast Cancer Study Group 9401: The study enrolled 525 women with high-risk breast cancer, who were randomized to receive nine cycles of "tailored" FEC or three cycles of "standard" FEC, followed by highdose chemotherapy with stem cell support. After a median 20 months of follow-up, 55 relapses and 15 deaths occurred with the tailored therapy compared with 78 relapses and 25 deaths in the high-dose arm. Eight patients developed acute myeloid leukemia/ myelodysplastic syndrome in the tailored arm. Two fatalities were related to therapy in the high-dose arm.

With a median follow-up of 27 months, there was no overall survival benefit to high-dose therapy versus the tailored regimen, said investigator Jonas Bergh. The difference in relapses between the two arms was not statistically significant. Significantly more toxicity was reported in the high-dose arm. The tailored arm used six different dose levels of epirubicin, from 38 mg/m^2 up to 120 mg/m^2 . For cyclophosphamide, the doses ranged from 450 to 1800 mg/m^2 . All patients started at the lowest doses and were increased based on blood counts.

In the high-dose arm, patients received two courses of conventional FEC at standard doses. The third course was given with a slightly elevated cyclophosphamide dose of 1.2 g/m^2 with G-CSF. Then patients received the STAMP V regimen given as a 96-hour infusion.

"I think our data underpins the potential importance of tailoring therapy, even to patients with solid tumors," Bergh said. "Some patients will require high doses, while others will require lower doses, most likely due to the individual, intrinsic variation in the handling of the drugs."

Abstract 4, the South African study: This trial enrolled 154 women with high-risk primary breast cancer with 10 or more positive lymph nodes. A majority of the patients were black, and all were under age 55, said principal investigator Werner Bezwoda, of University of Witwatersrand Medical School, Johannesburgh.

There was no induction regimen as in the U.S. studies. Patients were immediately randomized to either high-dose or standard therapy. The high-dose chemotherapy consisted of cyclophosphamide 4.4 g/ m^2 , mitoxantrone 45 mg/m², and VP16 1.5 g/m², with stem cell transplant.

The standard chemotherapy consisted of cyclophosphamide 600 mg/m², Adriamycin 50 mg/m² or epiadriamycin 70 mg/m², and 5-FU 600 mg/m², every 21 days for six cycles.

At follow-up of five years, 21 of 75 patients on the high-dose arm had relapsed, compared to 55 of 79 patients on the standard dose arm. This was statistically significant. Relapse-free survival and overall survival also was significantly better in the high-dose arm.

"High-dose chemotherapy using the CMVP combination was found to be able to be given safely to younger patients with high-risk breast cancer. The high-dose chemotherapy resulted in a significantly low relapse rate, and high-dose chemotherapy was associated with significantly longer disease-free and overall survival in this patient population.

"We've heard a number of studies which show that in the adjuvant setting, the structure of the trials and details of the treatment are different, and there are differences in results," Bezwoda said. "What this



should generate are attempts to test a number of hypotheses, those being whether induction therapy is indeed required, whether all high dose chemotherapies are actually equivalent, whether to be looking at things like dose intensity ratios or taking into account the total dose of chemotherapy that is actually received, whether single versus multiple high dose chemotherapy cycles are required, and obviously for the future, what are the most suitable post-high-dose chemotherapy approaches."

Where Do We Go From Here?

Discussing the PBT-1 study in metastatic breast cancer, Robert Livingston, of University of Washington, said the study lacked statistical power to detect a survival difference between the patients who experienced complete response.

"In partial responders, a standard policy of highdose consolidation with stem cell support is not justified after induction therapy," Livingston said. "However, in complete responders, the power of the trial is inadequate to detect even a large difference, if one exists.

"What can we say about the role of high-dose consolidation plus stem cell transplant for metastatic breast cancer in 1999? Neither historical controls nor the completed intergroup trial support its use on a routine basis," Livingston said. "However, an important role in complete responders cannot be excluded, due to inadequate power of the intergroup trial and the possible contribution of non-treatment related factors in a comparison across studies.

"For the future use of therapy with autologous stem cell transplants in metastatic breast cancer, where should we go? For the classic paradigm, conventional induction followed by autologous stem cell transplant, emphasis should be on complete responders, and a further randomized trial should be considered in that subgroup. This is particularly attractive if the adjuvant trials are interpreted as positive."

The South African study of high-dose therapy with stem cell support first represented "a new paradigm" that should be tested in a larger trial, Livingston said. "Unfortunately, the standard treatment was not really a standard regimen."

Karen Antman, of Columbia University, the third discussant of the studies, said dose "remains an important and promising strategy to explore in breast cancer."

"The strategic question here is whether high-

dose chemotherapy cures more patients and whether to use stem cells or growth factors is a tactic, not a strategy," Antman said. "Thus, we should be talking about high-dose chemotherapy and not bone marrow transplants. Other tactics include single versus multiple cycles, sequential single agent chemotherapy versus combinations, or induction versus immediate high-dose chemotherapy. Looking at dose, do we mean peak dose, dose rate, cumulative dose, or sequential dosing?"

The data are preliminary in the CALGB study, Antman said. "Only one-third of the predicted relapses have occurred. The study was not supposed to be analyzed for several more years," she said. "Some have commented on the lack of big differences, but with the control group at 70 percent, and toxic deaths at 7 percent, the maximum difference possible if the treatment cured all patients is 23 percent. This was a group selected to have a tumor mortality of 85 percent, and survival on both arms almost certainly will fall with time."

In the Scandinavian study, the planned dose for the tailored therapy significantly exceeded that for the transplant arm, Antman said. "Thus, a superior disease-free and overall survival for tailored therapy would support the importance of cumulative dose over early peak dose. If survival proves to be equivalent, with better quality of life, then patients might prefer short, intensive therapy over nine cycles of moderately high-dose therapy."

Until more data become available, physicians should encourage patients to participate in clinical trials, Antman said. "We can tell them that the mortality is zero to 1 percent for most commonly used regimens, and that the toxicity on cumulative dose studies such as the Scandinavian and Philadelphia trials are not very different," she said.

However, not all patients have access to trials, and there is only one randomized trial currently open in the U.S. for patients with four to nine positive lymph nodes, Antman said. A SWOG-Intergroup trial for greater than nine involved lymph nodes is planned, she said. "Physicians need to provide a careful explanation of what we know and what we don't know for patients considering high-dose therapy offtrial," Antman said.

"We have a number of questions that need to be asked in carefully designed studies: the magnitude of any benefit, optimal regimen and schedule, what drugs, how many cycles, and combinations versus sequential single agents," Antman said.



What's The Take-Home Message?

The Cancer Letter asked three oncologists and a technology assessment expert from an insurance firm to comment on the results of the highdose chemotherapy studies presented in the ASCO plenary session. Following are their answers to the question, "What message did you take home from the ASCO presentations?"

Robert Comis, chairman, Eastern Cooperative Oncology Group: "The ECOG study is the largest clinical trial ever done in the setting of metastatic disease. Clearly it looks like bone marrow transplantation for metastatic disease is not anywhere near as effective as any of us hoped, and I don't think it can be considered a standard treatment. I think that's clear in the setting in which we used it. It is probably as large a study as there is going to be for this setting. It appeared that survival was similar between the two groups. So, if a woman chooses to have a very intensive, morbid, but non-lethal treatment, as opposed to years of additional treatment, she may want to consider it.

"In the high-risk adjuvant setting, I agree that the data aren't mature enough. All of us had hoped that there would be a strong, clear signal, and that is not there either. We're all a bit disappointed that that signal isn't there. The most important thing that appears to be operational is selection. In the CALGB study, the survival is the same on both arms. This can be interpreted in two ways. One is that the intermediate dose level may be as effective as bone marrow transplant. The other interpretation is that it's selection. You select people who are young and healthy and they do better than historical controls.

"We have in ECOG an intergroup trial, ECOG 2190, which is a direct comparison of bone marrow transplant versus conventional treatment, in greater than nine positive nodes. That is a trial that will be more germane to this question. That study is closed to accrual.

"People are talking about the need for more trials and the lack of trials. I think that this group of studies in general looked at post-induction therapy and almost all the trials address this. I don't think we need any more studies of that.

"We need to figure out how to use the newer agents better. At the ASCO meeting, we had the follow-up data on the Herceptin trials, really exciting data, establishing a new paradigm for treatment, and everyone is hung up on bone marrow transplants.

"The idea of moving on is important.

"I'm not sure yet how this will play in the community. There is no question that the discussion between the physician and patient will be different. Up to now, it was based on conjecture. Here, I think, for metastatic disease, [the results] have to call into question the ad hoc discussion about what's best for an individual. I'm sure it's happening."

Craig Henderson, adjunct professor of medicine, University of California, San Francisco: "I took away what the two main speakers said, and that is, for metastatic breast cancer, there is precious little information to suggest that there is a benefit of bone marrow transplants. Dr. Peters' request to hold final judgment on his study is a reasonable one.

"The results from the randomized trials are nowhere near as dramatic and as large as we expected. This underscores the importance of not rushing to judgment on the basis of small, uncontrolled studies. Also, it's a lesson in how selection bias can play havoc on trial results. This is what happened with radical mastectomy. We concluded that radical mastectomy was better, but when we did randomized trials, we couldn't show that there was an advantage.

"Most of us have concluded that historical controls are misleading. There are so many factors that affect the outcome in breast cancer that it is difficult to match them and be sure you are dealing with same group of patients.

"I would suspect two things are going to happen. One is that patients will decide more frequently that they don't want transplants, and the second is that we will mount additional trials. One of the problems is that everything we know about the anticancer drugs that we use commonly, the cytotoxics, indicates that higher doses must be more effective, but we haven't shown that in trials. This is true of Adriamycin, in a trial I presented at ASCO last year, in two cyclophosphamide trials, and in high-dose chemotherapy/BMT. There will be a tendency for people to abandon high dose, but there will be a core who ask, 'What did we do wrong?' One example may be the number of courses we gave. I don't think this whole thing will die. But it will have an unbelievable impact on the economics of practices that depend on bone marrow transplantation as a major source of revenue."

Kathy Albain, associate professor of hematology/oncology, Loyola University Medical Center: "Bottom line for me would be that some issues



have been resolved and in others, the jury is still out.

"The average patient that comes to you with prior chemotherapy, metastatic disease, responding to treatment—that type of patient is probably not a candidate for high-dose chemotherapy. The other type of patient, one of whom I have right now, with no prior chemotherapy, young, in complete remission to the first regimen—that is where the jury is still out. We don't have enough power in that small subset of complete remission patients. That's how it has sorted out, as I see it, leaving open questions of how to approach that type of patient.

"There are there still research questions to look at: purging the marrow, using the Bezwoda series of high doses up front, followed by high-dose consolidation therapy.

"For the multiple node high-risk patient in the adjuvant setting, we have the provocative trial from South Africa, then the CALGB trial with high-dose versus moderately high dose.

"Hanging out there is the other North American trial, led by ECOG, chaired by Martin Tallman, [of the Division of Hematology/Oncology, Northwestern University Medical School]. The Tallman trial is standard therapy CAF, after which patients are randomized to either stop after six cycles or receive high-dose chemotherapy/BMT. It's awaiting followup. That is a true test of the question of standard versus high-dose. We will have to wait a year or so for the results.

"In the meantime, we have angiogenesis inhibitors, multiple drug resistance modulators, all sorts of things one could do to optimize the approach."

Arthur Levin, vice president for technology and clinical practice assessment, Prudential HeathCare, of Roseland, NJ—[Levin, an M.D., but not an oncologist, sent a representative from Prudential to the ASCO meeting.]

"The take-home message is that there is no proof that it works for high-risk primary and metastatic breast cancer. That's what I take away from it. They put up these five studies, and the studies have been ongoing for quite a while, maybe not as long as one would like, but all are at least three years out, and four of the five studies say it doesn't work. One of the five says it works, but that's a study that I think the oncologists have problems with.

"There have been many people in the insurance industry, but more importantly, in oncology and in the medical field, who felt that this was unproven and they felt strongly about it. I wouldn't say the insurance industry is vindicated, because it was people in the oncology community who were critical of this.

"There are many oncologists at many hospitals who have a great financial interest in this. There are a lot of people who are going to go broke if this doesn't pan out. Their livelihoods are at stake here. Even now, with release of these studies with very cautious tippy-toe language that ASCO uses, there are people who are going to try to convince patients to have [bone marrow transplants] outside of trials. I would say that is unethical. I think we are going to see all kinds of machinations in the community that has an interest in this to try to maintain this as a standard therapy. There is an obligation in the oncology community to stand up and say that's wrong.

"Any insurance company that refused to cover this outside of trials, based on these results, would be justified, in my opinion. Insurers differ as to whether they will cover trials. My personal feeling is that insurers should cover it, but only within trials, and I don't mean phony protocols, but serious studies designed to answer a scientific question.

"We cover transplantation for the women with more than 10 positive nodes, and for metastatic disease that is chemosensitive.

"We are not making any immediate changes to our coverage, but we're thinking about it. We'd like to see what some of the professional societies recommend based on these results. We are not rushing to alter our coverage decisions based on the ASCO meeting. None of these studies have been published in journals yet. We are going to wait until they are published, wait and see what the editorials and letters say. I would assume professional organizations would take positions.

"I think every woman with breast cancer knows about these results, and I hope they will be more critical of this therapy. I hope their physicians would be more critical, too."

OPRR Allows Duke To Resume Human Research Studies

The NIH Office for Protection from Research Risks has lifted the suspension of Duke University Medical Center's ability to conduct research involving human subjects.

In a May 14 letter to Ralph Snyderman, Duke chancellor for health affairs, Michael Carome, chief compliance officer for OPRR, wrote: "OPRR has determined that DUMC has developed the



satisfactory corrective plans that were required."

"We are grateful to OPRR officials for their assistance in helping us work through the necessary steps that have enabled us to resume the important work being done by our faculty and our IRB," Snyderman said.

OPRR had notified Duke on May 10 that all studies involving human subjects that did not have therapeutic benefit to patients should be suspended (**The Cancer Letter**, May 14).

On May 13, a team of DUMC officials led by Snyderman and Edward Holmes, dean of medicine, met with OPRR officials and reviewed the corrective actions the center planned to take to ensure compliance with federal regulations.

Funding Opportunities: HHS Program Aims To Increase Organ and Tissue Donation

HHS has begun a \$5 million extramural support program for fiscal year 1999 to fund 15 to 20 projects aimed at increasing organ and tissue donation.

The program plans to support projects for up to three years to implement and evaluate initiatives to increase organ and tissue donation. Pilot projects will test the effectiveness of promising new interventions, while replication projects will focus on implementing and testing at expanded or multiple sites those interventions already shown to be effective in more limited trials.

Applications may be submitted by a consortium of at least two organizations, with one having expertise in research and evaluation and the other in donation/ transplantation. One agency will be considered the "applicant" and will have overall responsibility for the project. The applicant must be a federally designated organ procurement or other nonprofit, private organization.

The final grant application guidance is available on three World Wide Web sites: http://www.hrsa.gov, http:// www.hrsa.gov/osp/dot and http://www.organdonor.gov. Applicants will have approximately 60 days to submit applications.

For further information, contact HRSA Division of Transplantation, Parklawn Bldg Room 4-81, 5600 Fishers Lane, Rockville, MD 20857, phone 301-443-7577.

Leukemia Society Offers Scholar Awards, Fellowships

The Leukemia Society of America offers four awards programs to support research in leukemia, lymphoma, Hodgkin's disease, and myeloma.

The society offers scholar awards, scholar awards for clinical research, special fellowhips, and fellowships.

Preliminary application deadline is Sept. 15. Complete application is due Oct. 1.

Application forms and instructions are available at http://www.leukemia.org or contact the society at phone 212-450-8843, fax 212-856-9686, or email lermandb@leukemia.org.

Foundation Offers Grants For Testicular Cancer Research

The Lance Armstrong Foundation offers research grants for the study of testicular cancer. Grant budgets may not exceed \$50,000.

Deadline for receipt of applications is July 15.

For applications, contact Steven Wolff, M.D., at the foundation, phone 512-236-8820, fax 512-236-8482, email <u>steven.wolff@laf.org</u>.

In Brief: Report On Interactive Health Communication Available

(Continued from page 1)

independent body convened by HHS. The report analyzes the emerging field of interactive health communication, identifies specific opportunities for reducing risks and expanding benefits associated with these new technologies. David Gustafson, of the University of Wisconsin-Madison, served as chairman of the panel. The report is available at http:// www.scipich.org/pubs/finalreport.htm, or it may be ordered at a cost of \$10 per copy by calling 800-336-4797. . . . RECENT APPOINTMENTS at Memorial Sloan-Kettering Cancer Center: Clifford Hudis was named chief of the Breast Cancer Medicine Service. Andrew Seidman was elected president of the American Society of Breast Disease. Murray Brennan was named to the Benno C. Schmidt Chair in Clinical Oncology. **Richard Payne** was named to the Anne Burnett Tandy Chair in Neurology.... ALLEN EAVES, professor and head of the hematology division at University of British Columbia, has been installed as president of the American Society for Blood and Bone Marrow Transplantation. Richard O'Reilly, chairman of pediatrics and chief of the BMT Service at Memorial Sloan-Kettering, is the newly elected vice president. James Armitage, University of Nebraska College of Medicine, became president-elect, and will assume the presidency in 2000. The society presented its public service award to Adm. Elmo Russell Zumwalt Jr., chairman of The Marrow Foundation and chairemeritus of the National Marrow Donor Program.



Copying Policy for The Cancer Letter Interactive

The software that comes with your issue allows you to make a printout, intended for your own personal use. Because we cannot control what you do with the printout, we would like to remind you that routine cover-to-cover photocopying of The Cancer Letter Interactive is theft of intellectual property and is a crime under U.S. and international law.

Here are guidelines we advise our subscribers to follow regarding photocopying or distribution of the copyrighted material in The Cancer Letter Inc. publications in compliance with the U.S. Copyright Act:

What you can do:

--Route the printout of the newsletter to anyone in your office.

--Copy, on an occasional basis, a single story or article and send it to colleagues.

--Consider purchasing multiple subscriptions. Contact us for information on multiple subscription discounts.

What you can't do without prior permission:

--Make copies of an entire issue of the newsletter. The law forbids cover-to-cover photocopying.

--Routinely copy and distribute portions of the newsletter.

--Republish or repackage the contents of the newsletter.

We can provide reprints for nominal fees. If you have any questions or comments regarding photocopying, please contact Publisher Kirsten Boyd Goldberg, phone: 202-362-1809, email: kirsten@cancerletter.com

We welcome the opportunity to speak to you regarding your information needs.

