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ABMT Trials Unlikely To Show Clear Benefit For Breast Cancer; Data Release Debated

The results of two long-awaited NCI-sponsored studies of bone marrow transplantation and high-dose chemotherapy for the treatment of breast cancer are scheduled for presentation at a plenary session of the annual meeting of the American Society of Clinical Oncology, May 15-18 in Atlanta.

The studies include the Eastern Cooperative Oncology Group randomized trial of ABMT in stage IV disease and the Cancer and Leukemia Group B study of ABMT in high risk stage II and III patients. Also, data from Swedish and South African studies will be presented.

The data are being prepared for presentation by ECOG and CALGB

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In Brief:

Stovall To Receive ACCC Award; Groopman, Sigal, Named To Board Of Scientific Advisors

ELLEN STOVALL, executive director of the National Coalition for Cancer Survivorship, will receive the Association of Community Cancer Center's Annual Achievement Award for Outstanding Contributions to Cancer Care, on March 26 at the association's 25th annual meeting in Washington, DC. Stovall, a 27-year cancer survivor, has been the NCCS executive director since 1992. Last year, she served as founder and president of The March: Coming Together to Conquer Cancer. Stovall was appointed in 1996 to the National Cancer Advisory Board, where she serves as chairman of the Planning and Budget Subcommittee. She also serves on the National Cancer Policy Board of the Institute of Medicine, the board of the Friends of Cancer Research, and the Cure for Lymphoma Foundation. Stovall organized the Cancer Leadership Council in 1993 to develop positions on health policy issues. She is a member of the Board of Trustees of the Foundation for Accountability, and serves on committees of several cancer professional organizations. ACCC, based in Rockville, MD, has a membership of 550 medical institutions, oncology practices, and cancer programs. . . . **JEROME GROOPMAN** and **ELLEN SIGAL** have been appointed to the NCI Board of Scientific Advisors. Groopman is chief of the Division of Experimental Medicine, Beth Israel Deconess Medical Center, Boston, and professor of medicine, Harvard Medical School. Sigal, who completed a term on the National Cancer Advisory Board last year, is chairman of Friends of Cancer Research. **David Ho**, director of the Aaron Diamond AIDS Research Center at Rockefeller University, completed his term on the board. The

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Early Release Of ABMT Data Not Warranted, NCI, ASCO Said

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investigators. However, preliminary conclusions have been shared with a relatively large number of people at the cooperative groups, ASCO, and NCI.

Interviews with individuals familiar with these preliminary results indicate that:

—The results of the PBT01 intergroup trial led by ECOG are unlikely to show a benefit for ABMT in stage IV breast cancer either in terms of increased time to progression of disease, the primary endpoint of the study, or long-term survival, a secondary endpoint, sources said. It is unclear whether some subgroups of patients would be likely to benefit from the procedure. It is also unclear whether the trial, which was begun in 1990 and enrolled 553 patients, has sufficient statistical power to resolve the issue.

—The data from the CALGB C9082 trial, which enrolled 874 patients, require additional follow-up and are unlikely to produce definitive answers about efficacy of the procedure in high-risk stage II and III patients who have more than 10 positive lymph nodes, sources said. Median follow-up in the trial is around 31 months.

Officials at NCI, ASCO, and the cooperative groups refused to comment on these preliminary results, which have spawned many rumors, and were the subject of a March 9 report on NBC Nightly News as well as subsequent coverage.

"I would not have confidence in preliminary data in terms of its accuracy or interpretation," said Jeff Abrams, NCI senior investigator in charge of the breast cancer treatment studies. "The investigators have not completed the analysis of the data, and we at NCI don't have anything that we would consider credible."

As most issues in oncology, this is a story about the integrity of a process. It took NCI a decade to overcome resistance from patients and physicians to generate these data on ABMT.

Since some physicians were making the unsubstantiated claim that the procedure represents the "best chance" in the treatment of high risk and metastatic disease, patients resisted enrolling in trials that involved randomization to another treatment. Many patients also sued insurers to get reimbursed for the treatment.

Now that partial results are in, the process of data analysis and peer review have become activated. In this case, preparation has involved an extraordinary number of people, and has triggered widespread informal discussion. As information spread, the press became interested, and even reporters who respect the scientific process have faced a choice between reporting the story accurately and thoroughly, or sitting on the sidelines and watching the story turn into a communications fiasco.

In 1997, bone marrow transplants were performed on 4,400 breast cancer patients in the U.S. and Canada, according to the International Bone Marrow Transplant Registry/Autologous Blood and Marrow Transplant Registry. The registry estimates that 62 percent of those transplants were performed for metastatic disease.

From Statistical to Scientific Conclusion

Despite early setbacks, both the ECOG and CALGB trials have completed enrollment and treatment.

Since the trials were not stopped early, the results do not involve either a major detriment or a major benefit. Generally, at the time when the data are released by the data safety monitoring committees, the committees know the answers on the major endpoints of the studies.

After the statisticians present the results for analysis to the scientific leadership of the cooperative groups, the real analysis of the data begins. Generally, scientists go through the data, patient by patient,

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verifying the endpoints, and drawing conclusions.

When that process is completed, the data are sent to NCI and submitted for peer review. In this case, the ECOG and CALGB investigators submitted preliminary data to ASCO in order to present the data, and informed NCI about potentially important findings. The ASCO abstracts are expected to be released in mid-April.

In preparation for the release of the results, NCI assembled an ad hoc group of about 20 officials, advocates, and academics who were asked to guide the Institute in communicating the results of the trials to the public. The ad hoc committee included representatives of the National Breast Cancer Coalition, the Susan G. Komen Breast Cancer Foundation, the National Alliance of Breast Cancer Organizations, and Y-ME National Breast Cancer Organization.

Sources said that at a meeting last month, the group considered whether the data warrant a clinical announcement. However, the group decided that a thorough analysis would be preferable to a rushed clinical announcement.

"I feel that when something is practice-altering, it merits consideration for a clinical alert, early release, and wide dissemination," said ASCO President Allen Lichter, who took part in the meeting.

"We have tried to look at these trials under that standard, and I can say—without trying to prejudge the final data and what the discussants are going to say—that these results will not be practice-altering," said Lichter, professor of radiation oncology and a dean at the University of Michigan Medical School.

"They are the first of many steps in a scientific journey to try to find the appropriate place for this therapy in the treatment of breast cancer," Lichter said to **The Cancer Letter**.

"This is not the end of the story; this is the beginning of the story."

When To Release Trial Results?

"If NCI has data on the effectiveness or non-effectiveness of a treatment, to not release that information to the public that needs that information [is] outrageous," Barbara Brenner, of the San Francisco-based Breast Cancer Action, said on the NBC Nightly News March 9.

Brenner's group was not represented on the ad hoc committee advising NCI.

The view that scientific findings should go to the news wires without the benefit of a thorough analysis is not widely shared in cancer advocacy circles.

"If the trial results are indeed negative, that shouldn't be a shock to anyone," said Fran Visco, president of the National Breast Cancer Coalition and a member of the President's Cancer Panel. "It's not as though we are keeping this top secret information from the public that is going to be totally surprised.

"We've known for years that there were no data to support this intervention, and the delay in getting the answer is the result of the medical community and patients demanding transplants outside randomized clinical trials," Visco said to **The Cancer Letter**.

Visco said the public does not benefit from the release of hastily analyzed data. "It's a very difficult decision to make as to when the results of a trial are released to the public," she said. "There are processes that have to be followed to make certain that when you do release results, you are getting the right results to the public. Maybe there is a way to speed up that process, but the decision on how to speed it up has to be made pretty carefully."

Susan Braun, president and chief executive officer of the Susan G. Komen Breast Cancer Foundation, said premature release of data would do harm. "As patient advocates, we believe it is imperative that this information be made available to patients at the earliest possible time," Braun said. "However, when patients who are faced with the difficult decision of whether to undergo stem cell transplant rely upon incorrect or incomplete information to make that decision, it is worse than having no information at all."

Consequences of Trials

Since high-dose chemotherapy with bone marrow transplantation is a toxic and very expensive treatment for breast cancer, insurers are eagerly awaiting its demise. Thus, the data presented at the ASCO meeting are certain to reverberate in courtrooms all over the U.S.

While ABMT is widely available outside clinical trials and in non-randomized trials around the U.S., at least one leading institution stopped offering the treatment as soon as NCI-sponsored clinical trials completed accrual.

"As an institution, Memorial Sloan-Kettering has supported the clinical trials of ABMT in the adjuvant setting," said Avice Meehan, MSK vice president for public affairs. "Once the national adjuvant trials

completed accrual, we no longer accrued patients or offered it as a treatment option pending the results of the trials."

MSK breast cancer specialist Larry Norton is the chairman of the CALGB breast cancer committee.

Meehan said ABMT for stage IV breast cancer has not been performed for quite some time at Memorial. "In stage IV breast cancer, it's a therapeutic approach we have used only in selected cases, and we are not currently using it," Meehan said to **The Cancer Letter**.

The history of each of the NCI sponsored trials of ABMT reflects the practical difficulties of testing an intervention that gains acceptance before its efficacy is established.

—The ECOG study (BPT01) is titled "Maintenance Chemotherapy Versus High-Dose Chemotherapy With Transplant for Metastatic or Recurrent Breast Cancer."

In December 1990, when it was begun by several Philadelphia institutions and Blue Cross/Blue Shield, the study was expected to complete accrual by January 1994.

Patients were apparently deterred by the study's design, which compared an aggressive treatment with a standard one. As prospective participants were opting to receive aggressive therapy off-protocol, the study fell short of its enrollment target. The study's enrollment received a boost when a second trial, conducted by Southwest Oncology Group, was closed because of low accrual and its participants were added to the Philadelphia study.

The enrollment target was reached in late 1997, when 553 women were accrued. The ECOG data safety monitoring committee reported the trial results to the group's scientific leadership last November.

Trish Bates, communications manager for ECOG, said some of the patients are still being treated. "The investigators are going through the data case by case," Bates said to **The Cancer Letter**.

The principal investigator on the trial is Edward Stadtmauer, of the University of Pennsylvania Medical Center.

—The CALGB study is titled "High-Dose Chemotherapy With Stem Cell Support Versus Lower Dose Chemotherapy for Stage II or Stage IIIA Breast Cancer."

Like the Philadelphia study, the adjuvant trial began in late 1990. By 1994, the trial reached its enrollment target of about 500 patients.

Accrual appears to have been more successful because the trial offered a more aggressive therapy for patients randomized into the control group, and because its principal investigator, William Peters, one of the pioneers of the procedure, was attracting a large number of patients to what was then his institution, Duke University. Peters is now the director of the Karmanos Cancer Center in Detroit.

While the trial was going on, the CALGB data safety monitoring committee decided to increase the enrollment in order to look for smaller differences. Ultimately, 874 patients were accrued. The committee decided to look for smaller differences because mortality from the procedure dropped from 15 percent to about 5 percent.

Though the CALGB data are inconclusive and need longer follow-up, the cooperative group decided to report the data as they currently exist because the information may be useful to patients and clinicians making treatment decisions, sources said.

NCI is sponsoring two other adjuvant ABMT breast cancer trials that are not ready for presentation. They are:

—"Evaluation of High-Dose Consolidation Chemotherapy With ABMT for Patients With Stage II or Stage IIIA Breast Cancer (INT-0121)." The study is limited to women with 10 or more positive lymph nodes, a relatively small group which accounts for about 5,000 of over 180,000 women diagnosed with breast cancer every year.

The study was begun in January 1991, and was expected to complete accrual in late 1994. The accrual target of about 500 was not reached until late 1997.

—"High-Dose Chemotherapy With Stem Cell Support Versus Intensive Sequential Chemotherapy With G-CSF Support for Breast Cancer Patients With Four to Nine Involved Nodes (S9623).

The trial, which was designed with input of patient advocates and started in 1996, has the enrollment target of about 1,000. So far, about 500 women have been enrolled.

NCI: Data Needs Validation, Analysis

As the NBC News report about the studies touched off a media frenzy, NCI issued the following press release:

NCI is sponsoring studies of the effectiveness of high-dose chemotherapy and autologous bone marrow or stem cell transplantation in the treatment of breast cancer. Preliminary results of two of these will be presented at the May meeting of the American

Society of Clinical Oncology. The results of two similar foreign studies will also be presented at the meeting.

Because of the importance of these studies, the NCI is eager that the results be made public as soon as possible. In February, NCI called together a group to determine how soon data analysis could be completed and the preliminary findings released. The meeting was attended by representatives of the Institute, ASCO, the U.S. investigators, and several patient advocacy organizations.

After discussing a full range of issues, particularly the importance of data accuracy and completeness, the group decided that more work was needed before results would be ready for release. Joining in this opinion were the representatives of the patient advocacy organizations.

The NCI recognizes the need for women and physicians to have information that will reliably guide treatment choices. Clearly, proper validation and full analysis of the data must be completed before the results can be used in making treatment decisions.

The imperative need for information about the benefits of various treatments can only be satisfied by well-designed and well-conducted clinical trials. A final but absolutely necessary aspect of clinical trials is the need to assure the correctness of data and the soundness of their analysis.

The investigators are now in this final phase: assuring that the data and the analysis are correct and complete. The results of this analysis have not been provided to NCI. NCI expects that preliminary analysis will be completed by April 15 and made available at that time. Data that have been more fully analyzed will be presented at the ASCO meeting.

Drug Marketing:

Zeneca Sues Eli Lilly, Claiming Misleading Promotion Of Evista

Zeneca Inc. of Wilmington, DE, has filed a suit alleging that Eli Lilly & Co. of Indianapolis is engaging in "false and misleading" promotion claiming that the Lilly drug Evista (raloxifene HCl) provides a breast cancer risk reduction benefit.

According to the suit, filed in the U.S. District Court for the Southern District of New York on Feb. 25, Lilly's claims have harmed Zeneca's efforts to market Nolvadex (tamoxifen) for the reduction of breast cancer risk in asymptomatic women.

Evista is approved for osteoporosis indications. However, studies presented at scientific meetings and published in peer reviewed literature claim a possible breast cancer benefit for the agent. To compare the two agents, NCI has funded a clinical trial, called the Study of Tamoxifen and Raloxifene (STAR), for post-menopausal women at high risk of developing breast cancer. The trial will be conducted by the National Surgical Adjuvant Breast and Bowel Project.

Evidence described in Zeneca's court documents includes a Lilly press release and an advertisement implying a breast cancer risk reduction benefit, as well as two letters from FDA demanding that the company stop making breast cancer claims. The complaint also describes market surveys that suggest that physicians are starting to view Evista as a drug that is equivalent to Nolvadex.

Zeneca claims that Lilly has violated the Lanham Act, a federal law that prohibits unfair competition, and seeks treble monetary damages and an injunction barring Lilly from making claims about Evista's ability to prevent breast cancer.

The action comes at a time when physicians who have little professional knowledge of cancer clinical trials are sorting through journal articles, news stories, and ads about potential breast cancer risk reduction benefits of Nolvadex and Evista.

Meanwhile, FDA is in a weakened position in regulating claims related to the use of drugs beyond the labeled indications. The courts are currently defining the agency's powers in regulation of off-label claims. Last July, Judge Royce Lamberth of the U.S. District Court for the District of Columbia ruled that the First Amendment protects the distribution of materials on off-label indications of drugs, provided that these materials had gone through peer review (**The Cancer Letter,** Aug 14, 1998). The agency is challenging the ruling, and many observers say it is almost certain that the matter will end up in the Court of Appeals.

Zeneca: 1 in 3 Doctors "Misled" By Lilly

Any claims of a breast cancer risk reduction benefit for Evista would have to be based on the Multiple Outcomes of Raloxifene Evaluation (MORE) trial. Data from that study, which is ongoing, has been presented at a number of cancer meetings, including last year's meeting of the American Society of Clinical Oncology, and the recent San Antonio symposium on breast cancer.

The primary endpoint of MORE is a lower risk of fractures. Though the results of the trial are yet to

be published in a peer-reviewed journal, the possibility of a breast cancer prevention benefit for Evista has been widely reported in the press.

Lamberth's ruling clearly protects journal articles. However, even prior to publication, the ruling may preclude FDA from taking action against a drug company that distributes copies of abstracts from the proceedings of a bona fide scientific meeting, said Richard Samp, chief counsel of the Washington Legal Foundation, a public interest law and policy center that brought the case that resulted in Lamberth's ruling.

Court documents don't mention the materials and citations Lilly reps are alleged to have used to promote the breast cancer benefit of Evista.

"We don't yet have published data that fits the parameters of Judge Lamberth's ruling," said Angela Sekston, a Lilly spokesman. "Our promotional activities are aligned with our product label, and they are in compliance with FDA guidelines.

"The company has set clear, appropriate standards for interaction between sales representatives and physicians," Sekston said.

Physicians interviewed by The Cancer Letter said they know of colleagues who are prescribing Evista for breast cancer risk reduction, relying on the buzz about studies nearing completion and studies about to be initiated rather than published scientific data.

Tamoxifen and raloxifene are not in head-to-head competition. They treat separate populations, which have some overlaps. Indeed, what is a physician to do about women who need osteoporosis therapy and are a high risk of breast cancer, or women who have completed five years of tamoxifen and need an osteoporosis drug?

As a result, prescribing at times appears to fly in the face of evidence-based medicine, several observers said.

"I have even heard of oncologists taking their patients with breast cancer off fosomax to put them on raloxifene to treat their osteoporosis," said Susan Love, adjunct professor of surgery at the University of California, Los Angeles, School of Medicine. "This is crazy, since raloxifene only increases bone density by 3-4 percent while fosomax increases it by 8-10 percent.

"In addition, raloxifene has only been studied for two years in women who are at low risk of breast cancer (postmenopausal women with osteoporosis who have 60 percent less breast cancer than the same women without osteoporosis) and the incidence is low. To use raloxifene in women with breast cancer or women at high risk is a leap of faith.

"The data is enough to initiate a study of raloxifene for risk reduction but not enough to act on," Love said.

Zeneca Alleges "Deception"

Whatever is going on in the field, Zeneca officials admit that Lilly's drug is cutting into the Nolvadex market for the breast cancer risk reduction indication.

"Lilly's claims are intended, and have already begun, to mislead doctors into believing that Evista has been proven by appropriate clinical trials to reduce the incidence of breast cancer," Robert Black, president of Zeneca Pharmaceuticals, a unit of Zeneca Inc, wrote in a "Dear Doctor" letter dated Feb. 25.

"Research reveals that as many as one in three doctors have been misled on this point," the letter states.

In the suit, Zeneca claims that Lilly has used the results of the MORE trial to establish the claim that Evista and Nolvadex are similar. "To make Evista a commercial success, Lilly has attempted to trade on the proven efficacy of Nolvadex by skillfully misusing safety data generated in the MORE Trial to position Evista as an alternative breast cancer drug," Zeneca's suit states.

The suits cites the following data from market studies to support the claim that physicians are being confused about Evista's breast cancer prevention benefit:

—"According to one market research study, physicians have begun to prescribe Evista at least as frequently as Nolvadex for breast cancer risk reduction.

—"In another study, more than a third of responding physicians said that the message communicated by the Lilly sales representative was that Evista was indicated for prevention of breast cancer," the document states.

—The study also polled oncologists, concluding that "96 percent of oncologists surveyed reported that the Evista sales representative discussed Evista's potential for prevention of breast cancer," the document states.

Potential Causes of Confusion

Interviews with breast cancer advocacy groups

and community physicians confirm that improper prescription of Evista occurs regularly.

However, several observers blamed the coverage of Evista as a cancer "breakthrough" by the press, exacerbated by the susceptibility of physicians to hype.

Evista is not marketed to oncologists, Lilly officials said, challenging the findings of one of the market surveys cited by Zeneca. "The focus of Evista promotional efforts has always been on primary care providers, OB/GYNs, rheumatologists and endocrinologists," said Lilly spokesman Sekston.

It appears that both Zeneca and Lilly have been excessive in their recent marketing campaigns for Nolvadex and Evista, triggering warning letters from FDA.

Zeneca's suit cites two FDA warning letters.

Last December, Lilly issued a press release titled "Evista Reduces Breast Cancer Incidence In Postmenopausal Women," which described the data from the MORE trial as a "significant breakthrough in women's health."

The press release, dated Dec. 11, 1998, said that the MORE interim results indicate that Evista "appears to reduce the incidence of newly-diagnosed invasive breast cancer…by 63 percent among postmenopausal women taking the therapy for more than three years and that "overall, there was a 55 percent reduction in risk of breast cancer.

In a letter dated Dec. 23, FDA said the press release "promotes Evista for unapproved new uses," in violation of product labeling approved by the agency. Evista is approved only for the prevention of osteoporosis in postmenopausal women, and states that "the effectiveness of raloxifene in reducing the risk of breast cancer has not been established."

The suit states that Lilly's print ads aimed at physicians and consumers were also misleading, and were withdrawn after a warning from FDA. The ad in question featured a photo of a woman and the tag: "Focus on her future with three combined benefits.

According to the ad, Evista (1) Prevents osteoporosis; (2) Lowers cholesterol; and (3) "Addresses your patients' concern about breast cancer." The ad further states that there is "no increased risk of breast or endometrial cancer with Evista in studies up to 39 months."

In a letter dated Jan. 12, FDA warned Lilly that the ad "implies a certainty regarding the possible effect of Evista on breast tissue that is not adequately substantiated by the data."

Sekston confirmed that the company has received the notices from FDA. "We did get a notice of violation, which is not uncommon in the pharmaceutical industry, and we did cease distribution of that press release immediately," Sekston said to **The Cancer Letter**. The advertisement was discontinued "even before the notice of violation was received," she said.

Zeneca, cannot claim a spotless regulatory record in its promotion of Nolvadex.

In a letter dated Nov. 24, 1998, FDA instructed the company to stop dissemination of promotional materials for Nolvadex. States one letter: "these advertisements contain prominent claims for the safety of Nolvadex, such as 'well tolerated' and 'well documented safety profile,' in the text of the advertisements. However, risk information is presented as a footnote."

In another apparent lapse of accuracy, a consultant to the company attempted to convince patient advocacy groups to publish inaccurately worded articles about Nolvadex in their newsletters.

The proposed article stated that FDA "is considering whether to approve tamoxifen… for use in preventing breast cancer in healthy women considered at high risk. In August, a panel of doctors who advise FDA voted to recommend this use."

The FDA Oncologic Drugs Advisory Committee voted 11-0 against the use of the word "prevent" in the Nolvadex label. Instead, the drug was approved for the "reduction in breast cancer incidence in high-risk women" (**The Cancer Letter**, Nov. 6, 1998).

Program Announcement

PA-99-070: Quick-Trials For Prostate Cancer Therapy

Letter of Intent Receipt Date: One month prior to application receipt date

Application Receipt Dates: June 9, Sept. 9, and Nov. 9, 1999; Jan. 9, March 9, May 9, July 9, Sept. 9, and Nov. 9 for 2000 and 2001

Continuing advances in molecular genetics and drug development have led to new approaches for inhibiting prostate tumor growth either directly or by impacting the tumor microenvironment. These agents include new classes of cytotoxic agents, agents acting via immune-stimulatory effects, agents that inhibit angiogenesis and metastasis or alter signaling pathways, and agents targeted specifically to novel prostate cancer cell targets. At present, there is a paucity of funding mechanisms targeted to stimulate the transition of promising and potentially

relevant advances in new drug development from the laboratory into the clinical setting.

The QUICK-TRIAL program is a pilot program to provide investigators with rapid access to support for pilot, phase I, and phase II prostate cancer clinical trials and patient monitoring and laboratory studies to ensure the timely development of new therapeutic approaches. QUICK-TRIAL will provide a new approach designed to simplify the grant application process and provide a rapid turnaround from application to funding. Features include a modular grant application and award process, inclusion of the clinical protocol within the grant application, six submission dates per year, and accelerated peer review with the goal of issuing new awards within four months of application receipt. Inclusion of the complete clinical protocol within the PHS 398 grant application is intended to simplify the application process by eliminating the need to duplicate protocol details in the Research Plan section. Investigators may apply for a maximum of two years of funding support using the exploratory/developmental (R21) grant mechanism for up to $250,000 direct costs per year.

Inquiries: Diane Bronzert, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, NCI, phone 301-496-8866, e-mail db85g@nih.gov

In Brief:

NIH Gives Advisors $50 Raise, Effective April 1, No Fooling

(Continued from page 1)

BSA has 34 members. . . . **THE PAY'S NOT SO GOOD, BUT THE ENTERTAINMENT IS FREE**: Groopman and Sigal arrive on the BSA in time to reap the benefits of a 33.3 percent increase in the honorarium paid to NIH advisors. Members of the BSA and all NIH peer review and advisory groups will be paid $200 a day while attending committee meetings, up from $150, BSA Chairman **David Livingston**, of Dana-Farber Cancer Institute, told the board at its March 8 meeting. "But you have to pay for lunch," Livingston said. (For the nine-hour meeting, the advisors made $16.66 an hour. With the increase, they would make $22.22 an hour for the same meeting.) When informed that the increase takes effect April 1, BSA members laughed. NIH officials confirmed the date of the increase, but said it was not meant to be a joke. The honorarium has been $150 since December 1987, sources said. . . . . **MATTHEW SCHARFF**, professor of cell biology at Albert Einstein College of Medicine, has stepped down as chairman of the NCI Board of Scientific Counselors Subcommittee B. Scharff was the first chairman of the subcommittee, which reviews the basic science components of the NCI intramural research program. The subcommittee was formed in the 1995-1996 reorganization of the Institute's divisions and advisory committees. Scharff also served on the NCI Executive Committee. "Matty has done a spectacular job and a lot of work," NCI Director **Richard Klausner** said at a March 8 meeting of the BSC. "He has been a voice of reason, pointing out what we're not paying attention to, and just giving a tremendous amount." Klausner presented Scharff with a commemorative gavel. "I am enormously impressed with how dedicated the Board of Scientific Counselors B has been," Scharff said. "The individuals have really done their homework. It has been a real reward for us that [Division of Basic Sciences Director] **George Vande Woude** and Rick Klausner have taken our recommendations very seriously. We really appreciate that while we are not always right, they look carefully at what we say. We have been inspired by Rick's brilliant leadership. It really is a pleasure to deal with a person who values the quality of science the way he does. That has motivated us in our review process, and we know it motivates the people we are reviewing. It has really made a change in what we see at NCI." . . . **BRUCE STILLMAN**, director of the Cold Spring Harbor Laboratory and a member of the BSC Subcommittee B, has been named chairman of the subcommittee, succeeding Scharff. . . . **ON THE CIRCUIT**: NCI Director **Richard Klausner** is scheduled to be the commencement speaker for Ohio State University's winter quarter commencement March 19 in Columbus. Ohio State expects to confer about 1,400 degrees at the ceremony. . . . **CANCER THERAPY AND RESEARCH CENTER** established a Center for Excellence for the Study and Treatment of Cancer-Associated Fatigue, with a grant from the Cancer Center Council, a volunteer organization. A grant from Ortho Biotech enabled the CTRC's Institute for Drug Development to form a drug development team to discover and develop ways to prevent fatigue, said **Daniel Von Hoff**, IDD director. . . . **CORRECTION:** A story in the Feb. 12 issue on the ORI finding of scientific misconduct by a data manager misidentified the institutions where the data manager, Thomas Philpot, was employed. Philpot worked at Rush-Presbyterian-St. Luke's Medical Center, Chicago, and MacNeal Cancer Center. MacNeal was affiliated with Northwestern University as an NSABP participating institution.

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