THE CANCER LETTER INTERACTIVE

Vol. 27 No. 25
June 22, 2001

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

Two Groups Take Different Approaches To Managing Toxicity Of Saltz Regimen

Two months after excessive mortality led two cooperative groups to suspend accrual to trials of a combination regimen of CPT-11, 5-flourouracil and leucovorin, the two groups have taken radically different approaches to managing toxicity.

—Cancer and Leukemia Group B introduced aggressive dose reductions for patients who exhibit signs of toxicity.

—In addition to making the same changes as CALGB, the North Central Cancer Treatment Group reduced the initial dose of the FDA-approved "Saltz regimen" for all patients, followed by a dose-escalation

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In Brief:

NIH Dedicates Louis Stokes Laboratories; Royston Retires As Kimmel Center President

LOUIS STOKES LABORATORIES, which will house scientific projects for nine NIH institutes and centers, was dedicated in honor of the first African-American member of Congress from Ohio. Stokes, who after 30 years in the House is now senior counsel at Squire, Sanders & Dempsey, and senior visiting scholar at the Mandel School of Applied Social Sciences at Case Western Reserve University, is recognized for his work in minority, poor, underserved, and disadvantaged communities. "Of all the facilities on the NIH campus, this is the first named in honor of an African American," NIH Acting Director **Ruth Kirschstein** said at the dedication ceremony. "We are doing something that he has done so often in his illustrious career and in his life. We are opening a new door—a door to state-of-the-art facilities, but more importantly, a door to myriad new opportunities and possibilities." . . . **IVOR ROYSTON** has joined Forward Ventures full-time, following his retirement as the founding president of the Sidney Kimmel Cancer Center, where he remains on the board of directors. Royston has served as a managing member of Forward Ventures, a life sciences and health care venture fund, since he co-founded it with managing member **Stan Fleming** in 1993. The company recently announced the closing of Forward Ventures IV, a $256 million venture fund focused on life sciences and health care. With the closing of this fund, Forward becomes the largest life science venture fund headquartered in Southern California and focused exclusively on life sciences, including biopharmaceuticals, medical devices, and biotechnology. Royston also founded Hybritech Inc.

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Review Planned Of 54 Deaths In First 60 Days On Studies

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for patients who tolerate the treatment.

To understand the causes of death, an independent contract research firm is preparing to examine the files of the 54 patients who died within 60 days of initiation of treatment on all the arms of the CALGB-led intergroup study C89803 and NCCTG study N9741.

A separate audit of patient files will be conducted by FDA. These examinations may produce strategies for screening patients to find those at risk of treatment-related death on the "Saltz regimen."

The "Standard" Becomes The Controversy

The Saltz regimen was approved by FDA as the standard of care for first-line therapy for advanced colorectal cancer. Following approval, the regimen became the standard comparator arm on a variety of colorectal cancer studies.

"You have a bunch of intelligent people looking at this, and trying to come up with an answer, and coming up with two different approaches, because we don't have data," said Leonard Saltz, a colorectal cancer expert at Memorial Sloan-Kettering Cancer Center and the principal investigator on the CALGB study.

"They are both reasonable approaches to address concerns," Saltz said to **The Cancer Letter**. "One is saying, let's start low, and go back up in those people who need it, the other is saying, let's keep the dose we were using, but make more aggressive modifications in the dose for people who are showing early signs of toxicity."

At the time the excess mortality was found, the CALGB study evaluating the Saltz regimen in the adjuvant setting had completed accrual, and all the patients had received initial treatment.

However, the CALGB strategy was adopted by sponsors of trials of new therapies that are being compared to the Saltz regimen. Sugen and Imclone have adopted the CALGB approach, sources said.

It is unknown what impact the dose reductions would have on survival, experts say. Would the narrow advantage associated with the Saltz regimen shrink or be lost when the initial dose is reduced?

In an attempt to answer this question, NCCTG will enroll another 700 patients to test the modified version Saltz regimen. Since this would not be a randomized trial, the question of the impact of the dose reduction would not be answered definitively, experts say.

"If one does a dose modification of the Saltz regimen, does that modified schedule have the same therapeutic efficacy as the original schedule?" said Richard Pazdur, director of the FDA Division of Oncology Drug Products.

"The NCCTG study might give us some insight into what's going on, but it doesn't replace a randomized study comparing the two dose schedules," Pazdur said.

NCCTG: Old Saltz Vs. New Saltz Unethical

In the NCCTG study, the dose of CPT-11 is reduced from 125 mg/m^2 to 100 mg/ m^2, and the dose of 5-FU from 500 mg/ m^2 to 400 mg/ m^2. Acknowledging that the trial would be imperfect, NCCTG leadership said a trial of the Saltz regimen versus modified Saltz regimen would be unethical.

"We don't believe that a randomized trial of original Saltz versus modified Saltz would be ethical to conduct, based on the first-cycle toxicity that we have observed on the original Saltz regimen," said NCCTG statistician Daniel Sargent.

"We wanted to try to get the best data we could on the efficacy of original Saltz versus modified Saltz, and the best data we could generate is to compare both the old Saltz and the new Saltz to the same arm, and that common arm would be Oxaliplatin/5-FU,"

THE CANCER LETTER

Member, Newsletter and Electronic Publishers Association

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E-mail: info@cancerletter.com

Subscription $295 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Founded Dec. 21, 1973, by Jerry D. Boyd

Sargent said. "We will have a comparison of old Saltz and of new Saltz to the Oxaliplatin regimen, and we will be able to make an indirect comparison between new Saltz and old Saltz. This is imperfect, but it is the best data we will be able to generate."

In the NCCTG trial, the death rate was 4.8 percent on the Saltz regimen arm, and 1.8 percent on each of the two arms testing Oxaliplatin-containing regimen.

In the CALGB trial, the death rate was 2.2 percent on the Saltz arm and 0.8 percent on the 5-FU/LV arm. Enrollment in the two trials was halted by the data and safety monitoring committees in April (**The Cancer Letter**, May 11, Vol. 27 No. 19).

Richard Goldberg, chairman of the NCCTG gastrointestinal cancer program and protocol chairman for the metastatic disease trial, said the addition of a new arm would allow NCCTG to collect pharmacogenomic data that could point to the causes of toxicity of the regimen.

"Previously, we said, 'Don't dose-reduce during the first four treatments. Wait till you have given all four,' " Goldberg said. "Now we are saying, 'If there is toxicity in week 1 and week 2, reduce the dose during week 3 and week 4.' We are allowing individualized dose modifications to occur sooner.

"Following the first cycle, we are allowing dose escalation for the Olympic athletes in the crew. So those people who tolerate it well can go up," Goldberg said.

Taking this logic one step further, Goldberg said he is troubled by the decisions of several pharmaceutical companies to keep Saltz as a standard regimen.

"I worry about what the study coordinators are going to do if they observe excess toxicity after the first cycle of treatment," Goldberg said. "Are they going to say, that's the way it goes. We are using big guns to treat big disease?

"Or are they going to say, we wish we had modified the doses and made them a little lower?"

Methodology Questions About Dose

The regimen's toxicity raises questions about the methodology for setting the doses for cytotoxic drugs, several experts said.

In most cases, clinical trials determine the maximum tolerated dose of the drug, and, typically, patients are given that dose from the outset.

"Traditionally, with cytotoxic drugs, we treat with the MTD or near-MTD doses," Pazdur said. "Newer cytostatic drugs, where doses are based at biologically effective doses, have tended to examine several doses of the drug. Is it possible to back off and take a look at less toxic schedules of cytotoxic drugs?"

Richard Schilsky, chairman of CALGB and associate dean at the University of Chicago, said patients who enroll in phase I studies that are used to determine the doses of drugs are not always representative of the population studied in larger studies.

"The idea of MTD is based on the notion of steep dose-response curves for most cytotoxic drugs in pre-clinical models, therefore justifying the idea that drugs should be dosed at the highest level a patient can tolerate," Schilsky said.

"The problem is that the highest dose a given individual can tolerate may be lower or higher than the average dose that appears tolerable for a population of patients. The key is understanding the inter-individual variation in a drug's effects so that doses can be optimized for individuals.

"In the case of CPT-11, this may be particularly important due to genetic variation in drug metabolism that could put some patients at high risk," Schilsky said.

Venturing further into theory, Goldberg said the value of MTD is uncertain in cases when the regimens are so toxic that only a few patients tolerate the intended dose of the drug.

"What is the meaning of the maximum tolerated dose?" Goldberg asked. "Only 60 percent of patients get the full dose of the Saltz regimen in Cycle 2. And if you look at the subsequent cycles, dose reductions continue to occur over time. So, the idealized regimen is only idealized for Cycle 1."

Saltz said his is not the only regimen to require an adjustment of the dose. In fact, about 40 percent of patients treated with 5-FU/LV require dose adjustment, he said.

"It is standard practice in oncology to aim high and watch carefully, and dose-adjust, so we don't under-treat those people who require a higher dose," Saltz said. "One thing that doesn't seem to happen is that we as oncologists rarely, if ever, escalate a dose, and I am a little concerned that that's not likely to happen in the modifications made by NCCTG. I hope it does, in those patients who should be escalated."

Patient Charts To Be Reviewed

A clearer picture of the problem is likely to emerge after a group of oncologists review the charts

of patients who died within 60 days of starting the treatment on the two trials.

The review was paid for by Pharmacia, which contributed the funds to the CALGB foundation, enabling the cooperative group to hire Theradex, an oncology clinical research firm, to conduct the review.

After Theradex collects the charts, one set will be set to FDA, and another will be reviewed by an independent panel of colon cancer experts. The review is expected to be completed by mid-July, sources said.

The reviewers' goal is to determine whether protocols were followed properly and whether clinical risk factors for severe toxicity can be identified.

No Criteria for Death Attribution in Trials

Though the work is yet to begin, the reviewers have already stumbled into a fundamental problem. "One of the things I have already learned is that there are no criteria for attribution of cause of death in cancer clinical trials," said Mace Rothenberg, chairman of the review committee and Ingram Associate Professor of Cancer Research at Vanderbilt Ingram Cancer Center.

"The cooperative groups don't have it, NCI doesn't have it, FDA doesn't have it," Rothenberg said. "So one of the factors likely to be at play here is that each individual investigator, along with the group operations office and biostatistician were applying common-sense criteria for determining whether deaths were drug-related.

"We have well established guidelines for toxicity grading, but when there is a death, it's left to the physician's judgment."

Rothenberg said that along with analyzing the data from the two trials, the group would attempt to develop criteria for establishing attribution of deaths on clinical trials.

"I didn't really give it a lot of thought before this," he said.

According to data presented last year to FDA, median survival among metastatic colon cancer patients receiving the Saltz regimen was 14.8 months, compared to 12.6 months for 5-FU/LV. Though thin, the survival advantage was statistically significant (p=0.042) (**The Cancer Letter**, March 24, 2000).

After the Saltz regimen became the standard of care, the NCCTG trial was redesigned. Since its start in the fall of 1998, the trial has been modified twice because of problems on the control arm. In the process, three of the trial's arms have been discontinued, and one arm added.

"This trial has been quite a laboratory," Goldberg said. "It demonstrates how trials of this magnitude take on a life of their own and have to be tended throughout their course."

Protocol Changes

The following are the dose modification changes to the studies.

CALGB 89803: Phase III intergroup trial of Irinotecan plus fluorouracil/leucovorin versus fluorouracil/leucovorin alone after curative resection for patients with stage III colon cancer.

a. If grade 2 diarrhea or neutropenia occur on the day of treatment, hold Irinotecan/LV/5-FU for one week, and then proceed with treatment on the following week with a one dose level reduction if toxicity has resolved. (Note: previous schedule called for the one dose level reduction without the hold in treatment.

b. If grade 3 or greater diarrhea or neutropenia occur after receiving only the first dose of treatment, hold Irinotecan/LV/5-FU until toxicity is fully resolved, then proceed with a two dose level reduction. (Note: previous schedule called for a one dose level reduction for grade 3 toxicity in this setting.)

c. Patient must be without a diarrheal movement (over pretreatment baseline), for at least 24 hours before the next treatment is given. If diarrhea occurs, within 24 hours of planned Irinotecan/LV/5-FU administration, then treatment is to be held that week.

NCCTG 9741: A randomized phase III trial of combinations of Oxaliplatin, 5-FU and Irinotecan as initial treatment of patients with advanced adenocarcinoma of the colon and rectum.

1. The starting doses on Arm A have been reduced to CPT-11 100 mg/m^2 and 5-FU 400 mg/m^2. This change is in response to the experience on this trial where patients treated on this regimen proved to have a high toxicity rate inlcuding a 4.8% death rate within the first two months. This result compares to a 1.8% death rate during that time interval in the other two study arms in this trial. To retain the maximum dose intensity on a patient-by-patient basis, provision for a single-dose escalation to the original regimen is specified for patients who experience grade 1 or less toxicity during cycle 1.

2. In order to provide adequate statistical power to evaluate the modified Arm A, the sample size has been increased to a total of 1,705 patients.

Cancer Policy:

Stronger Federal Role Needed To Improve Palliative Care

With federal research and training efforts centering largely on trying to cure patients with cancer, not enough has been done to further the field of palliative care, according to a new report by the National Cancer Policy board of the Institute of Medicine and National Research Council.

Changes are required across the health care system to overcome barriers that keep cancer patients from receiving adequate symptom control and supportive therapies, the board said.

Government agencies must allocate research funding for developing better interventions for managing cancer symptoms, and public and private insurers must re-examine their coverage of palliative care services.

The board expanded on its 1999 recommendations about ensuring quality care for cancer patients, and on those made in a 1997 IOM report on end-of-life care.

Few health care professionals are trained in palliative or end-of-life care, the board found. Compounding this situation are certain attributes of the health care system, particularly reimbursement policies for palliative and hospice care and disparities in care across various socioeconomic and age groups.

Palliative care for children is far from satisfactory, the report said. Little reliable information exists on quality of life and quality of care for patients.

Urges NCI To Fund More Research

NCI should step up its commitment to research aimed at improving symptom control and palliative care, the board recommended.

In 1999 NCI spent $26 million of its $2.9 billion annual budget—less than 1 percent—on research and training related to palliative and end-of-life care.

The board said NCI should mandate research on palliative care and symptom control by any health facility seeking to retain or achieve NCI recognition as a Comprehensive Cancer Center, and should designate certain places as "centers of excellence" in palliative care.

These centers would carry on a range of activities, such as evaluating practice guidelines, developing and assessing measures of the quality of palliative care, disseminating information to professionals and the public, increasing access to care for members of minority groups, and providing training for clinicians at all levels.

Coverage of palliative and hospice care for cancer patients is undermined by a system that focuses either on active treatment or on palliative or hospice care, and does not readily allow these approaches to be integrated, the report said.

The Medicare hospice benefit allows enrollment of patients only if they are expected to survive six months or less, and it does not cover potentially life-prolonging treatment in addition to palliative care—thereby making hospice enrollment tantamount to accepting death, an obvious deterrent for many patients.

The Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), should fund demonstration projects to devise better ways to deliver and reimburse palliative care for cancer patients when and where they need it.

The Centers should focus particular attention on fixing problems with the hospice benefit, the report said.

The committee's recommendations were informed by eight papers commissioned as part of the study.

This set of papers focuses on economic issues and barriers to high-quality end-of-life care for cancer patients, informational resources for patients and family members, palliative care for African-American patients and other vulnerable populations, special issues in caring for dying children, practice guidelines for clinicians on managing patients' psychosocial and physical symptoms, research on reducing cancer patients' distress, and training for health care professionals.

The study was sponsored by NCI, the Centers for Disease Control and Prevention, and the American Cancer Society.

Copies of the report, "Improving Palliative Care For Cancer: Summary and Recommendations," are available from the National Academy Press for $18 plus shipping charges of $4.50 for the first copy and $.95 for each additional copy; tel. 202-334-3313 or 1-800-624-6242 or order online at http://www.nap.edu.

The commissioned papers are available online at http://www.nap.edu and will be published later this year.

HHS News:

HCFA Renamed In HHS Effort At Medicare, Medicaid Reform

The Department of Health and Human Services has changed the name of the agency that runs Medicare.

HHS Secretary Tommy Thompson said the Health Care Financing Administration is renamed the Centers for Medicare and Medicaid Services.

The name change is part of a reform of the agency, Thompson said. The new name reflects the increased emphasis on responsiveness to beneficiaries and providers, and on improving the quality of care that beneficiaries receive in all parts of Medicare and Medicaid, he said.

Thompson said the Centers will:

—Begin a $35 million national media campaign to give seniors and other Medicare beneficiaries more information to help them make decisions about how they want to get their health care;

—Instill a new culture of responsiveness at the Centers for Medicare and Medicaid Services in serving beneficiaries, physicians and other health care providers, states and lawmakers;

—Enhance 1-800-MEDICARE (1-800-633-4227) to a 24-hour a day, seven days a week service that will provide far more detailed information to help beneficiaries to make Medicare decisions;

—Restructure the agency around three centers that reflect the agency's major lines of business;

—Reform the contractor process to improve the quality and efficiency of the Medicare claims processing services (Medicare carriers and fiscal intermediaries) that pay nearly a billion fee-for-service Medicare claims each year.

Thompson: "More Changes on the Way"

"We're making quality service the No. 1 priority in this agency," Thompson said. "These sweeping reforms will strengthen our programs and enable our dedicated employees to better serve Medicare and Medicaid beneficiaries as well as health care providers.... This is only the beginning. More changes are on the way."

The Centers administrator is Tom Scully.

The three new business centers being created as part of the reforms are the Center for Beneficiary Choices, the Center for Medicare Management, and the Center for Medicaid and State Operations.

The Center for Medicare Management focuses on the management of the traditional fee-for-service Medicare program, including development and implementation of payment policy and management of the Medicare carriers and fiscal intermediaries.

The Center for Beneficiary Choices focuses on beneficiary education, providing beneficiaries with the information they need to make their health care decisions. This center also includes management of the Medicare+Choice program, consumer research and demonstrations, and grievance and appeals.

The Center for Medicaid and State Operations focuses on programs administered by the states, including Medicaid, the State Children's Health Insurance Program, private insurance, survey and certification and the Clinical Laboratory Improvement Amendments.

Will Propose Legislation On Processing Services

To manage the Medicare program more effectively and responsively, the Centers for Medicare & Medicaid Services will develop a legislative proposal to be submitted to Congress that would provide for competitive bidding of claims processing services.

Medicare contracts with private health insurance companies to process and pay Medicare claims. Collectively, these contractors employ about 22,000 individuals and handle more than 900 million Medicare claims each year. Currently, these contracts are governed by laws that are more restrictive than general federal contract laws.

The agency would like to competitively award these contracts by using performance based incentives to improve the level of service to beneficiaries and providers, reduce administrative costs and improve efficiency.

"Contractor reform is an important part of the improvements we will be making over the next few months to serve our beneficiaries more efficiently," Thompson said.

NCI Contract Awards

Title: Collection, Storage, Advertisement and Distribution of Biological Response Modifiers. Contractor: McKesson BioServices Corp., Rockville, MD. Amount: $577,158.

Title: Production, Processing and Quality Assurance of Biological Response Modifiers. Contractor: Charles River Discovery and Development Services, Division of Charles River Laboratories, Rockville, MD. Amount: $4,281,744.

Professional Societies:

ASCO Survey Finds Docs' Quality Time With Patients Down, Due To Paperwork

The results of a recently completed ASCO survey of more than 2,500 cancer physicians confirms what many doctors have known for years, namely, the level of paperwork required to document patient care has become excessive, to the detriment of medicine as a whole, and patients in particular.

Concerned by what he called a "health care system out of control," ASCO President Lawrence Einhorn dedicated his presidency to tackling the issue of excessive documentation as required by Medicare.

For years, anecdotal evidence has been mounting to suggest that the increasing amount of documentation takes considerable time away from physicians' other more important responsibilities.

Now, the results of the first study to examine the scope of the problem provide hard evidence that documentation is, in fact, detracting from the amount of quality time physicians have to care for their patients and family members, conduct important clinical research, and mentor and teach the next generation of cancer doctors activities that are critical to improved patient care and treatment.

The study, "Impact of Regulatory Burdens on Quality Cancer Care," confirms that, on average, the amount of time that clinical oncologists spend filling out paperwork and documenting patient care has more than quadrupled over the past 25 years.

The study also found time spent conducting clinical research decreased by half, and time spent teaching medical residents also decreased by nearly half.

The study reports that the biggest impact of this "regulatory creep" into medicine is a significant increase in physician work hours and a significant decrease in job satisfaction among cancer doctors.

"People who choose to go into medicine choose this profession because they want to help people. Patients have always come first, still come first, and will always come first. However, HCFA and Congress and even the general public do not have a true sense of what it's like in a modern-day doctors' office," Einhorn said.

Based on data derived from this study, as well as the results of site visits to further substantiate evidence of the problem, ASCO is planning to call for reform of Medicare's documentation requirements. These requirements, dictated by the Health Care Financing Administration, are part of the federal government's attempt to ferret out fraud and abuse in the Medicare system. While safeguards are needed to ensure that fraud and abuse are not tolerated, ASCO believes the level and degree of documentation now required are excessive and detrimental to the quality of healthcare.

Although the study found that the amount of time spent with patients remained relatively stable over the past 25 years, the quality of that time has been greatly affected by the need to document information extraneous to the reason for the medical visit. For instance, under the guidelines issued by HCFA, doctors are often forced to conduct unnecessary diagnostic checks (eyes, ears, nose, and throat) and repeat previously asked questions (personal medical history, family medical history, etc.) to justify billing the level of service that appropriately reflects the actual medical care delivered.

Furthermore, each time a doctor sees a patient, the visit must be documented in painstaking detail. Doctors argue that a patient's diagnosis and treatment, not checklists published by the government, should drive documentation.

As a result of fear of the government's enforcement of documentation requirements, compliance offices have come into being, creating a full-fledged, costly, cottage industry within the healthcare sector, said Einhorn. The sole purpose of these compliance offices is to ensure that should the government conduct an audit of patient records, documentation of patient care is completed exactly according to government regulations, and medical services are coded precisely according to Medicare reimbursement rules.

Unfortunately, most of the people working in compliance offices do not have the medical training necessary to undertake such an effort.

"This situation is an example of unintended consequences," Einhorn said. "HCFA wants to prevent fraud and abuse, so it sets up documentation rules. Health care institutions want to avoid legal problems, so they aggressively enforce the rules. Although everyone has good intentions, the result has made practicing medicine increasingly difficult."

The true costs of this regulatory burden are being shouldered by society, Einhorn said. Patients are receiving less quality attention, residents are not getting the individualized instruction they need, and clinical research is suffering, said Einhorn.

NCCN, ACS Offer Publication For Patients About Nausea

The National Comprehensive Cancer Network and the American Cancer Society have released their second supportive care patient guideline, Nausea and Vomiting Treatment Guidelines for Patients with Cancer.

The publication is designed to help patients make more informed decisions about their treatment, the organizations said.

The patient guidelines result from a collaboration between NCCN and ACS. The publication content is derived directly from the professional oncology practice guidelines developed for physicians by the NCCN.

The patient guidelines also provide background information on different types of nausea and vomiting, their causes, various treatment options and a glossary of terms.

To order a free copy of NCCN/ACS Nausea and Vomiting Treatment Guidelines for Patients with Cancer or any of the other NCCN patient guidelines, see http://www.nccn.org or http://www.cancer.org.

Copies may also be ordered by calling NCCN (1-888-909-NCCN) or ACS (1-800-ACS-2345).

In Brief:

Royston Retires At Kimmel; Cancer Care Gives Awards

(Continued from page 1)

(1978) and IDEC Pharmaceuticals Corp. (1985). In 1977, Royston joined the faculty of the University of California, San Diego, as an assistant professor of medicine, where he assisted in the development of the UCSD Cancer Center. In 1996, President Clinton appointed Royston to a six-year term on the National Cancer Advisory Board. He is chairman of the board of directors of CancerVax Corp. and Sagres Discovery Inc., and a member of the board of directors of GenStar Therapeutics Inc., Favrille Inc., Avalon Pharmaceuticals Inc., and Conforma Inc. . . . **CANCER CARE** presented awards at its 18th annual Human Services Awards dinner: **Fred Hassan**, chairman and CEO Pharmacia Corp., received the 2001 Human Services Award for his leadership and work in cancer. The Beacon Award was presented to Avon Products Foundation for AVONCares, a program in partnership with Cancer Care for underserved women. The award was accepted by **Susan Kropf**, Avon president and COO. **Wayne Meichner**, executive vice president of merchandising at Saks Fifth Avenue, received the Fashion Leadership Award for his commitment to cancer initiatives for women. The Regulus Award was presented to **Christy Turlington**, model and activist, for her work on the Lung Cancer Awareness Campaign. . . . **MEDICAL COLLEGE OF WISCONSIN** received a $599,000 grant from the Ralph and Marion C. Falk Medical Research Trust to study the genetic link between chronic gastroesophogeal reflux disease and cancer of the esophagus, or Barrett's esophagus. **Reza Shaker**, professor and chief, Division of Gastroenterology and Hepatology and director of the Medical College of Wisconsin Digestive Diseases Center, is principal investigator. . . . **VANDERBILT UNIVERSITY** Chancellor **Gordon Gee** dedicated the **Frances Williams Preston** Building on June 20 in honor of the music industry leader's support of cancer research and the Vanderbilt-Ingram Cancer Center. Preston, president and CEO of the performing rights organization BMI, is president of the board of the T.J. Martell Foundation for Leukemia, Cancer and AIDS Research.The foundation established the Preston Laboratories at Vanderbilt in 1993. Since then, the foundation has provided more than $5 million for research in breast, prostate, colon, ovarian and lung cancers. . . . **INFORMATION SUMMARIES** on Complementary and Alternative Medicines are now available from the NCI Office of Communications. Click on http://cancernet.gov/treatment/cam.shtml for peer-reviewed statements that summarize current medical knowledge on several types of complementary and alternative medical treatments. . . . **ELECTRONIC SUBSCRIBERS:** Here is how to receive **The Cancer Letter Interactive** edition directly in your email, rather than having to click on a link back to our Web site. A simple change to your account will bring you the PDF file in your weekly email alert. Here's how: Go to http://www.cancerletter.com, click Sign On and enter your user name and password. Click on My Subscriptions. Under the Info Alert column, select PDF. Click OK. The next time an issue is posted, you will receive the PDF file. Or, here's an even easier way: send a request to info@cancerletter.com and include your user name. We will make the change for you. To view the current issue from the My Subscriptions page, click on The Cancer Letter, then select Current Folder. Scroll down to the most recent issue.

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Welcome to our *First International Congress on Monoclonal Antibodies in Cancer*, to be held in Banff, Alberta, Canada, at the Banff Springs Resort from August 30 – September 2, 2001. This symposium will educate physicians about new developments using monoclonal antibodies in the treatment of both solid tumors and hematological malignancies. The topics to be covered at this conference will include recent data using monoclonal antibodies developed for hematological malignancies including lymphoma, leukemia and myeloma. Our current understanding of the mechanism of action and resistance of these antibodies will be discussed. Radiolabeled antibodies for lymphoma including epratuzumab and tositumomab would be covered in detail. Novel antibody targeting HLA-DR (Hu1D10) and CD22 molecules will be discussed.

Substantial time will be devoted to our understanding of monoclonal antibodies targeted to growth factor receptors like HER-2 and EGF receptor. Other topics to be covered will include novel antiangiogenesis antibodies in development.

We would like to make this a multidisciplinary conference which is attractive to both basic scientists and translational researchers, as well as clinicians. There will be opportunity for poster displays and interactive discussions. We look forward to your participation in this important new meeting.

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