THE CANCER LETTER INTERACTIVE

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Expert Review Of ImClone Protocol Concludes C225 Approval Unlikely

The data from the controversial trial of C225 and CPT-11 cannot be reshaped into a format that could convince FDA to approve the monoclonal antibody, said three independent experts after reviewing a copy of a protocol ImClone Systems Inc. used to test the regimen in advanced colorectal cancer.

A copy of the proprietary protocol was obtained by **The Cancer Letter**. The reviewers were:

—Howard Ozer, director of Oklahoma University Cancer Center and Eason chair of oncology and hematology.

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In Brief:

Thomas Jordan To Help ASCO Enhance International Relations, Retires From BMS

THOMAS JORDAN, vice president of international oncology marketing for Bristol-Myers Squibb Co. until his retirement last fall, has signed a consulting agreement with the American Society of Clinical Oncology. Jordan, who served almost 20 years with BMS and prior to that, seven years with Adria Laboratories, will work with the ASCO leadership on the society's international relations. "ASCO is planning to improve outreach to the world by providing cancer education, in the hopes of improving cancer treatment," Jordan said. "It's exciting for me to have the opportunity to work with ASCO on this project." Jordan also will serve as a consultant to BMS. As director of oncology marketing for BMS, Jordan worked with oncology professional societies to establish some of the first educational awards provided by a pharmaceutical firm for cancer researchers, clinicians, and oncology nurses. The Oncology Nursing Society recognized Jordan's work by naming a doctoral scholarship in his honor. Jordan is a member of the ONS Foundation Board of Directors. . . .

ARNOLD LEVINE, biologist and co-discoverer of the p53 gene, announced his resignation as president of Rockefeller University on Feb. 10 for health reasons, after three and a half years in the position. Levine stepped down following the disclosure to the Rockefeller trustees that he had behaved inappropriately in a campus lounge with a woman graduate student from his laboratory in January after both had been drinking, according to news reports. The board selected **Thomas Sakmar**, head of the Laboratory of Molecular Biology and Biochemistry, as acting president.

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Reviewers: C225 Trial Design Can't Produce Data Needed

(Continued from page 1)

—Otis Brawley, professor of medicine, oncology, and epidemiology at Emory University Winship Cancer Institute and a member of the FDA Oncologic Drugs Advisory Committee.

—Mace Rothenberg, Ingram associate professor of cancer research at Vanderbilt Ingram Cancer Center, who was the principal investigator in two phase II studies that were part of the Pharmacia application for accelerated approval of CPT-11 for advanced colorectal cancer in 1996.

The reviewers were given copies of the protocol and the refusal-to-file letter in which FDA notified ImClone that its application for approval of C225 does not contain enough information to be reviewed (**The Cancer Letter**, Jan. 4, Jan.11, Jan. 25, Feb. 8). The reviewers were not paid.

The protocol describes a phase II study to test the hypothesis that CPT-11 and C225 could shrink tumors in patients whose disease progressed or remained stable on regimens containing CPT-11. The protocol was later converted into what the company hoped would be a registration trial.

The reviewers' critiques, which begin on page 4, focused on different problems with the protocol. However, all three agreed that the trial can't be expected to produce data to support either a full or an accelerated approval by FDA.

"Overall, this is a protocol that asks the wrong questions, and then is not tightly written and efficient," Brawley wrote. "The protocol generates far more questions than it could ever answer. It is a blueprint for the production of vague findings."

The reviewers' comments raise questions about the rigor of due diligence review Bristol-Myers Squibb conducted prior to paying as much as $2 billion for a 20-percent share in ImClone and about a 40-percent cut of proceeds from C225. Also, the findings provide a context for interpreting recent attempts by the pharmaceutical company to assume full control over development of the compound and interaction with FDA.

Bristol employs many first-rate experts in clinical trials who had the training and experience to catch the problems noted by the reviewers.

Though the anatomy of Bristol's decision to commit to ImClone and C225 remains unknown, sources familiar with the transaction say Bristol's business leadership was bullish on the deal. "It seemed this was a big product, and there was a lot of pressure to get the deal done," said one source.

The problems noted by the reviewers were fundamental:

—The entry criteria on the study were so vague that it can't be determined whether all the patients in the trial are indeed refractory to prior therapy.

—The Independent Response Assessment Committee is not mentioned in the protocol. Its formation following an Aug. 11, 2000, meeting with FDA officials was part of the attempt by the company to change the objective of the trial retroactively.

—Converting a run-of-the-mill trial to a registration trial is problematic, since a registration trial requires greater documentation on patients.

—The original protocol sought to enroll 49 evaluable patients with progressive disease and an equal number of patients with stable disease. Yet, while the trial was underway, the company altered it to include 120 patients with progressive disease.

"It is not clear whether the data presented to FDA encompassed both the stable disease and progressive disease groups, or whether it represented an expansion of the progressive disease cohort," Rothenberg wrote.

"This is an important point, since the protocol-specified analysis is based on an intention-to-treat analysis, which would include both the stable and progressive disease groups," Rothenberg wrote. "If

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the data presented to the FDA was comprised of only the subset of patients with progressive disease, then this should be considered a subset analysis, no matter how large the subset ended up being. While encouraging, subset analyses are never definitive. They are best used to help in the design of follow-up studies that address that question specifically and prospectively."

The company wrote the protocol, sources said.

Widely respected oncologists presented the findings at annual meetings of the American Society of Clinical Oncology in 2000 and 2001. These physicians had good reasons to regard this as a reasonable phase II, hypothesis-generating trial. More important, the trial gave their patients access to a sought-after therapy.

The authors of publications resulting from trials sponsored by pharmaceutical companies are chosen on the basis of prominence or because of the number of patients they enroll. Leonard Saltz, an oncologist at Memorial Sloan-Kettering Cancer Institute, was named lead investigator on the trial in the spring of 2000, after most of accrual was completed, sources said.

"There is nothing wrong with conducting a trial in which you are going to test the question that patients who are refractory to CPT-11 will now respond to a combination of CPT-11 and C225," Ozer wrote. "That's a perfectly fine hypothesis, but I don't think FDA would ever have suggested that this trial would support approval of a new drug."

No Binding Agreement With FDA

Drug companies have to comply with FDA determinations on safety of clinical trials, but when it comes to design, the agency's role is advisory.

Under a program called Special Protocol Assessment, FDA can enter into binding agreements with companies on trial design, but no such agreement could have existed between ImClone and FDA.

Agency officials declined to comment on the C225 application, but agreed to discuss the protocol assessment program, which has been available since 1997. Under that program, the agency can assess whether phase III protocols meet "scientific and regulatory requirements."

"Having agreed to the design, execution, and analyses proposed in protocols reviewed under this process, the agency will not later alter its perspective on the issues of design, execution or analyses, unless public heath concerns unrecognized at the time of the protocol assessment under this process become evident," the regulations state.

Companies that request protocol assessment meet with FDA as they are concluding phase II trials, and, once again, before going into phase III.

"We want to spend the time up-front to help sponsors design trials rather than in a salvage operation at the end of a poorly designed trial," said Richard Pazdur, director of the FDA Division of Oncology Drug Products.

"A poorly designed trial is a house of cards, lacking a foundation that will eventually make the determination of the drug's efficacy difficult, if not impossible," Pazdur said to **The Cancer Letter**.

"With poorly designed trials, truly effective drugs may not reach the market in a timely fashion, and everyone loses: the sponsor, FDA, and, mostly importantly, the American patient."

Meeting With FDA Scheduled For Feb. 26

ImClone and Bristol are scheduled to meet with FDA on Feb. 26. Based on the reviews of the protocol, they would be unwise to hold their breath for a favorable outcome.

Meetings of this sort give hapless sponsors the opportunity to petition for a reconsideration or to hammer out a plan for returning to the agency with better data.

Bristol and ImClone will not come to this appointment arm-in-arm. The companies have been locked in an extraordinary public feud, which involves officials firing off letters and making them available to the press.

The battle began on Feb. 5, when Bristol Chairman and CEO Peter Dolan demanded that ImClone step aside and allow Bristol to take over the dealings with FDA. Dolan also asked for a bigger percentage of proceeds from C225, cancellation of $800 million in milestone payments, and temporary removal of ImClone's two top officials, President and CEO Samuel Waksal, and his brother, Executive Vice President Harlan Waksal.

In a letter dated Feb. 12, Robert Goldhammer, chairman of ImClone's board, rejected Bristol's demands.

The letter states that a committee of the board "has concluded that there is no need, nor would it be in the best interests of ImClone Systems' stockholders, to renegotiate the terms of our existing partnership arrangements with Bristol-Myers Squibb."

Dolan responded on the same day. "Clearly, we

have a fundamentally different view of the serious issues created by the FDA refusal-to-file letter, subsequent events, and the appropriate course of action to take, including who should lead the effort going forward," he wrote.

Dolan's letter describes Bristol's efforts to resurrect C225 and the wrangling between the two companies:

"As you know, since the FDA's issuance of that letter, Bristol-Myers Squibb has provided significant resources and support to ImClone in an effort to respond to the FDA's concerns. These resources and support have been provided to ImClone even though we have no contractual obligation to provide them. Indeed, our agreement expressly provides that the initial Biologics License Application filing is ImClone's responsibility.

"ImClone management has advised us that they intend to take the lead at the FDA meeting on Feb. 26. Given the potential importance of this drug to critically ill cancer patients, we will continue our voluntary efforts to collect the CT and MRI scans and radiographic and other clinical data that we have been collecting in anticipation of the FDA meeting on Feb. 26, and to provide that information to ImClone. We will continue to provide ImClone with our views on the best approach to take with the FDA on Feb. 26. We also plan to attend the Feb. 26 FDA meeting.

"I must consider the best interests of Bristol-Myers Squibb Company and its shareholders. Accordingly, we are considering our business and legal options with respect to our relationship with ImClone, but will wait until after the FDA meeting to determine what further actions we may take."

Retrospectively reconstructed data from a flawed trial are extremely unlikely to convince FDA to change its mind on C225, reviewers said.

"An audit of all existing data may be the only way to be absolutely certain about the validity of the results to date," Ozer wrote. "Such an audit could at least salvage the trial and test the original hypothesis. However, it will not provide grounds for approval of C225 as a treatment for advanced colorectal cancer."

Rothenberg agrees. "The bottom line is that a phase III trial that included a C225-alone treatment arm would have… provided a clearer picture of the impact of C225 in patients with refractory colorectal cancer," he wrote.

Spokesmen for ImClone and Bristol did not respond to a request for a detailed discussion of the protocol with **The Cancer Letter**.

Retrospective Data Clean-Up Can't Help C225 Phase II Trial; Protocol Far Too "Fuzzy"

Howard Ozer, director of Oklahoma University Cancer Center and Eason chair of oncology and hematology:

I can't see how anyone can retrospectively clean up the data from this trial and make it part of a package that would convince FDA to approve C225. Bristol, ImClone—or whoever is in charge—will now have to conduct a randomized phase III trial that would compare a CPT-11-containing regimen with a C225 regimen.

This protocol is confusing with respect to eligibility requirements. You can't see what the ultimate denominator is. Who is in this trial? How they actually define refractory and stable disease is fuzzy. They do have good criteria for defining response to their combination of drugs, but there is very little about eligibility specifics.

If I were a physician entering a patient on this trial, I wouldn't know what to do to assess whether the patient is refractory or stable. I wouldn't know how to demonstrate that my patient is really and honestly progressing on CPT-11.

I can see how you could have reasonable disagreements on the definition of progressive disease, but that's why you need a definition. If you have a definition, you will not have a disagreement. If you don't define it, then different investigators will define it differently. Ordinarily, you would see this very clearly defined in a protocol.

Without a definition of refractory disease, a patient on this protocol could go immediately from a CPT-11-containing regimen to this experimental regimen of CPT-11 and C225.

For example, a patient could be entered immediately following the second cycle of CPT-11, which just might be the cycle that elicited the response. You would not then know whether the patient is responding to CPT-11 or C225.

The original goal was to accrue 49 progressive disease patients and 49 stable disease patients. Ultimately, ImClone says 120 progressive disease patients were accrued. To go back retrospectively and add more patients with the stratification for refractory disease already poorly defined makes the data even more fuzzy.

The science is not difficult at all. Any good institution could design this sort of trial. It just needs

good peer review. If a fellow brought this to me, I'd say there is nothing wrong with this trial design for testing this hypothesis, but the eligibility criteria would have to be cleaned up. I would tell that fellow that he or she needs to finish this protocol by defining the eligibility criteria.

I would, first of all, eliminate the stable disease population. I am not sure why that's there. Then I would spell out a rigorous definition of refractory disease, and I would require that patients have a minimum number of courses in order to be documented as refractory.

Because the sites are likely to vary in their definition of refractory disease, the company put together an independent review committee, IRAC (independent response assessment committee). They were trying to put some kind of an overall quality control on the protocol, but this is a retrospective manipulation, and that's inappropriate methodology in clinical trials.

A retrospective analysis introduces a bias. In this case, it's equivalent to introducing a sliding scale grading system after you've given a test to a class and found that only 20 percent passed, and now you go back to fix it by assigning a sliding scale and letting 50 or 70 percent—whatever your target number is—pass the test. That's fine when you are grading students in a school. It's not so fine when you are trying to find out whether a drug actually works better than the standard therapy.

There is nothing wrong with conducting a trial in which you are going to test the question that patients who are refractory to CPT-11 will now respond to a combination of CPT-11 and C225. That's a perfectly fine hypothesis, but I don't think FDA would ever have suggested that this trial would support approval of a new drug.

Had the response rate in this trial been 80 percent, I am certain that FDA would have continued to work with them. But that, clearly, was not the case.

If indeed the true response rate to C225 in CPT-11-refractory patients is 20 percent, then that's indeed a very significant result. Unfortunately, given the trial design based on flawed eligibility requirements, that result remains suspect.

An audit of all existing data may be the only way to be absolutely certain about the validity of the results to date. Such an audit could at least salvage the trial and test the original hypothesis. However, it will not provide grounds for approval of C225 as a treatment for advanced colorectal cancer.

ImClone Protocol Generates More Questions Than Answers

Otis Brawley, professor of medicine, oncology, and epidemiology, Emory University Winship Cancer Institute:

The problem with this protocol is that it asks the wrong questions necessary to gain approval. In many respects it reflects the thinking of "the old school of oncology" in which it was believed that a drug that causes tumor to shrink is good and definitely means the patient lives longer. The profession has gotten beyond that; there are a number of diseases where the concept has not proven true. The question one should ask in a trial to gain approval is, "Does treatment with the drug improve the quality or the quantity of the patient's life?"

A small phase II trial to assess response is useful and should be done, but to justify a larger phase III trial comparing the accepted standard treatment with an experimental treatment. An alternative approach in patients with disease refractory to standard therapy would be to do a phase II trial with rigorous quality of life measures. If one can prove that the drug decreases pain, discomfort and other morbidities of metastatic disease refractory to other treatments, then one has made a true contribution. The quality of life component of this protocol was without the rigor necessary to prove the treatment improves quality of life.

The trial as written would have been an "OK phase II study," if it were performed in a single institution by one specific principal investigator, who saw all the patients enrolled.The major difficulties with a multi-institutional trial, as written, include the fact that the inclusion and exclusion criteria are vague, to say the least. There are broad criteria as to what is a patient who has stable or progressive disease, while getting 5-FU and CPT-11.

Very detailed exclusion criteria are necessary when running a clinical trial in a number of institutions, because a number of doctors will be reading these criteria and trying to apply them. Indeed the fact that this drug received a lot of hype and positive press means a physician hoping to do the best for his or her patient might use the vagueness of the inclusion and exclusion criteria to their advantage enrolling patients the authors of the trial would have excluded.

There is, of course, the question, "Why include the individuals with stable disease in the clinical trial?" In my opinion, there are two trials in this protocol. A

trial of patients with nebulously stable disease while on 5-FU and CPT-11, and a trial of patients with nebulously progressive disease while on 5-FU and CPT-11. This might be called "stratifying" in an extremely loose employment of the word.

The study of a stable disease cohort is actually a study biased against the CPT-11 and C225 combination. It is difficult to argue that a patient with stable disease on a 5-FU and CPT-11 regimen would have benefited if they have stable disease on the new experimental regimen. Also, stable disease and progressive disease are possibly very different diseases. Hence, again the argument that they described two different trials in one protocol.

It should be noted that pretreatment evaluation doesn't specifically require an x-ray, a CT, or MRI scan to establish tumor size. The protocol doesn't specifically state that all imaging studies, both those done before and after conclusion of treatment, would be forwarded to centralized reviewers. It is unclear who was to make the call of response, stable disease, or disease progression in the original protocol. The Independent Response Assessment Committee eventually used to evaluate responses is not mentioned in the original protocol. In an ideal study, three radiologists would be engaged prospectively to assess before- and after-treatment films, as patients completed the trial.

The radiologists should separately see the films from just prior to administration of study treatment and the data and films that are used after completion of study treatment. Each radiologist would individually decide what the response is. Any differences of opinion among the radiologists should be carefully noted and discussed.

Overall this is a protocol that asks the wrong questions, and then is not tightly written and efficient. The protocol generates far more questions than it could ever answer. It is a blueprint for the production of vague findings.

Phase III Trial Would Give Clearer Picture Of C225 Role

Mace Rothenberg, Ingram associate professor of cancer research at Vanderbilt Ingram Cancer Center:

The protocol, as written, is comprised of two groups of patients: one with "stable disease," and one with "progressive disease" following treatment with CPT-11. Biologically, these could represent two very distinct groups.

Those with progressive disease must have greater than or equal to 25 percent increase in tumor dimensions and are a fairly homogeneous group. On the other hand, stable disease encompasses patients with anywhere from a 49percent shrinkage to a 24 percent enlargement in tumor dimensions. This is a much more heterogeneous group of patients. For example, a patient who had received two cycles of CPT-11 and had 49 percent shrinkage of tumor could have been eligible for this trial.

A mere 1 percent additional shrinkage in tumor diameter following treatment with C225 plus CPT-11 would have converted this patient with "refractory" disease into a "responding" patient.

It is not clear whether the data presented to FDA encompassed both the stable disease and progressive disease groups, or whether it represented an expansion of the progressive disease cohort.

This is an important point, since the protocol-specified analysis is based on an intention-to-treat analysis, which would include both the stable and progressive disease groups. If the data presented to the FDA was comprised of only the subset of patients with progressive disease, then this should be considered a subset analysis, no matter how large the subset ended up being. While encouraging, subset analyses are never definitive. They are best used to help in the design of follow-up studies that address that question specifically and prospectively.

There is an inherent contradiction in the way patients with stable disease are treated by the protocol. At entry, patients with either stable or progressive disease on CPT-11 were considered to be "refractory" to therapy and therefore eligible for this trial, implying lack of benefit from single agent CPT-11. However, once on C225, patients without progressive disease could continue to receive therapy, implying that those patients with stable disease were deriving benefit from therapy. This is internally inconsistent.

It appears that sequential scans demonstrating stable or progressive disease on CPT-11 were required for patients to be eligible for this study. These scans are of critical importance because of the non-controlled nature of this phase II trial. Since each patient's response to combined CPT-11 and C225 therapy was, ultimately, going to be compared to the response (or lack of response) that that patient had had to prior CPT-11 therapy, retention and review of those scans by the IRAC would be essential for demonstration of the impact of the CPT-11 and C225 combination.

It's hard for me to imagine that this study was

intended for use as a registration study. I think that it is more likely that the sponsor considered the results so compelling that it was decided to proceed directly to registration without performing additional studies that would have addressed some of the key questions that remained. These questions include:

—Must C225 be administered in combination with CPT-11 in this setting, or would similar results have been obtained with C225 alone?

—Were adequate phase I studies done to determine the appropriate dose of C225 to be used in this setting?

—Why weren't baseline scans demonstrating stable or progressive disease on previous CPT-11-containing regimen retained and reviewed by the IRAC?

—Why wasn't the study conducted exclusively in a more homogeneous patient population, such as those with progressive disease on or shortly after single agent CPT-11?

—What happened to the quality of life data that the protocol required?

The bottom line is that a phase III trial that included a C225-alone treatment arm would have addressed many of these questions and provided a clearer picture of the impact of C225 in patients with refractory colorectal cancer.

Funding Opportunities:

RFA Available

RFA-RR-02-004: NIH ERA Small Business Funding Opportunities

Letter of Intent Receipt Date: March 22, 2002

Application Receipt Date: April 17, 2002

NIH and the National Center for Research Resources invite applications for the development of commercial products and services supporting NIH Electronic Research Administration. For information eRA, see http://era.nih.gov. The funding mechanism will be the SBIR Fast-Track; see http://grants.nih.gov/grants/funding/phs398/phs398.html.

This RFA is posted at http://grants.nih.gov/grants/guide/rfa-files/RFA-RR-02-004.html.

Inquiries: Jerry Stuck, commons coordinator, NIH eRA, Office of Extramural Research, OD, NIH, 6705 Rockledge Dr., Suite 1040, Bethesda, MD 20892-7980, phone 301-435-0690, ext. 615; e-mail js706d@nih.gov

RFP Available

RFP/N01-CN-85093-40

NCI Division of Cancer Prevention, Chemoprevention Agent Development Group, is interested in evaluating inhibitors of carcinogenesis in vitro, to identify chemopreventive agents against cancer. The objective of the studies is to determine the efficacy of chemopreventive agents in an array of in vitro model systems representing different cell substrates, those of human origin in particular. The studies are designed to rank-order and prioritize agents for further development. The NAICS code is 54171. Those not currently in the In Vitro Master Agreement Pool and who wish to be considered for inclusion should consult the Research Contracts Branch web site at http://amb.nci.nih.gov under Current Requests for Proposals and refer to RFP/N01-CN-85093-40.

Inquiries: Dorothy McMillan, contract specialist, Prevention and Control Contracts Section, Research Contracts Branch, NCI, Bethesda, MD 20892-7226, phone 301-435-3828; fax: 301-402-8579; e-mail: dm308v@nih.gov.

Program Announcement

PA-02-060: Structural Biology of Membrane Proteins

This PA encourages basic research on the structures of membrane proteins at atomic resolution. Considerable research is ongoing in membrane protein structure and function, yet relatively few investigators have applied the techniques of x-ray crystallography, electron diffraction, or nuclear magnetic resonance spectroscopy to study directly the structures of their proteins. Membrane proteins and membrane complexes of interest to NCI include those associated with the biology, diagnosis and treatment of cancer. Proteins of specific interest include those membrane proteins whose alterations have been shown to be linked to the development and progression of cancer. Membrane proteins that are part of cancer related signaling pathways are also of interest. Of special interest are the proteins associated with the extracellular matrix (for example laminins and fibronectin). Proteins with potential as diagnostic markers and/or therapeutic targets will also be of high interest. NCI is also soliciting applications focused on the development of new approaches and technologies for the isolation, purification, and structure determination of these proteins. Applicants strictly focused on technology should consider applying under the NCI Innovative Molecular Applications of Technology Program: http://otir.nci.nih.gov/tech/funding.html.

This PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-02-060.html.

Inquiries: Daniel Gallahan, chief, Structural Biology and Molecular Applications Branch, program director, Cancer Cell Biology Branch, Division of Cancer Biology, NCI, Room 5000, EPN, 6130 Executive Blvd., Rockville, MD 20892-7385, phone 301-435-5226; fax 301-480-2854; e-mail dg13w@nih.gov

In Brief:

Levine Leaves Presidency Of Rockefeller University

(Continued from page 1)

Levine is credited with improving the university's ties to Memorial Sloan-Kettering Cancer Center and Weill Medical College of Cornell University, as well as increasing the number of grants the university received, and recruiting more graduate students and faculty. . . . **CAROL BROWN,** of the Gynecological Service at Memorial Sloan-Kettering Cancer Center, was elected chairman of the Cancer Caucus at the American Medical Association meeting recently in San Francisco. . . . **CAROL REED ASH,** who holds the Kirbo endowed chair in oncology at the University of Florida College of Nursing, has been appointed associate director for cancer control and population sciences for the University of Florida Shands Cancer Center. She will coordinate and implement all of the center's cancer control activities and will collaborate with **W. Stratford May Jr.**, director of UF Shands Center. Ash developed GatorSHADE, a skin cancer prevention program for elementary school students and their parents. She is also a principal investigator of an NCI-funded cancer education program for nurses in developing countries. . . . **NATIONAL COALITION** for Cancer Survivorship presented its Ribbon of Hope Awards at its gala Feb. 9 in Washington, DC. **Lilly Tarkitoff**, co-founder of the Revlon/UCLA Woman's Cancer Program, presented **Sam Donaldson**, of ABC News, with the NCCS Lilly Tartikoff Hope Award. **Jeffrey Nugent**, president and CEO of Revlon, accepted the NCCS Private Sector Leadership Award. Former **Sen. Connie Mack** presented the Public Service Leadership Award to **Reps. Bentsen, Capps, Myrick,** and **Pryce**, co-chairmen of the House Cancer Caucus; NPR's **Cokie Roberts** presented the Natalie Davis Spingarn Writer's Award to New York Times reporter **Robert Pear**. HBO Vice President **Sheila Nevins** presented the NCCS Excellence in Media Award to **Margaret Edson**, Pulitzer prize winning playwright of "WIT!" The NCCS President's Award was presented to **James Fordyce**, chairman of the Albert & Mary Lasker Foundation. The Catherine Logan Service to Survivorship Award was presented to patient advocates **Maria Hinestrosa** of Nueva Vida and **Karen Jackson** of Sisters Network Inc. . . . **TWO INSTITUTIONS** tied for top patient accrual in clinical trials sponsored by the Radiation Therapy Oncology Group in 2001. Roswell Park Cancer Institute Department of Radiation Oncology and University of Texas Medical Branch, Galveston, tied for patient accrual among RTOG affiliate members.

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