THE CANCER LETTER INTERACTIVE

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ODAC Vote On CPT-11 Changes Standard Of Care For Advanced Colorectal Cancer

In two separate votes March 16, the FDA Oncologic Drugs Advisory Committee changed the standard of care for colorectal cancer and affirmed increased survival as the ultimate standard for front-line care in advanced colorectal cancer.

In unanimous votes to recommend approval for CPT-11 (irinotecan hydrochloride), a drug supported by strong survival data, and shot down Eloxatin (oxaliplatin), a drug supported by problematic survival data.

CPT-11 is sponsored by Pharmacia & Upjohn. Oxaliplatin is sponsored by Sanofi Pharmaceuticals and licensed in the U.S. by Eli Lilly & Co. Both drugs were proposed for use in 5-fluorouracil and leucovorin regimens.

The change in standards used in clinical trials was almost immediate. Discussion of changing the comparator in clinical trials began immediately

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In Brief:

Bast Named VP For Translational Research And Co-PI Of Core Grant At M.D. Anderson

ROBERT BAST, head of the Division of Medicine at M.D. Anderson Cancer Center and the principal investigator on the M.D. Anderson five-year, $10 million NCI SPORE grant for ovarian research, was appointed vice president for translational research at the center. In his new position, Bast will work with **Margaret Kripke**, senior vice president and chief academic officer, to facilitate collaborations between clinicians and laboratory investigators throughout the center. Bast will also serve as co-principal investigator of the Cancer Center Support Grant from NCI with **John Mendelsohn**, president of M. D Anderson. . . . **NATIONAL SURGICAL ADJUVANT BREAST AND BOWEL PROJECT**, an NCI funded clinical trials cooperative group, is establishing a Minority Representation Committee to advise the group on how to increase the representation of racial and ethnic minority women and men in NSABP clinical trials and in its membership. **Bertha Ford**, whose background is in oncology nursing and procedural aspects of clinical trials research, will serve as chairman of the committee. For applications, to be returned by April 5, contact **D. Lawrence Wickerham**, at 412-330-4657. . . . **LEUKEMIA & LYMPHOMA SOCIETY**, through its First Connection Program, is offering newly diagnosed patiets with blood-related cancers counseling from patients in remission. Matched with a

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ODAC Votes Down Oxaliplatin For Lack Of Clear Survival Data

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after the vote to approve CPT-11, and a week after the vote, investigators conducting a six-arm trial of colorectal cancer treatments decided to drop the 5-FU/LV arm of the study, said Richard Goldberg, chairman of the gastrointestinal program of the North Central Cancer Treatment Group, and principal investigator in the intergroup study N9741.

"The use of 5-FU/LV as a standard needs to be seriously questioned," said Richard Pazdur, a colon cancer expert and director of the FDA Oncology Drug Products Division. "Discussion at ODAC confirmed that CPT-11 and 5-FU/LV should be strongly considered as a standard first-line comparator to any new treatment being developed."

ODAC's thumbs-down vote on oxaliplatin was no less significant. Committee discussion of the application demonstrated how a drug that has been shown to be active in colon cancer was hindered by a poor development strategy for the U.S. market. With the approval of CPT-11 raising the bar, the drug's prospects in the U.S. now look even more uncertain.

"The story of oxaliplatin shows a disconnect between the demonstration of biological activity and clinical benefit," Pazdur said to **The Cancer Letter**. "The missing picture was how this drug benefits patients in the first-line setting."

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Other researchers seem unable to hide their frustration with Sanofi. "This is an absolute nightmare in clinical development," said a prominent clinical researcher involved in testing oxaliplatin. "It takes a singular effort to take an agent which is as promising as oxaliplatin and have so little to show for it.

"This doesn't happen by chance."

Of Survival And Other Standards

Dramatic realignment of therapies available for colon cancer brings into focus the criteria used by FDA to approve drugs.

While the industry and many clinical researchers pressure the agency to accept less stringent measures of efficacy, FDA officials and ODAC demand demonstration of the survival advantage.

Last summer, after reviewing breast cancer data, the committee unanimously reaffirmed survival as the gold standard for approval of cancer drugs (**The Cancer Letter**, June 18, 1999). Both sides have spoken in the context of breast cancer. Now, the debate can be repeated in the context of colon cancer.

"In my opinion, the requirement that a new drug or regimen must show a survival advantage over a reference regimen in first-line treatment of metastatic colorectal cancer was appropriate in the circumstance when 5-FU was the only drug available for treatment," said NCCTG Chairman Goldberg, director of gastrointestinal cancer research at Mayo Clinic. "Once other options became available that could influence survival in second-line treatment, the demonstration of a survival advantage over standard therapy as the sole determinant of a single drug or multi-drug regimen's activity became problematic."

Pazdur said the CPT-11 application demonstrates that it's practical to demonstrate a survival advantage in this setting.

"When drugs are truly effective, survival advantages can be shown despite crossover," Pazdur said. "The FDA analysis of the CPT-11 data demonstrated a survival advantage over 5-FU/LV even though as many as 40 percent of patients initially treated with 5-FU/LV were crossed over to CPT-11 at disease progression."

Moreover, other measurements, such as time to progression, are not as reliable as survival, Pazdur said. "The measurement of time to progression in unblinded trials is fraught with measurement bias," Pazdur said. "This is especially problematic when we are dealing with small differences in time to progression. Obviously, if we had a major impact on

time to progression, it could be considered, but usually differences have been small. This surrogate endpoint does not confer the determination of a clinical benefit."

Oral Drugs And The Saga of Comparators

Observers said that the change in the standard of care raises questions about the approval standards—and usefulness—of an entire class of drugs: oral equivalents of 5-FU/LV.

These include the Bristol-Myers Squibb sponsored drug UFT (tegafur/uracil) capsules, combined with oral leucovorin, and packaged under the name Orzel. Also in the pipeline for colon cancer are Xeloda (capecitabine), a breast cancer drug sponsored by Hoffmann LaRoche, and eniluracil (GW776C85), sponsored by GlaxoWellcome.

With the standard of care changed, these drugs will now be used in patients willing to forego the survival advantage of CPT-11 in favor of a less toxic, more convenient therapy.

"This dramatically changes the lay of the land for oral drugs," Goldberg said to The Cancer Letter. "There is no oral CPT-11 available at this time. Therefore, regimens that incorporate UFT with CPT-11 will still require intravenous administration. The need for combination with an intravenously administered companion drug takes away the one of the potential advantages of an oral agent."

For FDA, the question of standards to be used in approval of oral 5-FU/LV treatments emerged late last year, when ODAC voted unanimously to approve Bristol's oral UFT/LV combination (**The Cancer Letter**, Sept. 24, 1999). However, even before it went to the committee, the drug became bogged down in the agency's "fixed combination" regulations, which require that all components of a drug contribute to its safety and efficacy.

The application sank deeper as the agency began to develop methodology for assessing equivalence claims. At an ODAC meeting last December, Robert Temple, director of the FDA Office of Drug Evaluation I, said the agency needs to develop standards for evaluation of such claims since approvals based on equivalence can erode the standards of care (**The Cancer Letter**, Dec. 17, 1999).

Though no specific examples were mentioned at that session of ODAC, industry observers recognized veiled references to Mayo Clinic Regimen of 5-FU/LV to which the BMS drug was being compared.

On March 17, the day the agency was obligated to issue an "approvable" or "not approvable" letter for UFT, Bristol withdrew its application.

"The company elected to withdraw and resubmit these applications to afford the FDA additional time to review new analyses of existing data provided by BMS during the review process," the company said in a press release.

Industry sources said pulling the application allowed the company to avoid receiving a "not approvable" letter and a battle with the agency.

"I am anxious to have UFT available as an option, because it's easy to take and easy to give," Goldberg said. "Were it available, I would recommend it to someone who does not want intravenous treatment."

Oral drugs could prove useful in the adjuvant setting, too, observers said. That use is being studied in a clinical trial by the National Surgical Adjuvant Breast & Bowel Project. The trial, C-06, has accrued about 1,500 patients to compare a UFT and oral LV regimen with intravenous 5-FU/LV in stage II and III colon cancer. The study is expected to be concluded in about four years.

Changing The Standard Of Care: A Discussion

The CPT-11 regimen was given the approval recommendation on the basis of two randomized, prospective, multicenter trials involving over 400 patients.

One study was a three-arm comparison of CPT-11 and 5-FU/LV administered weekly (Saltz Regimen) with 5-FU/LV (Mayo Clinic Regimen), and CPT-11 as a single agent. Another study compared two infusional regimens of 5-FU/LV, each in combination with CPT-11, to these same regimens alone.

According to FDA, comparison of the CPT-11 combination arms to the 5-FU/LV arms demonstrated statistically significant differences in survival time, time to tumor progression and response rates.

The three-arm study, conducted in the U.S, showed the best results in the Saltz Regimen arm:

—Median survival in that arm was 14.8 months, compared to 12.6 months for Mayo Clinic Regimen and 12 months for CPT-11 as a single agent (p=0.042).

—Median time to progression was seven months for the Saltz Regimen, 4.3 months for Mayo Clinic Regimen, and 4.2 months for CPT-11 as a single

agent (p=0.004).

—Response rate was 39 percent for Saltz regimen, 21 percent for Mayo Clinic Regimen, and 18 percent for CPT-11 as a single agent (p<0.001).

According to FDA, the Saltz Regimen arm demonstrated more frequent grade 3 and 4 late diarrhea, nausea, vomiting, and alopecia, but less frequent severe neutropenia and severe mucositis than the Mayo Clinic Regimen arm.

Little discussion was required for ODAC to recommend approval. Immediately after voting to change the standard of care, the committee moved on to a discussion of the implications of this decision.

An edited transcript of that discussion follows.

RICHARD SCHILSKY, ODAC Chairman and Associate Dean for Clinical Research at the University of Chicago: "Should this regimen—CPT-11 plus 5-FU/LV—be considered the standard against which all future regimens would be compared?"

KATHY ALBAIN, Professor of Medicine at Loyola University Medical Center: "I think you would have a hard time justifying [5-FU/LV] in an informed consent situation in a clinical trial."

SCHILSKY: "Do you feel an ethical obligation to offer this combination regimen?"

ALBAIN: "Yes, I do."

RICHARD SIMON, Chief of the NCI Biometric Research Branch: "We have, basically, a risk-benefit situation. There is some benefit, but we don't see some great tail on these curves. All these patients are dying. We have a couple months benefit in median survival, including additional toxicity. I think it should be up to the patient. I think there has to be clear informed consent as in any study of what the available treatments are."

SCHILSKY: "I completely agree with what you said with respect to the general practice of medicine. I think we don't want to spend much time discussing that, because people will practice medicine as appropriate in the context of the doctor-patient relationship. It probably would be useful for the agency and for the industry to spend a little time talking about whether a CPT-11 plus 5-FU/LV regimen should henceforth be the comparator arm in future randomized trials."

GEORGE SLEDGE, Professor at the Departments of Medicine and Pathology at the Indiana University School of Medicine: "As I understand it, in the second line indication, there is a two- to three-month survival advantage. In a front-line indication, there is a three-month survival advantage. So, there is an argument that whether you give this in first-line or second-line therapy, there is a two- to-three month survival advantage."

KIM MARGOLIN, Staff Physician at the Department of Medical Oncology and Therapeutics Research at City of Hope National Medical Center: "I don't think we can do that as a discussion. All sorts of other things need to be taken into account. As a general rule, I'd say yes, this should establish a new standard. But I would want to talk to that clinical trials group and those responsible for designing the trial."

SCHILSKY: "Let me just pose one or two questions to help frame the discussion. I guess one would be, it's clear that there are lots of new agents in development, and there are agents that will be shown in the future to be safe and effective in treating colorectal cancer. And one of the questions that lots of people are grappling with is, in a study that's being designed today to be presented to some ODAC, three, four, five years hence, if the control arm in that study is 5-FU/LV, is that going to be viewed by this committee to be a suitable control arm, in view of the fact that CPT-11 will now be available as a component of front-line therapy? The other issue is sort of a more practical one. It is clear that if FDA follows our recommendation for approval that the sponsor will be out promoting CPT-11 as a component of front-line therapy, would it be practical to conduct randomized trials in the future in which the control arm does not include CPT-11?"

DAVID JOHNSON, Director of the Division of Medical Oncology at Vanderbilt University Medical School: "I have several comments. The first would be that at least in my time on the advisory panel, it's been made abundantly clear to me personally that the FDA looks very strongly on using as a comparator an FDA-approved regimen. Rightly or wrongly, that's something that the industry will have to take into account. If I may give a couple of examples—this may be especially relevant for Dr. Albain—I know of no ongoing cooperative group trial that uses an FDA-approved regimen, with one exception, for the comparator arm."

SCHILSKY: "Is that in general?"

JOHNSON: "Non-small cell lung cancer. I am not sure why that was a question. It's the only real cancer. Everything else is simple. So, if the FDA position is that only FDA-approved regimens would be acceptable in that setting, then there is no reason to discuss it. And I think that's the position generally

have today. Why would anyone accept a non-approved regimen? There is a second question: Is it ethical? Now, with this wise body—and I am actually surprised that you asked us, because we are clearly at the cross-point of all knowledge—because if we rule on this, then it's over, as far as I am concerned. But the answer, as a clinician, would one be willing to treat one's patient without CPT-11, and the answer is clearly yes. I think it has been said, the risk/benefit ratio, and one has to assess each patient individually and make a decision, provide information to the patient, which also encourages the patient to read the package insert, and make decisions about that. The more relevant issue is even is a study were to start today, looking at four or five years down the road, this whole group would have changed by that time. And I think even if we thought that it was wise to do so, another panel may not…"

SCHILSKY: "What about the practical? Here is the issue: any trial going forward would have to have to have a statement in the consent form that the alternative therapy for the patient would be CPT-11 plus 5-FU/LV, which has been shown to be superior to 5-FU-leucovorin in a prospective, randomized trial. I think that's a clear ethical obligation that we would have to the rest of the patients is to make sure that they are aware of that alternative. Once stated, I would have a real question as to how many patients would be willing to accept randomization to 5-FU/LV."

SCOTT LIPPMAN, Professor of Medicine and Cancer Prevention at M.D. Anderson Cancer Center: "From the clinical trials perspective, there really isn't any question. There could be some extenuating circumstances, but this is now a standard arm to which new approaches are compared. There are studies probably that are ongoing that don't CPT-11 arm."

MARGOLIN: "This brings up one line in all those consents form that we would tell patients that if new findings occur, we would be obligated to [inform] them."

SCHILSKY: "I would think it will have some impact on that study, with respect to whether 5-FU/LV control arm can and should be continued as a control arm on that study. The study was actually designed with the potential to block the control."

Wither Oxaliplatin?

It would be unrealistic to expect an orderly development strategy from a drug with oxaliplatin's troubled history. The drug has changed hands frequently. It originated in Japan, moved to Paris-based Rhone-Poulenc Rorer, then Debiopharm of Lucerne, then back to Paris, to Sanofi.

The data—and the approval strategy—were European: The studies were designed to assess response rates and progression-free survival. Trials designs were designed without input from FDA. The 5-FU/LV comparator regimens were not commonly used in the US, and survival assessments involved extensive statistical analysis that went beyond the simple log rank test.

The company tried to overcome these little problems by assembling a who's-who in colon cancer to sit with company officials during the presentation, and by hiring Mace Rothenberg, Ingram Associate Professor of Cancer Research at Vanderbilt University, to arrange and present the application.

"The regulatory standard for first-line therapy in colorectal cancer is to improve overall survival," said FDA medical reviewer Steven Hirschfeld, opening his assessment of the application. "That principle has been affirmed many times in discussions by this committee and the predecessor, and in the transcripts of those discussions particular mention is made that results which are based on tumor measurements, such as response rate or progression-free survival are difficult to interpret."

The company's pivotal trial was not up to snuff, NCI's Simon said. "This is really not a randomized study at all," he said. "This strikes me as essentially immature data, which is not ready to be presented to FDA at this point. You have 90 patients censored in the survival analysis on the oxaliplatin arm, and 79 patients censored on the survival analysis on the control arm, with a median of follow-up of only 20 months."

After Simon was through, Johnson went after what little remained.

"What I have heard so far today is a pretty strong presentation from the standpoint of convincing me that oxaliplatin has some sort of activity in colorectal carcinoma," Johnson said. "The sponsor is, however, seeking an indication for first-line therapy, and as a clinician I am struggling with how I am going to present this to my patients for whom 5-FU/LV could be the alternative. I am further struggling with what is going to convince me to give this as a front-line therapy, since you have not shown us a survival advantage. If I give oxaliplatin, what I've seen is a lot more toxicity, and I haven't seen a survival

advantage. It seems like I could add neurotoxicity to 5-FU."

Goldberg, a consultant to the company, said ODAC's unanimous decision was understandable, but disappointing.

"The committee did what it had to do, based on the data it had available for oxaliplatin," he said to **The Cancer Letter**. "It was unfortunate that the data available was not stronger. I came away disappointed that patients would not have access to oxaliplatin, except under restricted circumstances. I believe that the European data supports the fact that oxaliplatin, especially when combined with 5-FU/LV, is active in colorectal cancer."

The Future, And A Suite At The Pierre

After ODAC shot down oxaliplatin, Sanofi consultant Esteban Cvitkovic approached committee chairman Schilsky.

"Dr. Cvitkovic said that this decision from the committee is unfortunate for the American public, but good for him, because all the rich Americans with colon cancer will keep coming to see him in Paris," Schilsky said. "Also, he wanted me to know that he was on his way to New York, to spend a weekend in a suite at the Pierre, paid for by a rich American with colon cancer."

After sharing his disappointment and travel plans to Schilsky, Cvitkovic was observed communicating similar sentiments and information to FDA reviewer Hirschfeld. "Because of you American people will suffer!" Cvitkovic shouted.

The drug's future in the U.S. is uncertain, observers say.

The intergroup trial was not designed to provide data that would support registration. "The 6C trial was designed to sift through the known active regimens to try to decide which should be the reference regimen," Goldberg said. "Now that ODAC has recommended that the Saltz regimen be considered standard, the question arises: 'Do the oxaliplatin-containing regimens in the 6C trial need to show a significant survival advantage over the Saltz regimen to permit U.S. approval of oxaliplatin in first-line treatment?'

"If the oxaliplatin regimens show comparable activity but a favorable toxicity profile in comparison to the Saltz regimen, will that warrant an ODAC recommendation for approval?" Goldberg said.

Rothenberg said the company could pursue approval in second-line therapy.

"With CPT-11 now approved for front-line treatment, the development strategy for oxaliplatin in the US will shift to the salvage setting," Rothenberg said to **The Cancer Letter**. "After all, once patients have progressed after CPT-11 and 5-FU/LV, there is no known effective therapy for them. This could be the quickest way to demonstrating the benefit of oxaliplatin that would satisfy the FDA."

Another possibility is the adjuvant setting, where the drug is being tested in the NSABP trial C-07, which is expected to produce results in about four years.

After watching the oxaliplatin nosedive at ODAC, colon cancer survivor Sallie Forman said patients can play a role in avoiding such disasters.

"It's not a good business practice for a company to make a presentation with data that does not substantiate its claim," said Forman, a public policy consultant who served as a patient representative on the committee. "If they fail to make their case through the review process, that could also be a loss for the patients."

As the ultimate stake-holders, patients should be given a role earlier in the regulatory process, Forman said.

"It would be helpful if patients could be involved at the earlier stages of the development process, before the applications get to the ODAC," she said.

Possible Accelerated Approval For Mylotarg

In another action, on March 17, ODAC decided that Mylotarg (gemtuzumab ozogamicin), a monoclonal antibody-based agent, was shown to have improved safety, but not superior efficacy, compared to conventional salvage treatments for CD33-positive Acute Myeloid Leukemia patients.

Though Wyeth-Ayherst Laboratories, the sponsor, sought accelerated approval for CD33-positive relapsed acute myeloid leukemia, the committee said the agent would be appropriate only for relapsed AML patients ages 60 and over.

By identifying a subgroup of patients who stand to benefit from the therapy, the committee may have provided the basis for FDA to give agent accelerated approval, which would be conditional on the company demonstrating patient benefit in post-approval studies.

Mylotarg was developed by Celltech Group and Wyeth-Ayherst Laboratories, the pharmaceutical division of American Home Products.

If approved, the agent will be marketed by Wyeth-Ayerst.

NCI Programs:

NCI, CDC To Collaborate On Surveillance System

NCI and the Centers for Disease Control and Prevention last week said they will collaborate to develop a comprehensive, federally integrated cancer surveillance and cancer control research system, using the resources of both agencies.

The agencies signed a Memorandum of Understanding to coordinate training, technical assistance, methodology development, and other aspects of cancer registry management, as well as allow for coordination of cancer information.

NCI has collected cancer incidence, mortality, and survival data from its Surveillance, Epidemiology, and End Results program for more than 25 years. SEER currently covers the states of Connecticut, Hawaii, Iowa, New Mexico, and Utah, the metropolitan areas of Atlanta, Detroit, Los Angeles, San Francisco Greater Bay, and Seattle-Puget Sound, and selected populations of American Indians in Arizona, Alaska natives in Alaska, and residents of 10 rural counties in Georgia.

Since the National Program of Cancer Registries was established by Congress in 1992, CDC and the states have collaborated to support cancer registries in 45 states, the District of Columbia, and three territories.

"The NPCR and SEER programs together cover virtually the entire U.S. cancer patient population," said Robert Hiatt, deputy director of the NCI Division of Cancer Control and Population Sciences. "By using data from both programs, NCI and CDC will be creating an infrastructure for cancer control and surveillance research efforts nationwide.

"We see this joint effort as critical to moving forward with a national cancer surveillance plan that includes other partners as well, such as the American Cancer Society, the American College of Surgeons, the North American Association of Central Cancer Registries, and the National Cancer Registrar's Association," Hiatt said.

"NCI and CDC have been working with partner organizations for a number of years to assure the availability of a core set of cancer data that both agencies can use to better understand and tackle the burden of cancer in the United States," said Nancy Lee, director of CDC's Division of Cancer Prevention and Control. "Our two agencies will begin to use pooled data from selected registries that meet national standards of quality. This information will also help direct effective cancer prevention and control programs by giving us data to determine cancer patterns among various groups of people, monitor cancer trends over time, and identify where cancer screening efforts need to be enhanced."

NCI and CDC will continue to expand their registries, while coordinating public release of pooled data, the agencies said. NCI expects to expand SEER coverage to populations that currently are underrepresented in the SEER program, such as American Indians, non-Mexican Hispanics, rural African-Americans, high-poverty Americans, and areas with high cancer mortality rates.

In the NPCR, the CDC will continue to work with the states to achieve high national standards for data completeness, timeliness, quality, and use, the agency said. With NCI and the states, CDC plans to assess regional and national cancer rates and provide access to data for public use.

Management and governance of the coordinated federal cancer surveillance system will occur through a small team of program experts from NCI and CDC, who will report to their respective agency directors, as well as to the Health and Human Services Data Council.

Funding Opportunities:

RFAs Available

RFA CA-01-004: Community Clinical Oncology Program

Letter of Intent Receipt Date: June 9, 2000

Application Receipt Date: July 14, 2000

The NCI Division of Cancer Prevention invites domestic institutions to apply for cooperative agreements for the Community Clinical Oncology Program. Using the national resource of highly trained oncologists in community practice, the CCOP: 1) provides support for expanding the clinical research effort in the community setting; 2) stimulates quality care in the community through participation in protocol studies; 3) fosters the growth and development of a scientifically viable community cancer network able to work closely with NCI-supported clinical cooperative groups and cancer centers; 4) supports development of and community participation in cancer prevention and control intervention research, which includes chemoprevention, biomarkers and early detection, symptom management, rehabilitation, and continuing care research; 5) involves primary care providers and other specialists in cancer prevention and control clinical trials; and 6) increases the involvement of minority and underserved populations in clinical research. Combining the expertise of community physicians and other health

care professionals with NCI-approved cancer treatment and prevention and control clinical trials provides the opportunity for the transfer of the latest research findings to the community level.

Inquiries: Joseph Kelaghan, acting chief, Community Oncology and Prevention Trials Research Group, Division of Cancer Prevention, NCI, Executive Plaza North - Rm 300, 6130 Executive Blvd., MSC-7340, Bethesda, MD 20892-7340, phone 301-496-8541; fax 301-496-8667; e-mail address: jk85i@nih.gov

RFA HD-00-007: Global Network for Women's and Children's Health Research

Letter of Intent Receipt Date: April 14, 2000

Application Receipt Date: July 13, 2000

National Institute of Child Health and Human Development, National Institute of Allergy and Infectious Diseases, NCI, National Institute of Dental and Craniofacial Research, National Institute of Mental Health, National Center for Complementary and Alternative Medicine, and the Fogarty International Center, in partnership with the Bill and Melinda Gates Foundation, invite applications for participation in a Global Network for Women's and Children's Health Research. The RFA will use the U01 award mechanism.

Inquiries: Susan Meikle, Pregnancy and Perinatology Branch, National Institute of Child Health and Human Development, 6100 Executive Blvd., Rm 4B03, MSC 7510, Bethesda, MD 20892-7510, phone 301-496-0431; fax 301-496-3790; e-mail meikles@mail.nih.gov

Program Announcement

Participation of NCI in the NIH Mentored Quantitative Research Career Development Award

NCI originally was not a participant in PA-99-087 for the Mentored Quantitative Research Career Development Award using the K25 grant mechanism. NCI will participate in this PA for all future grant application receipt deadlines beginning with the June 1, 2000 deadline. The PA is available at: http://grants.nih.gov/grants/guide/pa-files/PA-99-087.html

Inquiries: Lisa Begg, Cancer Training Branch, Office of Centers, Training and Resources, NCI, 6116 Executive Blvd., Suite 7011, Bethesda, MD 20892-8346, phone 301-496-8580; fax 301-402-4472; e-mail: beggl@mail.nih.gov

Meet Us In San Francisco

The Cancer Letter editors Kirsten Boyd Goldberg and Paul Goldberg invite readers attending the American Association for Cancer Research annual meeting April 1-5 in San Francisco to stop by our display (booth #1213) in the exhibit hall of the Moscone Convention Center.

In Brief:

CTRC, UCLA Receive Gifts; NCCF Distributes Gold Pins

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peer for age, diagnosis and gender when possible, the personal connection is designed to give the patient in the early stages of diagnosis not only access to resources and counseling, but also a better understanding of the treatment process ahead. . . . **CANCER THERAPY AND RESEARCH CENTER** received $1 million gift from H-E-B Grocery Company to fund the H-E-B Ambulatory Surgical Center. The center, designed specifically for cancer patients, will include treatment capabilities for biopsies, brachytherapy, and other outpatient surgical procedures preformed in three operating rooms. The H-E-B naming gift is part of an overall $35 million CTRC Capital Campaign launched earlier this year. . . . **UCLA JONSSON CANCER CENTER** received $1million for the Carol and Saul Rosenzweig Endowed Chair for Cancer Therapies Development. The endowed professorship will support scientific and clinical research programs for a variety of cancers. . . . **NATIONAL CHILDHOOD CANCER FOUNDATION** is distributing gold lapel ribbons in support of childhood cancer research. For a free pin, phone 800-458-6223. . . . **AVON BREAST CANCER CRUSADE** will contribute nearly $14 million for breast cancer research, education and support services to five academic health centers that will each receive $2.2 million. The five centers are: Herbert Irving Comprehensive Cancer Center Columbia-Presbyterian Medical Center, Winship Cancer Institute of Emory University and Grady Memorial Hospital, University of Alabama at Birmingham Comprehensive Cancer Center, Robert H. Lurie Comprehensive Cancer Center of Northwestern University, and the Chao Family Comprehensive Cancer Center at University of California, Irvine Medical Center. The remaining $3 million will be awarded to Cancer Care Inc. and the National Breast Cancer Coalition Fund. . . . **DENNIS SLAMON,** director of the Revlon/UCLA Women's Cancer Research Program at Jonsson Cancer Center, received a $10,000 award as co-recipient of the UC-San Diego-Salk Institute Translational Medicine Award. Slamon was honored for his contributions to the field of antibody therapy, which led to the development of the drug Herceptin. Genentech Inc., the manufacturer of Herceptin, is the other recipient.

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