THE CANCER LETTER FAX

Vol. 22 No. 17
April 26, 1996

Price $265 Per Year US
$285 Per Year Elsewhere

FDA Advisors Recommend Approval Of Topotecan For Ovarian Cancer

An FDA advisory committee last week unanimously recommended approval of topotecan hydrochloride (Hycamtin, SmithKline Beecham Corp.) for the treatment of patients with metastatic ovarian cancer after failure of initial or subsequent chemotherapy.

The FDA Oncologic Drugs Advisory Committee voted 8-0 to recommend marketing approval for Hycamtin, based on a review of data

(Continued to page 2)

In Brief

Louise Strong Named President, AACR; Donald Coffey Is President-Elect

LOUISE STRONG assumed the presidency of the American Association for Cancer Research at the association's annual meeting this week in Washington, DC. Strong, professor of experimental pediatrics, section chief of medical genetics, and a geneticist in the Department of Experimental Pediatrics, M.D. Anderson Cancer Center, succeeds **Joseph Bertino**, chairman of molecular pharmacology and therapeutics, Memorial Sloan-Kettering Cancer Center. **Donald Coffey** was elected president-elect. Coffey is a professor of oncology, pharmacology and molecular sciences and the Catherine Iola and J. Smith Michael Distinguished Professor of Urology at Johns Hopkins Oncology Center. Four AACR members were elected to the Board of Directors for three-year terms: **Waun Ki Hong**, chairman of the Department of Thoracic/Head and Neck Medical Oncology, M.D. Anderson; **Eric Fearon**, associate professor in internal medicine, University of Michigan Medical Center; **Stephen Friend**, director of molecular pharmacology, Fred Hutchinson Cancer Research Center; and **Susan Cole**, professor of oncology, pharmacology, toxicology and pathology, Queen's University, Ontario. . . . **BARNETT KRAMER** has been named deputy director of the NCI Division of Cancer Prevention and Control, division director **Peter Greenwald** announced last week. Since 1990, Kramer has been associate director of the Early Detection and Community Oncology Program in DCPC. He is also editor-in-chief of the Journal of the National Cancer Institute. He succeeds **Edward Sondik**, who is leaving to become director of the National Center for Health Statistics, Centers for Disease Control and Prevention. . . . **SUSAN HIGMAN**

(Continued to page 8)

ODAC Recommends Approval Of SmithKline's Topotecan

(Continued from page 1)

from two large, international, multicenter trials conducted on patients with recurrent ovarian cancer.

Hycamtin is the first topoisomerase I inhibitor to be recommended for approval in the US. The drug inhibits the enzyme topoisomerase I, which is involved in the replication of DNA in human cells.

"We are extremely pleased with the Hycamtin data which resulted in the committee's positive decision," Colin Broom, group director, oncology, for SmithKline Beecham, said in a statement. "There is a desperate need for more effective second-line treatments that offer women with recurrent ovarian cancer a hope of prolonged survival."

"Well-Designed Studies"

ODAC members said they agreed with the company's assertion that the data from the studies demonstrated that the new drug is at least as effective as paclitaxel (Taxol, Bristol-Myers Squibb Co.), the current standard therapy.

"We do appreciate well-designed studies that give us answers," said Janice Dutcher, an ODAC member and a professor of medicine, Montefiore Medical Center, Albert Einstein Cancer Center. Dutcher substituted for committee chairman Paul Bunn, who had a prior commitment and was absent from the April 19 meeting.

Phase III Trial Data

The company presented data from a phase III trial involving 226 women with recurrent ovarian cancer after first-line platinum therapy.

Patients were randomized to a 30-minute infusion of Hycamtin 1.5 mg/m^2 /day for five days or to a three-hour infusion of paclitaxel 175 mg/m^2 every 21 days. The Hycamtin group consisted of 112 patients. The paclitaxel group had 114 patients.

In the Hycamtin arm, 4.5 percent of patients had a complete response and 16 percent had a partial response. In the paclitaxel arm, 2.6 percent had a complete response and 10.6 percent had a partial response.

The median response duration was 32 weeks for Hycamtin and 19.7 weeks for paclitaxel. The median time to progression was both statistically and clinically significant, indicating that patients receiving Hycamtin experienced progressive disease less rapidly—23 weeks compared to 14 weeks for paclitaxel.

The median survival was 61.3 weeks for Hycamtin and 42.6 weeks for paclitaxel. The difference in survival was not statistically significant.

The trial included a cross-over design that allowed patients on either arm to choose the other arm following initial therapy.

Three patients who failed to respond on the paclitaxel arm responded to Hycamtin, said Maurie Markman, director of the Cleveland Clinic Cancer Center.

Phase II Trial

In a phase II noncomparative multi-center study in 111 women with recurrent ovarian cancer after first-line platinum therapy, the objective response rate was 14.4 percent.

The median duration of response was 16.3 weeks. The median time to progression was 11.3 weeks and the median survival was 52.4 weeks.

In the study, the median time to response was 10.4 weeks.

FDA reviewer Steven Hirschfeld said oncologists using Hycamtin should give adequate time to treatment before ceasing therapy due to lack of response.

The efficacy of Hycamtin was confirmed in the

THE CANCER LETTER

Founded 1974
Member, Newsletter Publishers Assoc.

Editors: **Kirsten Boyd Goldberg, Paul Goldberg**
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Subscriptions: subscrib@www.cancerletter.com
World Wide Web URL: http://www.cancerletter.com

Subscription $265 per year US, $285 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc., also publisher of The Clinical Cancer Letter.

two additional open noncomparative studies included in the file submitted to the committee, the company said. The two studies were not presented at the meeting.

In each study, the dosage of Hycamtin was 1.5 mg/m^2 administered intravenously over 30 minutes daily for five days and repeated every 21 days.

Side Effects Manageable and Predictable

Suppression of blood cells produced in the bone marrow, the principal side effect demonstrated by Hycamtin in clinical trials, was predictable, noncumulative, reversible and manageable, the company said in its presentation.

Combining the data from all four ovarian cancer studies, 18 of 445 patients (4 percent) withdrew from study due to hematologic or infective complications.

Grade 4 neutropenia occurred in 79.5 percent of patients in all four trials. Grade 4 thrombocytopenia occurred in 23.4 percent. Grade 3 and 4 anemia occurred in 36.8 percent of patients. Fever or infection with grade 4 neutropenia occurred in 20.7 percent. Sepsis occurred in 4.7 percent of patients. Three patients died due to neutropenia.

The most frequently reported non-hematologic side effects were gastrointestinal, including nausea and vomiting.

In the phase III trial, no statistically significant difference was observed between Hycamtin and paclitaxel in quality of life as measured by 15 parameters, Broom said.

G-CSF was used for treatment in 7 percent of courses and for prophylaxis after the first course in 19 percent of courses.

ODAC member Robert Ozols, senior vice president, medical science, at Fox Chase Cancer Center, said the company presented no data on the efficacy of the use of growth factors in treatment with Hycamtin.

"I would recommend that growth factors not be used," Ozols said. "The next step with this drug is to evaluate it in combination with other drugs."

ODAC voted unanimously that the toxicity profile of Hycamtin was acceptable for patients with recurrent ovarian cancer.

SmithKline Beecham has begun a first-line combination chemotherapy study with Hycamtin in patients with ovarian cancer.

Hycamtin is also being studied for a number of other tumor types, the company said.

Cancer Drug Initiatives Likely To Shorten Approval Times, FDA Official Tells ODAC

The oncology initiatives announced by President Clinton last month are likely to shorten FDA marketing approval of cancer drugs and will ensure that drug companies conduct post-marketing studies to define the role of new therapies, an FDA official said last week.

Under the initiatives announced by the White House on March 29, FDA said it would accept evidence of tumor shrinkage as the basis for approval of treatments for refractory disease (**The Cancer Letter**, April 5).

"This probably will make it somewhat easier to study cancer therapies and shorten the time for first and subsequent marketing approvals," said Robert Justice, team leader in the FDA Division of Oncology Drug Products. "It will also ensure that important phase III studies are done."

In exchange for accelerated approval, drug sponsors will be required to conduct post-marketing phase III studies.

"Before, we often would require a commitment that a phase III trial be done to define the role of a drug, but we had no teeth to enforce that," Justice said to the agency's Oncologic Drugs Advisory Committee at its meeting April 19. "Under accelerated approval, we can potentially withdraw approval if the company does not follow through."

In addition to accelerated drug approval, FDA said it would implement a program of expanded access to therapies approved by other countries, clarify its policy on filing of Investigational New Drug applications, and formalize the involvement of cancer patient representatives on the agency's cancer advisory committees.

According to Justice, FDA will have a formal presentation on the initiatives at a later ODAC meeting. At the meeting last week, he described FDA's new requirements under the initiatives.

Accelerated Approval Mechanism

The accelerated approval regulations were originally published in the Federal Register, Dec. 11, 1992, Justice said. However, only two oncology drugs, Doxil and Zinecard, have been approved under this mechanism, he said.

"We looked at our experience with HIV drugs and we also reviewed some of our prior oncology approvals for refractory disease, and we found that in many cases we were using objective responses as the primary basis for approval, although supported with some data on clinical benefit, such as improvement in symptoms," Justice said to the committee.

"What's new is that we have decided to accept as surrogates for clinical benefit verified objective responses in solid tumors and meaningful remissions in hematologic malignancies," he said. The responses have to be supported by photographic measurements, Justice said.

"What's not new: The response rate must be acceptable for the degree of toxicity and the clinical trial design must be appropriate," Justice said. "It does not mean that we will only require phase II trials for accelerated approval. Phase III trials in second-line therapy can often be much more informative and better for all involved.

"Phase III trials will usually be required to demonstrate clinical benefit, particular if there is already existing effective therapy," Justice said.

NDAs as well as secondary indications for approved drugs can use the mechanism, he said.

The regulations apply to drug and biological products that have been studied for safety and effectiveness in serious or life-threatening illnesses that provide meaningful therapeutic benefit over the current treatment, Justice said. Meaningful benefit is defined as the ability to treat patients unresponsive to or intolerant of available therapy, or an improved patient response over available therapy.

Post-approval studies do not have to be in the same patient populations as the accelerated approval studies. "It may be much more important to know a drug's role in first-line therapy if it has activity in refractory malignancy than to do a large study to determine its activity in the refractory population," Justice said.

Approval May Be Withdrawn

Justice also said that:

—Post-marketing restrictions for safe use can be required if necessary. For example, distribution of a drug can be restricted to certain facilities or physicians with special training or experience, or, distribution can be conditioned on performance of specified medical procedures. These restrictions must be commensurate with specific safety concerns.

—Accelerated approval can be withdrawn under the following conditions: if a post-marking clinical study fails to verify clinical benefit; if use after marketing demonstrates that post-marking restrictions are inadequate to assure safe use; if the applicant fails to adhere to post-marking restrictions; or if promotional materials are false or misleading.

—Approval may with withdrawn following a hearing. The appropriate advisory committee would be present at the hearing to review the approval and make recommendations.

—Restrictions could be removed if no longer necessary for safe and effective use of the product, or if post-marking studies verify and describe the product's clinical benefit.

Role For Tumor Markers?

Markers for tumor response could be accepted if a company showed that the marker is a valid surrogate for clinical benefit, Justice said in response to a question by ODAC ad hoc patient representative Beverly Zakarian. of Cancer Patients Action Alliance.

"A company that wants to do a trial, for example, using CA-125 as a response criteria in ovarian cancer would have to make a strong argument that this is truly a surrogate for clinical benefit," Justice said.

ODAC member Richard Gelber, of Dana-Farber Cancer Institute, said the accelerated approval mechanism could speed access to new agents. "A concern is that the term `surrogacy,' if loosely defined, could be used to allow approval of agents that may in fact be touted to have benefit that they really don't have," he said. "We need studies of what surrogates are really useful."

Expanded Access to Therapies Abroad

Under the second of the four oncology initiatives, when a cancer therapy is approved by a recognized foreign approval authority, FDA will contact the US sponsor and encourage the initiation of an expanded access protocol, Justice said.

If there is no US sponsor, FDA will contact the foreign sponsor and encourage the filing of an IND and submission of an expanded access protocol.

FDA will require an English-language version of the relevant data submitted to the foreign regulatory authority for consideration of the expanded access protocol. If FDA review finds the data adequate, the agency will permit use of the therapy for appropriate patients under the expanded access

protocol.

The expanded access protocol will go through the same review process FDA uses for its Treatment IND mechanism, Justice said.

The expanded access protocol should be directed at the same patient population and use the same route, dosage and scheduling as the foreign approval, he said.

The drug sponsor would be required to pursue marketing approval with due diligence, defined as having credible plans for early initiation of studies needed for a marketing application, Justice said.

To reduce the risk that expanded access protocols may interfere with accrual to trials needed for approval, trials must be carefully designed to ensure adequate enrollment, Justice said.

"Expanded access will make investigational therapies available to patients shortly after approval in other countries," Justice said. "The reliance on foreign data could ease the burden on sponsors preparing a US expanded access protocol.

"In addition, we hope that we can obtain some information from limited data collection on patients on the expanded access study to support approval," Justice said.

Clarification of IND Policy

Under the third initiative, FDA said it will clarify its existing policy on filing of Investigational New Drug applications.

An IND is not required when the marketed product will be used in the same patient population and the same manner for which the agent was approved, and the study is not intended to support approval of a new use or a significant change in the labeling or advertising, Justice said.

"We still get many [unnecessary] INDs, primarily from individual investigators, sometimes from cooperative groups," Justice said. "Some reasons might be an IRB or an investigators assume an IND is required, or a manufacturer agrees to donate product for a study and may be concerned that unless there is an IND, FDA will view the donation of the product as a promotional activity.

The clarification says FDA will not accept INDs for the study of lawfully marketed products if the studies are not intended to support approval of a new indication or a significant change in product labeling or advertising; or the study does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risk, or decreases the acceptability of the risks, Justice said.

Information from previously conducted clinical trials on the safety and effectiveness of the proposed study can be used to determine the degree of increased risk for the intended study population, he said.

"We are just reminding investigators that they should determine whether an IND is necessary using these criteria, and on request, FDA will provide guidance to investigators and manufacturers about the need for an IND."

In the future, ODAC should advise FDA whether the agency needs to accept INDs for treatment regimens involving high-dose therapy with bone marrow transplants or stem cell rescue, Justice said.

"When do we want to accept an IND that involves high-dose therapy with marrow rescue? If there is already data on a particular regimen, are we serving any purpose by review the protocol for that same regimen?" Justice asked.

"The potential impact of this initiative is that clinical research could be fostered by relief from burdens associated with filing an IND, and for us, it would conserve resources for reviewing other applications for new investigational therapies," Justice said.

Patient Representation on Advisory Committees

Under the fourth initiative, FDA will invite cancer patients to serve as ad hoc representatives on its cancer advisory committees.

ODAC has included an ad hoc patient representative since February 1995, but this initiative formalizes the position, said Patricia Delaney, associate director of the Cancer Liaison Program in the FDA Office of AIDS and Special Health Issues.

FDA advisory committees have included positions for consumer representatives for more than 20 years, but the term "consumer" until recently did not include cancer patient advocates.

"Ad hoc patient representation means that the FDA advisory committees now will have the additional benefit of the point of view of the patient who has experience with the type of cancer for which drug approval is being sought," Delaney said.

"It is intended that the ad hoc patient representative will vote, however, the committee charter may need to be changed to extend the vote to the ad hoc patient representatives, and thus, the right

to vote will not be effective immediately," Delaney said.

The patient representative will be screened for conflict of interest in the same way that other members of the committee are screened, Delaney said.

The representative will review the NDA submission as well as FDA review of the submission. The representative will be required to sign a commitment to protect confidential information.

"The specific process for recruitment, assessment, selection and utilization is being considered by FDA staff," Delaney said. "In the meantime, the Cancer Liaison Program staff, the FDA Office of Consumer Affairs, the Advisors and Consultants staff, and the cancer patient survivor community will work together to select qualified and appropriate cancer patient representatives for each ODAC meeting until a formal process is announced in the Federal Register."

Delaney said the National Breast Cancer Coalition's Project Lead program is training breast cancer survivors to participate on advisory panels such as ODAC. FDA encourages other advocacy organizations to conduct similar training programs, she said.

On Capitol Hill

Porter Asks Varmus To Assess Impact Of Construction On NIH

The plans for financing the construction of the new NIH Clinical Center became the focus of questioning of NIH Director Harold Varmus at the House Appropriations Subcommittee on Labor, HHS & Education last week.

Following testimony by Varmus, subcommittee chairman John Porter (R-IL) asked the NIH director to assess the impact of the rapid pace of construction of the 250-bed Clinical Center would have on the extramural and intramural research supported by the Institutes.

"How do you answer critics who think that [construction of the Clinical Center] is being done—in part at least—at their expense?" Porter asked the NIH director at the hearing April 18.

The President's budget proposal for fiscal year 1997 contains a $467 million increase for NIH. However, $274 million of that money is slated to finance construction of the Clinical Center.

Most of the funds for the construction of the center are expected to come out of next year's budget.

To ease the pressure on extramural research, the President's budget proposes an inflation adjustment of 2 percent, at least 1.5 percent below the anticipated 3.5 percent to 4 percent inflation in biomedical research.

"The Office of Management and Budget has advised us that funding the building in a single year promotes efficiency, and of course it also guarantees that we will be able to complete the building, because we have the money in hand in a single year," Varmus said. "It also allows us to absorb the impact of the cost of the building in a single budgetary year."

Varmus said he expected the inflation adjustment to match the inflation rate in fiscal 1998.

The President's budget proposes a $12.406 billion for NIH. NCI would receive $2.28 billion, an increase of $29 million over the current year (**The Cancer Letter**, March 22).

NCI Director Richard Klausner was scheduled to testify before the appropriations subcommittee April 24.

The text of the exchange between Varmus and Porter follows:

PORTER: Some people in the extramural community would support a new clinical center. But they balk at funding it at the expense of research grants.

VARMUS: There is no way that we can pay for this building without paying for it. So, clearly, any money that's spent for it could be seen as money that would go elsewhere.

But in fact, as the budget was constructed, the agreement to ask for the money was an add-on in the budget. I don't believe that the money is being taken away from extramural research.

This is a very tight budgetary environment. And the money that's being requested is requested in response to a clear need.

PORTER: You've said that you are going to increase the number of new extramural grants awarded in the next year. Rather than provide a full inflation adjustment, although you've said that 4 percent is probably higher than the inflation has been. Two percent is probably too low, wouldn't you agree?

VARMUS: Two percent is lower than the inflationary figure. Inflation is going to be about 3.5 percent.

PORTER: What reaction will there be to the two percent adjustment in the extramural community?

VARMUS: I don't believe that a two percent increase is going to cause a significant burden. It's a one-year reduction. I would hope to return to previous cost management figures or something close to the inflationary rate in 1998. I know from my experience as an investigator that if we know ahead of time what the increase is going to be, I believe it would be possible for our investigators to adapt to it.

PORTER: Other than that adjustment, a great deal of your increases last year would be lost, particularly in intramural research; would they not?

VARMUS: That will be seen in the coming year. We are concerned about that, but we believe that we can make economies in intramural budget that would allow research to proceed at a reasonable pace.

PORTER: If we could find a way within our score-keeping rules to fund the clinical center in increments over three or four years, which I believe would be the time necessary to build it, would you prefer that approach in order to lessen the budget impact on research?

VARMUS: There are trade-offs, obviously, for the solution you propose, and I'd welcome further discussion of it.

PORTER: Have you pursued the option of seeking private sector contributions to the construction of the clinical center, and if so, to what extent?

VARMUS: We've considered them. We have a business manager of Boston Properties who is advising us about the way in which we can try to supplement funds for the construction of the clinical center, and we do have an authorized vehicle, the National Foundation for Biomedical Research, that could receive the donation that could be put to that purpose.

We don't, however, think it's likely, given the fairly small amounts of money that have been forthcoming from private donors in the past, to envision raising a very large amount of money for the clinical center.

PORTER: As you know, the subcommittee has already heard from public witnesses, many of whom represent specific disease groups. As in previous years, a number of these groups have urged us to increase funding to their disease, relative to others, based on the dollars currently spent per death or per case identified.

As a subcommittee, we have tried to avoid getting embroiled in this dollars per death debate, believing that other criteria are equally relevant. I know that you share our concern on this issue. Can you lay out for us what basis we should use to allocate biomedical research dollars.

VARMUS: Clearly, the magnitude of the impact of illness is a factor to be considered as we put the budget together. But, as many of my colleagues, budget-building by body count is not the right way to go, nor is simple economic impact the right way to go. You have to consider the opportunities for scientific advancement that spreads more widely through our portfolio. You have to consider the quality of applications that we get in certain categories.

We need to recognize that if we simply considered impact on the economy or on mortality figures, that we would be spending very little on rare diseases. We know, first of all, that rare diseases are very important, certainly, to those who are afflicted by them, and, secondly, that many of the most important discoveries that we have made have come from the pursuit of rare diseases.

Unless we adapt our budgeting of research monies in accord with the scientific priorities as well as the public health impact, we are going to be failing to take advantage of many opportunities that currently exist.

NCI Director Says Centers May Become More Specialized

Cancer centers may become specialized based on the scientific disciplines or expertise they develop, NCI Director Richard Klausner said to a meeting of cancer center directors last week.

Thus, as some centers may develop an expertise in genetics, others may be specialize in drug development or informatics, Klausner said.

"My bias is that [NCI] programs need to be flexible," Klausner said at the annual meeting of the Association of American Cancer Institutes April 19. "On some level, we may have seen a broadening range of cancer centers, because they may reflect different areas of interest, productivity and expertise.

"I don't think we need to ask any place to try or to pretend that they do everything equally well," Klausner said. "That just isn't true of any institution."

Questioned At AACI Meeting

Klausner outlined his plan for specialization of cancer centers in response to a question by Robert Young, president of the Fox Chase Cancer Center.

"As I listen to some of the things I am hearing, it suggests that you are beginning to think of the possibility of centers of excellence that are related to scientific disciplines," Young asked. "Could you give us an idea of the additional concepts that might be feasible through a centers-type structure."

The edited text of Klausner's response follows:

"One is centers of excellence. Some are technology centers.

"The technology that we use is changing dramatically, and we've put very little investment into making sure it's available.

"One of the types of centers I want to create is to recreate [the NCI Frederick Cancer Research Center], as a service center for the entire community; for informatics, for repositories, for development of diagnostics, etc.

"I think there are lots of possibilities for centers. That's why I am asking for review [by an advisory panel]. I am not asking for review because I am looking to undo programs. I am looking to make them work better."

NIH, NCI Begin Discussions With HCFA On Reimbursement

NIH and NCI officials have begun negotiations with the Health Care Financing Administration in an attempt to convince that agency to begin reimbursement for medical care costs for patients involved in cancer clinical trials, a senior NIH official said last week.

"We are talking with the administrator of HCFA about having a similar approach to Medicare and Medicaid patients and in the managed care setting with respect to clinical research," William Harlan, NIH associate director for disease prevention, said at a meeting of the Association of American Cancer Institutes April 19.

The prospect of talks with HCFA emerged last month, at a press conference announcing a program by the Department of Defense to reimburse the medical care costs for patients involved in cancer clinical trials (**The Cancer Letter**, March 8).

In Brief

Sigurdson Named Surgical Oncology Chair, ECOG; Young Joins AMC Center

(Continued from page 1)

was promoted to vice president for managed care and network development at Fox Chase Cancer Center. Higman has been administrator for managed care since 1993. She joined the center in 1981. . . . **ELIN SIGURDSON,** a member of the department of surgical oncology, Fox Chase Cancer Center, recently was named Surgery Committee chairman for the Eastern Cooperative Oncology Group. . . . **WALTER YOUNG** has joined the AMC Cancer Research Center, Division of Public Health Applications, as a senior scientist. Young has been director of the Division of Prevention Programs in the Colorado State Health Department since 1987.

Komen Foundation Accepting Research Grant Applications

The Susan G. Komen Breast Cancer Foundation is accepting applications for research projects in both clinical and basic areas for its second grant cycle for 1996.

The foundation plans to award one-year grants to qualified applicants and institutions conducting basic or clinical breast cancer research projects. The program offers grants up to $150,000. The grants will be provided for the period Dec. 1, 1996 through Nov. 30, 1997. The number of awards will depend on the amount of funding granted per project; $2 million is to be granted.

Grant recipients are determined through a peer review process recognized by NCI.

Application deadline is June 17. Applications may be obtained by contacting Elda Railey, tel: 214/450-1789.

NCI Contract Award

Title: Mutli-disciplinary investigations of environmental causes of cancer

Contractor: Westat Inc., Rockville, MD; $4,947,621.