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FDA Discloses Responses, Toxicities For Burzynski's "Antineoplastons"

FDA officials earlier this week disclosed a summary of safety and efficacy data from clinical trials conducted by Houston-based alternative medicine practitioner Stanislaw Burzynski.

According to the data disclosed by FDA lead deputy commissioner Michael Friedman at a hearing of the House Committee on Government Reform and Oversight, Burzynski's therapy with "antineoplastons" produced responses in 36 of 828 patients treated for a broad range of tumors.

The overall response rate of 4.3 percent included patients enrolled

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In Brief:

AACR Grants Record Number Of Awards To Young Investigators; Kersey Leads ASBMT

AMERICAN ASSOCIATION FOR CANCER RESEARCH granted 250 young investigator awards--a record--to support the travel of young scientists presenting abstracts at the association's annual meeting, held last month in New Orleans. The grants included: 64 AACR Minority Scholars in Cancer Research, supported by the NCI Comprehensive Minority Biomedical Program; 25 AACR-AFLAC Scholars in Cancer Research, supported by AFLAC Inc.; 95 awards from corporate sponsors Bristol-Myers Squibb, Pharmacia & Upjohn, Rhone-Poulenc Rorer, Genetics Institute, and PharMingen; 17 awards from AACR's general fund; 28 awards to Asian scientists from ITO EN Ltd., *of Japan; and 10 Brigid G.* Leventhal awards by Women in Cancer Research. In addition to the young investigator awards, 21 faculty members from historically black colleges and universities attended the meeting through grants funded by AACR and NCI. . . . **JOHN KERSEY** was elected president of the American Society for Blood and Marrow Transplantation at the society's annual meeting March 27 in Miami. Kersey is director of the University of Minnesota Cancer Center. . . . **TIMOTHY EBERLEIN** was named interim director of the Cancer Center at Washington University School of Medicine, Barnes-Jewish Hospital and BJC Health System. Eberlein was also named Bixby Professor, head of the Department of Surgery, and surgeon-in-chief at Barnes-Jewish Hospital. He is the former Richard E. Wilson Professor of Surgery at Harvard Medical School, and vice chairman for research at Brigham and Women's Hospital. . . . **KISHAN PANDYA** was named

(Continued to page 8)

FDA Says Sodium Toxicity Contributed To 7 Deaths

(Continued from page 1)

in phase II trials as well as patients who received treatment through "special exceptions" from FDA, the agency said.

The FDA summary said the response rate was 8.4 percent in the group of 404 patients enrolled on protocols. Toxicity included elevated levels of serum sodium, a condition that "contributed to the death of at least 7 patients" enrolled in the trials, the summary said.

Burzynski submitted the data to FDA in an annual report. The agency has not audited the data.

Regulations allow the FDA commissioner to disclose "a summary of selected portions of the safety and effectiveness data that are appropriate for public consideration of a specific pending issue." Such disclosures can be made in cases where the existence of a new drug application or an investigational new drug application has been publicly acknowledged.

Friedman made the disclosure at an April 22 hearing called by Rep. Dan Burton (R-IN), chairman of the government reform and oversight committee, to consider access to unapproved treatments. Burton is a co-sponsor of the Access to Medical Treatment Act (H.R. 746), a bill that aims to ease restrictions on practitioners of alternative medicine.

The Cancer Letter obtained the FDA summary of Burzynski's data.

"The benefits have been, in some categories, not observable," Friedman said at the hearing April 22. "Under no observable areas did we see overall, more than 80 percent of the patients having even a temporary benefit. There were toxicities subsequent to this treatment. More than half of the patients had significant elevations of serum sodium. We believe that there were serious side effects from the situation."

Burzynski's attorney Richard Jaffe said that his client was traveling and could not be reached for comment.

According to the data summary, no responses were reported in the trials of Burzynski's antineoplastons treatment for cancers of the breast, lung, and prostate. Similarly, no responses were reported in melanoma and soft tissue sarcoma, documents indicate. The highest responses were claimed in brain tumor studies, where 28 of the 207 patients (13.5 percent) enrolled in trials demonstrated a response. With special exception patients included, the response rate was 7.7 percent in brain tumors.

Overall, half of the patients who responded to the treatment withdrew from the study due to patient request, worsening condition, or growth of tumor, the data summary said.

The document states that last summer, FDA stopped issuing special exceptions for patients to receive Burzynski's treatment for breast cancer and non-small cell lung cancer.

"Because of the very low response rates in breast cancer and in non-small call lung cancer, and in view of the significant toxicity experienced by some patients, the agency mandated that starting on Aug. 29, 1997, no additional patients with these tumors should be given antineoplastons as special exceptions," the summary said. "Patients could still receive antineoplastons on protocol until the protocol accrual goal has been reached."

Data Are Sketchy, Unaudited

The disclosures could be useful to patients who may believe that Burzynski, one of the most publicized alternative medicine practitioners in cancer, is able to produce high responses across a broad range of tumors, several observers said.

Beyond that, the data are too sketchy to permit a serious evaluation, said Barrie Cassileth, a psychosocial oncologist and author of The Alternative Medicine Handbook. "It's not possible

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to comprehend these results without knowing the stage of disease of these patients," Cassileth said to **The Cancer Letter**.

"I hope that this partial, unaudited portion of information will be followed quickly with a fuller presentation of results," Cassileth said. "We need a context in which to evaluate both the side effects and the response rates."

Though sketchy and unaudited, the data point to "disappointing efficacy and significant toxicity," said Wallace Sampson, editor-in-chief of Scientific Review of Alternative Medicine, a journal published by Prometheus Press.

"Responses are consistent with natural history of disease left untreated or disease that received treatment prior to antineoplastons," Sampson said.

"Claimed responses in brain tumors are consistent with the natural history of brain tumors, as determined by scans," he said. "Brain tumors vary in size as a consequence of cystic change, especially in patients who had been irradiated prior to receiving antineoplastons. Claimed response in lymphoma is consistent with natural waxing and waning of lymphoma masses."

In his testimony, Friedman said FDA supported the continuation of Burzynski's clinical trials. "We fully support the conduct of clinical trials, because that's the way we'll get answers," Friedman said.

In a memorandum explaining his decision to disclose Burzynski's data, Friedman said FDA regulations enabled him to make the disclosure since the existence of Burzynski's clinical investigation was publicly acknowledged.

"In relation to the recent series of congressional hearings on unapproved products in which the existence of an IND or NDA has been publicly disclosed and the safety and effectiveness of the investigational product... has been made the subject of public debate, I have determined that it is appropriate for me to disclose publicly... a summary of selected portions of the safety and effectiveness data available for the product in order to achieve a more accurate public understanding of the product," Friedman said in the document.

The memorandum, dated April 21 and addressed to top level FDA staff, said the disclosure provision—21 CFR 314.430 (d)—is generally invoked "in the context of public advisory considerations."

A copy of the memorandum was obtained by **The Cancer Letter.**

The Data Summary

According to an FDA summary, none of the 53 patients who received oral antineoplastons experienced a tumor response. In the case of intravenous antineoplastons, 404 patients were treated on protocols, and another 424 were treated as special exceptions.

The text of the FDA summary of Burzynski's data follows:

"In protocol patients there have been 34 reported responses for a response rate of 8.4 percent, including 14 patients in whom tumor was reported to be undetectable by X-ray for at least one month (complete response) and 20 patients in whom tumor was reported to have shrunk by least 50 percent lasting for at least one month (partial response).

"In special exception patients there have been 2 responses in 424 patients for a response rate of 0.5 percent. Overall, there have thus been 36 responses reported by the investigator in 828 patients for a reported response rate of 4.3 percent.

"The validity of these responses has not been evaluated by FDA audit. Of the 36 reported responders, 50 percent withdrew from study due to patient request, worsening condition, or growth of tumor, 44 percent were still receiving antineoplastons at the time of the annual report, and one patient (4 percent) discontinued antineoplastons while the tumor was reported to be responding; of the 36 responders, 11 deaths have been reported to date. Death has been reported for 64 percent of all protocol patients and 61 percent of special exception patients.

"In the following table response rates as reported are presented by tumor type for the common tumors, i.e. those with at least 20 patients:

Claimed Tumor Responses/No. Patients treated (%)

	All Patients	Protocol Patients
Brain tumors	29/378 (7.7%)	28/207 (13.5%)
All other tumors	7/450 (1.5%)	6/197 (3.0%)
Breast cancer	0/74 (0%)	0/17 (0%)
Colon Cancer	1/56 (2.0%)	0/8 (0%)
Lung Cancer	0/88 (0%)	0/29 (0%)
Lymphoma	3/59 (5.1%)	3/34 (8.8%)
Prostate	0/29 (0%)	0/13 (0%)
Melanoma	0/24 (0%)	0/8 (0%)
Ovarian	0/22 (0%)	0/5 (0%)
Soft Tissue Sarcoma	0/22 (0%)	0/8 (0%)
Unknown Primary	0/22 (0%)	0/6 (0%)

"Of the 404 patients enrolled on phase 2

protocols, approximately 65 percent have reportedly had an elevated level of serum sodium (hypernatremia). 7 percent of protocol patients reported extreme elevation of sodium to levels of 160 mEq/L or higher, and 1.7 percent were reported as having elevations of 180 mEq/L or higher. Given the proximity of the date of death for some patients to documented episodes of hypernatremia, and considering the severity of the reported abnormality, it is likely that hypernatremia contributed to the death of at least 7 patients (1.7 percent). Other adverse events described in the annual report include nausea, vomiting, allergic skin reactions, dizziness, fatigue, drowsiness, joint pains, muscle pains, and other blood electrolyte abnormalities such as low potassium.

"Among protocol patients 4 percent died while still receiving antineoplastons. The most commonly reported reasons for withdrawal from the study were 'patient request' in 45 percent and 'growth of tumor' or 'worsening clinical condition' in 36 percent.

"Because of the very low response rates in breast cancer and in non-small cell lung cancer and in view of the significant toxicity experienced by some patients, the Agency mandated that starting on Aug. 29,1997 no additional patients with these tumors should be given antineoplastons as special exceptions. Patients could still receive antineoplastons on protocol until the protocol accrual goal had been reached."

NCI Programs:

NCI Offers Expertise To Aid Preclinical Drug Development

NCI has begun a new program designed to provide academic investigators with the expertise they need to move potential new cancer therapies from the laboratory into clinical testing.

The program, called Rapid Access To Intervention Development, invites researchers to submit proposals for use of the Institute's pre-clinical drug development capabilities to surmount difficulties that may be preventing a potential therapy from reaching early clinical trials.

The NCI Developmental Therapeutics Program has always provided this service to academic investigators and their corporate partners if they were willing to let the Institute file the Investigational New Drug application with FDA. A special committee, called the Decision Network, selects potential therapies for this service.

In contrast, the RAID program is designed to return products of pre-clinical drug development and responsibility for IND filing to the originators of the potential therapy, according to a document describing the program that NCI mailed to grantees last week.

The NCI Board of Scientific Advisors approved the RAID program at a meeting last month. The concept was presented earlier to the National Cancer Advisory Board (**The Cancer Letter**, Jan. 23).

Proposals Due Aug. 1

Following is the text of the NCI document, titled "Rapid Access To Intervention Development, Process and Procedures." The first deadline for proposals is Aug. 1.

What Is RAID? *RAID is a new program* designed to facilitate translation to the clinic of novel, scientifically meritorious therapeutic interventions originating in the academic community. It will do this by making available to the academic research community, on a competitive basis, NCI resources for the pre-clinical development of drugs and biologics. It is intended to remove the most common barriers between laboratory discoveries and clinical trials of new molecular entities. The goal of RAID is clinical "proof of principle" that a new molecule or approach is a viable candidate for expanded clinical evaluation. In principle, RAID is applicable to interventions of all sorts. During its initial phases, RAID's focus will be on therapeutics. If the program is successful, NCI will consider broadening the scope of RAID to include diagnostics and preventives.

Why RAID? There are novel ideas and candidate molecules in the academic community that deserve expeditious clinical testing. Often an alliance with a corporate partner will adequately and expeditiously achieve this goal. Where *private-sector involvement* is not possible, RAID will help academic institutions bridge the gap between discovery and clinical testing, so that efficient translation of promising discoveries may take place even in the absence of development capacity or clinical expertise in the institution where the discovery was made. RAID should therefore enable entry into the clinic of promising molecules that are not otherwise likely to receive an adequate and timely clinical test.

What can RAID do? RAID is designed to accomplish the tasks that are rate-limiting in bringing discoveries from the laboratory to the clinic. Ordinarily, these tasks will be accomplished by the use of NCI's development contracts and will be facilitated by direct consultation of the originating laboratory with NCI

staff. Which tasks will be necessary to accomplish in any particular case will vary from project to project. In some cases RAID will support only the one or two key missing steps necessary to bring a compound to the clinic; in other cases it may be necessary to supply the entire portfolio of development tasks needed to file an IND. Examples of tasks that can be supported by RAID include, but are not limited to:

—Definition of or optimizing dose and schedule for in vivo activity

—Development of pharmacology assays

—Conduct of pharmacology studies with a pre-determined assay

—Acquisition of bulk substance (GMP and non-GMP)

—Scale-up production from lab-scale to clinical-trials lot scale

—Develop suitable formulations

—Develop analytical methods for bulk substances

—Production of dosage forms

—Stability assurance of dosage forms

—Range-finding initial toxicology

—IND-directed toxicology, with correlative pharmacology and histopathology

—Planning of clinical trials

—Regulatory affairs, so that FDA requirements are likely to be satisfied by participating investigators seeking to test new molecular entities in the clinic

—IND filing advice

The output of RAID's activities will be therefore both products and information to be made fully available to the originating investigator for support of an IND application and clinical trials.

The RAID program will function as a collaboration between NCI and the originating laboratory. If some of the tasks to be accomplished in any development project are best done in the originating laboratory, supporting funds may be provided if *suitable funding mechanisms* are available (for example, as supplements to existing grants).

Isn't RAID competing with private industry? No. In fact RAID operations are likely to add value to an idea or concept by leveraging the risk in clinically testing a novel, previously unvalidated concept. Molecules whose clinical development have been promoted by RAID are likely to be much more attractive licensing candidates for industry.

Who can use RAID? RAID is intended for academic discovery laboratories. It is expected that most applicants for activities funded by RAID will have an appointment in an institution with an NIH-assured Institutional Review Board, or have formal collaborations with a staff member of such an institution. This will allow facile access to a potential location for clinical trials.

Can companies use RAID? Since RAID is designed to facilitate access of academic centers to clinical trials opportunities arising from their research, ideas arising solely from a corporate source without academic collaborators are not eligible. The existence of research collaborations between academic investigators and companies does not affect eligibility for support from RAID for individual products, provided that the particular product to be supported by RAID is not already licensed to a company. Products already licensed to a corporate partner are excluded from consideration for RAID support.

Does RAID discourage company involvement? Not at all. Applicants are still free to negotiate with companies for licensing opportunities while RAID projects are underway. In the event of successful licensure, the RAID project(s) currently active will be drawn to an orderly conclusion in collaboration with the originating laboratory and the licensee, the data made available as a Master File, and/or an actual product transferred to the originating laboratory.

Does NCI acquire intellectual property from RAID? No. It is expected that originating parties will have acquired intellectual property protection prior to involvement of NCI. In the event of "added value" by an NCI contractor (e.g., a novel formulation or dose form), such a development may rise to the level of invention as determined by patent law, and the contractor may elect to pursue patent protection of their invention under Bayh-Dole provisions. Obviously, the originating academic party will thereby have acquired a valuable potential ally in commercializing the subject of the research. Standard NIH Materials Transfer Agreements will form the basis for sharing confidential information with NCI.

How is RAID new? The NCI Developmental Therapeutics Program and the Cancer Therapy Evaluation Program have for many years interacted with academic and corporate communities through the Decision Network (DN) process. The DN is similar to RAID in that decisions are made to expend contract research resources. However, DN-directed activities in most cases have assumed that NCI would hold the relevant INDs and sponsor any clinical trials with products emerging from the DN process. The DN will continue to consider opportunities from the NCI intramural, extramural corporate, or extramural academic communities where the originators are certain at the outset that NCI's holding the resulting IND and managing clinical trials is a desired goal. By contrast, the products of the RAID program will, in general, be

returned directly to the originating laboratory for the proof-of-principle clinical trials that are the object of the program.

Does RAID actually sponsor clinical trials? No. There are several existing peer-reviewed mechanisms (e.g., Cooperative Groups, Cooperative Agreements, and Research Project Grants) which actually fund the conduct of clinical trials. RAID is designed to address the very frequent concern that clinical trials remain undone or receive lower priority for funding because a pre-clinical component is missing. RAID is intended to supply the pre-clinical necessities to allow a subsequent clinical trial to proceed. The design and conduct of the clinical trial will be peer-reviewed and fielded through existing mechanisms. It is anticipated that prominent support by RAID of pre-clinical aspects of a clinical trial concept will increase enthusiasm for funding the clinical trial through existing mechanisms.

Outline of the RAID process and review of applications: The RAID program will be administered by the Division of Cancer Treatment and Diagnosis. DCTD contractors will perform the work pertaining to projects approved for RAID. Depending on the needs of a particular project, these might be contract staff at the Frederick Cancer Research and Development Center at Fort Detrick, MD, or contractors at other sites across the country. There will be significant differences in the speed of review, criteria for review, and time-frame of interaction with NCI in comparison to the usual funding mechanisms (grants or contracts).

—NCI will announce a call for receipt of proposals twice per year (Feb. 1 and Aug. 1). Applications for the RAID Program may be requested at any time. Applications may be received from and returned to: RAID, Office of Associate Director, Division of Cancer Treatment and Diagnosis, NCI, Developmental Therapeutics Program, Executive Plaza North Suite 843, 6130 Executive Blvd., Rockville, MD 20852.

—Applications will be reviewed for support by a specially constituted RAID Review Group, consisting of selected NCI staff and outside experts from academia and industry. NCI staff will participate in an advisory capacity, and not be voting members of the RAID Review Group. RAID Review Group members will be bound by confidentiality agreements customary for review of NIH grants.

—Review will result in assignment of priority scores. NCI will commit to develop these projects accorded high merit by the review process. The number of projects to be supported in any review cycle will be a function of the level of merit and availability of funds. Review will be completed by April 1 and October 1 for proposals received February 1 and August 1, respectively.

—NCI staff will meet with successful applicants, and time lines for completion of tasks will be in place by May 1 or November I of each cycle.

Format of applications: (Up to 20 single spaced pages)

—Abstract: (300 words or less)

—Background: a summary of the field to allow appropriate understanding of the scientific and medical context from which the opportunity emerges

—Hypothesis: a clear statement of the hypothesis that entry of the relevant molecule into the clinic will test.

—Specific Request: a clear statement of the tasks specifically being requested from NCI to allow a test in the clinic. Also, a clear statement about the anticipated future role of the applicant or applicant institution in the development of the project once the NCI becomes involved.

—Justification: why the project under consideration represents a particularly innovative or promising approach to the treatment, prevention, diagnosis, or detection of cancer.

—Uniqueness: a discussion by the applicant of related or signaler molecules already under development by NCI or known to be in development under industrial sponsorship, and why NCI should undertake development in light of this.

—Additional support: a clear statement by the applicant of all current, anticipated, and hoped for sources of support for the project. This includes a summary of the status of past, planned, or ongoing negotiations with companies related to licensure or future development of the product.

—Intellectual Property: a statement by the applicant of any patents issued or pending with respect to the product

—Appendix: background preprints or reprints (maximum of five; not included in the page limitation)

Note that the applicant is not expected to ask for specific funds or estimate costs in the RAID proposals. A central function of NCI staff in the RAID review process will be to outline costs utilizing U.S. government internal or external contract sources to achieve the desired goals.

Review Criteria:

—Strength of the hypothesis: the extent to which this discovery is associated with a compelling hypothesis that strongly merits a clinical test.

—Novelty: the extent to which this discovery will enable clinical testing of new approaches to cancer that have not been adequately explored and are not likely

to be explored without RAID assistance.

—Costs and Benefits: appropriateness of the anticipated costs (as estimated by the RAID Review Committee) in light of the possible payoffs.

What RAID Is Not:

—RAID is not intended to be a pipeline for materials for NCI-held INDs. It is assumed that most of the products in the RAID program will be studied clinically under investigator-held INDs within the originating (or a collaborating) institution. If this turns out to be impossible in particular cases for unanticipated reasons, NCI can consider assuming responsibility for clinical trials sponsorship on a case-by-case basis.

—RAID is not an unconditional commitment to develop a particular compound for the clinic. Development will proceed sequentially in a logical order and the start of one segment of the process (e.g., toxicology) will depend on satisfactory completion of preceding segments (e.g., formulation). Insurmountable difficulties in one segment may force abandonment of individual projects, as they do in any development program.

—RAID does not commit NCI to support the full-scale development of a particular product. The goal of RAID is to provide the raw materials for proof-of-principle clinical testing. Once this is accomplished, NCI can consider further involvement in the clinic, as part of its general clinical trials program.

—RAID is not meant to assist industry in its development projects. Industrial collaborations with NCI are encouraged through its standard decision-making processes.

—RAID is not a grant program to a particular laboratory. It is expected that the great majority of resources committed through RAID will be through use of NCI new-agent development contracts and of NCI staff expertise in service of highly meritorious projects originating in academia. It may happen that some steps in the process are best carried out in the originating laboratories, in which case NCI will initially attempt to provide necessary support through existing suitable funding vehicles, but this pathway for support may not be the ultimate avenue used. The focus will be on using NCI staff expertise to define the most effective and cost-efficient means of getting tasks accomplished.

Oversight: The NCI Board of Scientific Advisors will convene a RAID Oversight Committee consisting of outside advisers and a subgroup of its own members. This group will periodically review the status of all projects conducted in the RAID program. This will include assessment of progress and determination whether particular projects should be continued or terminated, based on progress, likely progress, or difficulties in reaching the desired project goal.

Inquiries: Edward Sausville, DCTDC, NCI, DTP, EPN Suite 843, 6130 Executive Blvd, Rockville, MD 20852, tel: 301-496-8720, fax: 301-402-0831, email: sausville@dtpax2.ncifcrf.gov

Funding Opportunities:

Program Announcement

PA-98-053

Title: **Midcareer Investigator *Award In Patient-Oriented Research***

Application Receipt Dates: Feb. 1, June 1, Oct. 1

The purpose of this PA (K24) is to provide support for clinicians to allow them protected time to devote to patient-oriented research and to act as mentors for beginning clinical investigators. The target candidates are outstanding clinical scientists engaged in patient-oriented research who are within 15 years of their specialty training, who can demonstrate the need for a period of intensive research focus as a means of enhancing their clinical research careers, and who are committed to mentoring the next generation of clinical investigators focussing on patient-oriented research.

Patient-oriented research is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator directly interacts with human subjects. This area of research includes: 1) mechanisms of human disease; 2) therapeutic interventions; 3) clinical trials, and; 4) the development of new technologies.

This award will enable candidates holding clinical degrees to undertake up to five years (a minimum of three years is required) of patient-oriented research, thereby further developing their research skills, devoting time to patient-oriented research, and acting as a mentor and role model for beginning clinical researchers.

The applicant must have independent research support at the time of application for this program. Candidates must have a clinical degree or its equivalent, including the MD, DO, DDS, DMD, OD, DC, ND (Doctor of Naturopathy), and doctorally prepared nurses. Individuals holding the PhD degree may apply if they have been certified to perform clinical duties, such as a clinical psychologist, clinical geneticist, etc. Candidates must have completed their specialty training within 15 years of submitting the application, and there is no age limit for candidates. NIH plans to support 60 and 80 awards in FY99 and in each succeeding year through FY03.

Inquiries: (See full PA for contacts at other institutes) Lester Gorelic, CTB, NCI, 6130 Executive Blvd Rm 520, Bethesda, MD 20892-7390, tel: 301-496-8580, fax: 301-402-4472, email: gorelicl@dcbdcep1.nci.nih.gov

NCI RFPs Available

SOL RFP N02-PC-85074-39

Title: **Geographic Information System for the Long Island Breast Cancer Study**

Deadline: Approximately June 5

The NCI Division of Cancer Control and Population Sciences intends to support the phase I implementation of a geographic information system to support the Long Island Breast Cancer Study Project. Services and materials to be provided include GIS software, data conversion services, database development, computer hardware, site preparation, delivery, installation and testing, training, documentation, and operation, maintenance and support.

The RFP may be accessed through the Research Contracts Branch Home Page: http://rcb.nci.nih.gov/RFP.HTM.

Contracting officer: Theresa Shroff, email: ts144t@nih.gov, tel: 301-435-3796, fax: 301-402-8579.

SOL RFP N02-CM-87031-74

Title: **Storage And Distribution Of Chemicals**

Deadline: Approximately June 12

The NCI Developmental Therapeutics Program is seeking an organization to provide for the storage and distribution for their repository of chemical and drug samples. This contract is responsible for the receipt, storage, distribution, documentation, and inventory of synthetic compounds, bulk chemical drugs and crystalline natural products. The repository consists of more than 600,000 compound samples. Responsibilities shall include the receipt, weighing, distribution and storage of new and previously acquired chemical samples. This is a recompetition of contract N02-CM-57205 performed by McKesson BioServices Inc.

The RFP may be accessed through the Research Contracts Branch Home Page: http://rcb.nci.nih.gov/RFP.HTM.

Contract specialist: Odessa Henderson, e-mail: henderso@rcb.nci.nih.gov; fax: 301-402-6699; tel: 301-496-8620.

NCI Contract Awards

Title: Extension of Current Contract for Management and Operation of the NCI Frederick Cancer Research and Development Center for 18 Months, to Sept. 25, 1999. Includes a two-year option to extend to Sept. 25, 2001. Contractor: Science Applications International Corp., San Diego, CA; $165,955,269.

Title: Science Enrichment Program. Contractors: University of Kentucky, Principal Investigator: Donald Frazier, $1,857,883. San Diego State, PIs: Cynthia Darche Park, Vernon Avila, $1,863,768.

Title: Biomedical Genetic Monitoring of Rodents. Contractor: Texas A&M Research Foundation, College Station, TX, $454,464.

Letter to the Editors:

Since 1992, Where Has *All* The OAM Grant Money Gone?

To the Editors:

Sen. Arlen Specter (R-PA) is absolutely right when he demands that NIH should make a high priority of asking Office of Alternative Medicine Director Wayne Jonas to report to Congress and the American people on how the OAM is using taxpayers' money for "research" on alternative medical treatments (**The Cancer Letter**, April 10).

In 1992, when Sen. Tom Harkin (D-IA) fathered the OAM, he announced that its goal was to prove the effectiveness of alternative treatments. A few in the litany of these were bee pollen pills for allergies, 714-X (camphor) for prostate cancer, therapeutic touch for aches and pains, and homeopathy for everything else. The budget of the OAM, $2 million at its birth, has risen to a proposed $20 million.

From 1994, when the first $1 million in OAM grant awards were a year old, to this date, I have been searching the published literature for reports of the results of the work of the OAM grantees. I have not found a single one. What has happened to the grant money that has been spent for research in the past five years? Perhaps the General Accounting Office could find out.

Saul Green
Zol Consultants Inc.
New York, NY

In Brief:

Survivors Day Planned June 7

(Continued from page 1)

associate director for clinical operations in hematology-oncology, University of Rochester Cancer Center, and chairman of the University of Rochester Oncology Consortium. Pandya serves on the faculty of the medical center. . . . **ERIC LANDER**, director of the Whitehead/MIT Center for Genome Research, received the Wick R. Williams Memorial Award presented by Fox Chase Cancer Center. . . . **NATIONAL CANCER SURVIVORS DAY** is scheduled for June 7 by the National Cancer Survivors Day Foundation, sponsored by Coping magazine, Glaxo Wellcome Oncology/HIV, Pharmacia & Upjohn, and SmithKline Beecham Oncology. Contact the foundation, tel: 615-794-3006.