THE CANCER LETTER

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Cancer Patient Lobby Outlines Agenda For FDA Reform, Seeks Role In Discussion

Testifying before a congressional panel, a cancer patient advocacy group called for an end to the FDA practice of barring drug companies from distributing information on off-label uses of cancer drugs.

The National Coalition for Cancer Survivorship also asked Congress to ensure that FDA expedite its process for approval of agents used to treat life-threatening conditions, and, particularly, to eliminate the

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In Brief

Mansfield To Head NCI Radiation Research; Cowan Is Acting Chief, Medicine Branch

NCI DIV. OF CANCER TREATMENT personnel news: **CARL MANSFIELD**, professor of radiation oncology, Thomas Jefferson Univ., has accepted the position of chief, Radiation Research Program. Mansfield is former chairman of Jefferson's radiation oncology department. He is a former president of the American Radium Society and the American Cancer Society, Philadelphia Div. He received an ACS award for his work against cigarette marketing in Philadelphia. . . . **KENNETH COWAN**, head of the Medicinal Breast Cancer Section, will serve as acting chief of the Medicine Branch, temporarily replacing Robert Wittes, who is acting division director, DCT. . . . **MATTHEW SUFFNESS**, program director for natural products grants in the NCI Developmental Therapeutics Program, died of pneumonia June 14 at Holy Cross Hospital in Silver Spring, MD. He was 52. He had received a bone marrow transplant last November. Suffness came to NCI in 1976 as head of the plant and animal products section, Natural Products Branch. He became chief of the Branch in 1983, and in 1988 became program director of natural products grants. Suffness was instrumental in work that led to the Cooperative Research and Development Agreement between NCI and Bristol-Myers Squibb Co. for the development of Taxol. He was editor of a 1995 textbook, "Taxol: Science and Applications," and authored more than 60 articles on cancer drug development. Survivors include his wife, Rita Suffness of Silver Spring; a brother and a sister. . . . **CORRECTION: The Cancer Letter** June 16 erroneously attributed an official statement about the conclusion of the investigation of physician David Plotkin by the HHS Office of Research Integrity. The statement quoted in the story appeared in a draft press release. The complete statement that appears in the final press release reads: "The ORI investigators believe the initial suspicion of possible scientific misconduct resulted from a review of incomplete records."

Cancer Patients Seek Place In Discussion Of FDA Reform

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requirements that make the approval for biologic agents more time-consuming than approval for drugs.

Just as importantly, Ellen Stovall, NCCS executive director, asked that patient advocates be given a place at the table whenever FDA reform is discussed.

"It is essential that those of us with cancer and other serious medical conditions be involved in decisions about the future of FDA because our survival depends on it," said Stovall, addressing the Subcommittee on Oversight and Investigations of the House Commerce Committe.

The hearing, the subcommittee's second on the subject, was held June 19.

The patient agenda described by Stovall was not very different from the agendas of branded drug manufacturers, academic cancer centers and other care providers.

While patient advocacy groups and those providing cancer care have been growing increasingly close for years, their interests appear to have become virtually inseparable this year, as the rhetoric of budget-cutting grew stronger on Capitol Hill.

In the case of FDA reform, the emerging alliance of patients, providers, industry and legislators could well result in a formidable challenge to the regulatory agency, observers said to **The Cancer Letter**.

Truckloads Of Data

One point that emerged repeatedly through the hearing was that treatments for life-threatening diseases should not be scrutinized with the same rigor as treatments for more benign illnesses.

"The more important the drug, the less is already available to treat the condition in the study, the more one should move to requiring enough information to make everyone believe that if a drug is marketed and used as labeled, it will do a lot more good than harm," Louis Lasagna, director of the Tufts Center for the Study of Drug Development, said to the subcommittee.

To a great extent, this approach has been adopted by the agency, Lasagna said.

"Even now, 50 percent of the drugs that are approved are approved with the understanding that additional studies would be performed," Lasagna said.

The majority of such conditional approvals are made in the area of AIDS drugs, where consumer pressures are immense, Lasagna said.

"The agency has shown that it's susceptible to consumer pressure," Lasagna said. "The AIDS advocates happen to be the most articulate, the most passionate, the most politically astute group that exists.

"They shame the cancer advocates by their effectiveness, and they have gotten the agency to get off the dime and work very effectively," he said.

Other changes recommended by Lasagna included establishing some reciprocity in drug approvals with other countries and a move away from FDA's insistence that applications be accompanied by raw data.

"One important change would be to have the filings include certified summaries rather than a truckload of data," Lasagna said.

Barton: Not Bashing For Its Own Sake

FDA would be unlikely to win popularity contests in the regulation-be-damned 104th Congress, where the agency has been repeatedly accused of incompetence, wastefulness and intimidation tactics.

"The large corporations that develop and market drugs are not here today," said Rep. Thomas Bliley (R-VA), chairman of the Commerce Committee, who took part in the subcommittee hearings June 20.

"In private, [drug companies] tell of inefficient and incompetent drug reviews that cost millions and even tens of millions of dollars. [FDA officials] make promotional restrictions that defy the First Amendment to the Constitution," Bliley said.

"In public, [drug companies] avoid such statements. Why? Because this agency holds life-and-death power over the approval that supports the

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terribly expensive research efforts to find new drugs," he said.

Rep. Henry Waxman (D-CA) disagreed.

"I've been around FDA issues for aroud 20 years, and I have never seen a pharmaceutical company large or small reluctant to come in and say privately or publicly what's on their mind," Waxman said. "I would hope that if there is any expert or involved party in the FDA approval process that has some suggestions to make to Congress that they come forward and say publicly what they have to say. I think they owe it to the American people."

Bliley's bellicose words notwithstanding, Rep. Joe Barton (R-TX), chairman of the subcommittee, said FDA-bashing was not among his objectives.

"We are not bashing simply for the sake of bashing an agency," Barton said. "This subcommittee is going to find out what the agreed-upon problems are, and then hope to develop a consensus as to what possible solutions are."

Wyden's "FDA Modernization Act"

One proposal currently on the table appears to address most of the concerns raised by Stovall.

The bill, introduced last week by Rep. Ron Wyden (D-OR), ranking minority member of the subcommittee, is also the first FDA reform proposal to emerge so far this year.

"For the good of the patients, FDA should relax some of its restrictions which currently bar the exchange of scientifically valid information concerning unapproved uses between practitioners, research scientists and manufacturers," Wyden said at the hearing.

The bill, "FDA Modernization Act of 1995" (HR1742), includes the following provisions:

- FDA would be given authority to grant early, conditional approvals for promising drugs and devices which appear to be effective in fighting serious or life-threatening disease. Final approval would rest upon the manufacturer's ability to demonstrate that the initial promise of effectiveness was proven in broader use.
- The agency would be given authority to use independent panels to approve and oversee early stage trials of new drugs and devices.
- The bill would relax restrictions on the exchange of scientifically valid materials that support the use of cancer drugs off-label.
- The review process for biologics would be revamped and modernized.
- The restrictions on the export of drugs and devices that have not been approved by FDA would be relaxed.

FDA Biologics Review Hasn't Kept Pace With Industry

The following is the excerpted testimony by Ellen Stovall, executive director of the National Coalition for Cancer Survivorship, at the June 19 hearing of the Subcommittee on Oversight & Investigations of the House Committee on Commerce.

While [FDA] has made some progress in reducing approval times for drugs, additional steps should be taken to bring pharmaceutical products to consumers in a more timely manner.

This is particularly true in the case of products relating to life-threatening conditions, such as cancer, for which the risk-benefit analysis is different from that of less serious conditions. These products should receive the highest priority.

With regard to regulating biologics, NCCS feels FDA's current system has not kept pace with developments in biotechnology. This system often subjects biologics to unnecessarily burdensome requirements, as compared with those for drugs.

To hasten the availability of biologics to individuals with cancer, most biologics should be subject to approval and regulatory requirements more closely resembling those for drugs. Overregulation requiring biologics manufacturers to obtain separate approval for establishment licenses or lot releases should be alleviated.

FDA has interpreted its authority over drug labeling in such an expansive fashion that the free flow of information about off-label uses has been severely restricted.

For example, FDA has prohibited the distribution by pharmaceutical interests to physicians of medical journals containing information about off-label uses.

Additionally, FDA has regulated educational activities, such as medical symposia, in a manner that might be viewed as heavy-handed and even unconstitutional. At the very least, the excessive zeal of the FDA in this arena has exerted a chilling effect on the sharing of information within the medical community.

FDA policy denies individuals with cancer access to valuable information about medically appropriate indications from pharmaceutical sponsors, who are often the best source of up-to-date information.

FDA's insistence on the primacy of the labeling, despite the fact that the labeling may be often woefully out of date, has justified some insurers in declining to pay for off-label uses.

Thus, many patients have been denied the value of their insurance coverage by virtue of a reimbursement policy that has its roots in a misguided application by FDA of its authority over labeling.

More than three years ago, FDA representatives told NCCS and others in cancer patient advocacy that they support our position on reimbursement for off-label uses appearing in medical compendia or peer reviewed literature. However, stating that FDA is not a reimbursement agency, they have failed to follow through with their promise of public support for the concerns of people with cancer by taking a position in favor of reimbursement of off-label uses.

FDA's silence on this important issue is akin to their lack of responsiveness on other crucial regulations, which has made it easier for insurers to deny coverage arbitrarily.

FDA is hyper-vigilant in the way it guards information about drug usage. This was dramatically illustrated to me several years ago, when I was involved in a legislative effort to require the Medicare program to cover medically recognized off-label use of drugs.

Our legislative proposal, introduced by Sen. Jay Rockefeller (D-WV) and Rep. Sander Levin (D-MI), provided that Medicare would automatically cover any off-label use of an anticancer agent.

Finally, we were able to persuade the Health Care Financing Administration that the proposal should not be opposed by the Bush Administration.

However, when FDA learned that a legislative proposal would recognize off-label uses of drugs for reimbursement purposes, FDA became a fierce opponent of the legislation.

Fortunately, we were able to prevail, and now Medicare reimburses off-label uses based on the solid medical information found in compendia and peer-reviewed literature, but only for anticancer agents.

For a number of years, NCCS and others in the cancer community have urged FDA to alter its restrictive policy concerning dissemination of information about off-label uses.

Most recently, along with five other leading organizations representing individuals with cancer, NCCS submitted comments to the agency urging them to change their policy.

Despite our concerns, the agency and the Clinton Administration have refused to alter FDA's policy on the promotion of off-label uses. We can only ask why these seemingly useless policies still exist.

We implore Congress to ensure that both consumers and physicians have access to accurate information concerning off-label uses, as recognized in the medical compendia or peer-reviewed literature.

Those of us who are dealing with a diagnosis of cancer have the right to this information, and we want to be able to participate in making decisions about our treatment.

To make these decisions, we must have access to complete, accurate and up-to-date medical information.

Univ. Of Chicago Apologizes For Chemotherapy Overdose

Univ. of Chicago Hospital last week apologized for the death of a cancer patient who was mistakenly given an overdose of the chemotherapy drug cisplatin, the hospital said.

"Despite the many checks and balances we have in place to prevent medication errors, this terribly unfortunate accident did occur,"Ralph Muller, president of the hospital, said in a statement June 14. "We deeply regret this human error and have already taken steps to redouble our efforts to verify medication orders."

The patient, a 41-year-old letter sorter for the US Postal Service, died June 13. He was admitted to the hospital on May 26 to receive a third cycle of chemotherapy for treatment of germ-cell testicular cancer that had metastasized to the abdomen.

The patient was to receive two drugs, cisplatin and etoposide. The hospital said the correct dose of cisplatin was originally prescribed.

"When completing the order for the pharmacy, the physician mistakenly transcribed the etoposide dose as the cisplatin dose, resulting in a higher-than-intended cisplatin dose," the hospital said.

After a nurse noticed the error, attempts were made to remove the drug from the patient's system. As the patient's kidneys began to fail, he was placed on dialysis, the hospital said. Ultimately, the patient developed pneumonia and died, the hospital said.

The physician responsible for the error was suspended from clinical duties, Muller said. The physician, who was not identified, graduated from medical school in 1982 and had worked at the hospital for less than a year, the hospital said.

Advisors Set Aside $17.5 M For Drug Discovery Groups

Advisors to the NCI Div. of Cancer Treatment approved in concept the recompetition of the National Cooperative Drug Discovery Groups.

The NCDDG program, begun in 1983, supports four groups. The DCT Board of Scientific Counselors unanimously approved the set-aside of $17.5 million over five years to fund three to four cooperative agreements.

The RFA is expected to be released next month, and awards would be made by September 1996.

The excerpted text of the concept statement follows:

National Cooperative Drug Discovery Groups. Recompetition of cooperative agreements (RFA), first year award $3.5 million, total $17.5 million over five years. Developmental Therapeutics Program, Edward Sausville, director.

The National Cooperative Drug Discovery Group program was implemented at the recommendation of the Board of Scientific Counselors in order to attain a more desirable balance between rational approaches to the discovery of new and improved anticancer treatments and the traditional, more empiric in vitro and in vivo screening approaches. Rapid developments in biomedical research over the past decade have provided unprecedented opportunities for rational drug design and the development of new screening approaches based on recently discovered molecular targets important to cancer and sophisticated preclinical evaluation of new treatments.

The NCDDG program with its emphasis on multidisciplinary and investigator-initiated approaches is ideally suited for the timely exploitation of new advances for drug discovery. The NCDDG cooperative agreement mechanism provides a framework for DCT to support and facilitate the efforts of diverse and often high-risk approaches to identify and develop clinical trial candidates. Although the NCDDG projects do not provide support for clinical trials, the mechanism permits and encourages a role for NCI in the timely and informed clinical evaluation of products discovered by NCDDGs.

Since its inception in 1983, the NCDDG program has been recompeted several times using different themes: mechanism of action approaches, disease-oriented approaches, model development, and a search for new agents from natural sources, such as plants and marine organisms. These targeted projects have been very successful in identifying new leads or therapeutic approaches, some of which are currently in development to clinical trial. Some examples are listed below:

•A polyamine analog, N^1, N^{11}-bis(ethyl)norspermine (BENSPM), was conceived, synthesized and evaluated in an NCDDG and has now entered Phase I clinical trial.

•06-benzylguanine (OBG) and several related compounds which inhibit alkylguanine transferase are undergoing active investigation as a means to prevent DNA repair. A combination study of OBG and BCNU is currently in Phase I clinical trial.

•A combination of two antitransferrin receptor IgG monoclonal antibodies (MAbs) has caused complete regression of 10-day established tumors. The Decision Network has accepted these MAbs for clinical development, and acquisition of additional material is underway.

•A novel second generation diphtheria toxin-related interleukin-2 fusion protein is in Phase II clinical trial in patients with T-cell leukemias or lymphomas bearing high affinity interleukin-2 receptors.

•Treatment of brain tumors with biodegradable polymers impregnated with drugs has progressed to the clinical trial stage. Successful clinical results with BCNU will lead to a similar approach with other active antitumor agents.

•Topotecan, a camptothecin analog, has undergone Phase II clinical trial and was developed in one of the first groups to be awarded. This drug may be the first NCDDG-derived drug to receive market approval.

•Promising lead compounds are in development from several of the Natural Products Drug Discovery Groups including: topoisomerase inhibitors of the coralyne and nitidine classes; wortmannin, a highly selective inhibitor of phosphinositol-3-kinase; and the cryptophycins, powerful new mitotitic inhibitors with strong in vivo activity.

In FY92, $16 million was allocated to the NCDDG program. However, in recent years support for the program has been reduced to about $9.6 million in FY 1995. This support included four groups that are expiring in FY95 with a total budget of about $3.2 million. The remainder is for groups that will be funded in FY95 from two recent solicitations for NCDDGs based on mechanism of action considerations and identification of drugs from natural sources.

It is proposed that cooperative agreements be established to form NCDDGs for the discovery of agents to treat human malignancies, with an emphasis on high-priority diseases such as breast cancer, or to exploit new molecular targets as sites of action for the discovery of more effective therapies. Each group will be assembled by a principal investigator to form a multidisciplinary and multi-institutional consortium of those skills needed to prosecute successfully the proposed discovery and preclinical evaluation. The biological approach or biochemical targets of attack will be selected by the applying group. If a specific tumor type is selected by an applicant as a target, the applicant will be expected to show the relationship between the proposed research and

the anticipated preferential efficacy against the selected malignant disease. While developmental studies toward clinical trials, including bulk supply, formulation, detailed pharmacology, and protocol toxicology, are beyond the scope of these drug discovery awards, each applicant will be required to have a plan for the subsequent development of agents discovered in the NCDDG program. The inclusion of industrial partners to pursue such efforts will be strongly encouraged. Groups will also be encouraged to bring their candidate compounds to NCI for development through the Decision Network process.

Successfully competing groups will be funded via cooperative agreements. The applying group is expected to define its objectives in accord with its own interests. NCI participation would commence with award. A representative of NCI would participate in the important deliberations of the group as a full member. This relationship would facilitate technology transfer from government-owned databases and the use of appropriate contract resources to enhance the efficiency and effectiveness of the group's effort.

The PI will be the conceptual focus of the group and, depending on the needs of the project, will extend invitations to appropriate scientists, regardless of their institutional affiliations, to participate as group members. The multi-institutional approach is envisioned because the existence of all of the highly creative talents in the required scientific disciplines will rarely be available in a single institution. Thus, the cooperative agreements may involve academic, nonprofit, and/or commercial/industrial institutions. Although activities related to the clinical introduction of a new agent (e.g., clinical formulation development, preclinical toxicology, and performance of Phase I clinical trials) are excluded from group activities, the collaborative effort among scientists working in the academic, research, and commercial environments in close liaison with the Government will enhance the efficiency of subsequent developmental tasks.

NCI To Recompete GI SPORE, Add One To Two New Awards

Advisors to the NCI Div. of Cancer Biology, Diagnosis and Centers approved the recompetition of the Specialized Programs of Research Excellence in gastrointestinal cancers.

Under the recompetition, NCI will expand the program to add one or two new SPOREs.

The DCBDC Board of Scientific Counselors last week approved the set-aside of $5 million for the GI SPOREs for the first year of funding.

The excerpted text of the concept statement follows:

Specialized Program of Research Excellence in Gastrointestinal Cancers. Recompetition of P50 grant, $5 million for first-year funding. New and competing renewal P50 applications may request a maximum annual direct cost of $1.5 million and maximum annual total cost of $2.5 million per individual SPORE. Future year increases are limited to 4% but may not exceed this cap. Funding for successful P50 renewal applications will be for five years. Initial funding for new P50s will be for three years. **Program director:** Andrew Chiarodo, chief, Organ Systems Coordinating Branch, DCBDC.

The objective of this initiative is to recompete the Specialized Programs of Research Excellence in Gastrointestinal Cancers and to expand the program with the addition of one or two new SPOREs. SPOREs are at institutions that will make a strong institutional commitment to the organization and conduct of these programs. Each SPORE must demonstrate a balanced approach to research on prevention, etiology, screening, diagnosis and treatment of human gastrointestinal cancers, and the translation of basic research findings into more applied, innovative research settings involving patients and populations; the SPORE could be used in rehabilitation and quality of life research. Each SPORE may address any cancer of the gastrointestinal tract with emphasis on cancers of high incidence, e.g. colorectal and pancreatic cancers. Applicants are encouraged to address pancreatic cancer either directly or by extending studies of other gastrointestinal cancers to pancreatic cancer.

The SPORE must develop human cancer tissue resources that will benefit translational research in these cancers; develop extended collaborations in critical areas of research need with laboratory scientists and clinical scientists within the institution and in other institutions; provide career development opportunities for new, independent investigators who wish to pursue active research careers in translational gastrointestinal cancer research; and participate with other SPOREs on an annual basis to share information, assess scientific progress in the field and identify new research opportunities that may have an impact in reducing incidence and mortality from these cancers. It is expected that each SPORE will support a mix of interactive basic and applied research that "translates" into areas of early detection, diagnosis, therapy and prevention and control. The SPORE mechanism is not intended to support basic research to the exclusion of clinical or applied research.

Special requirements of SPORE: An institution selected for a SPORE award must assemble a critical mass of basic and clinical scientists dedicated to the translation of basic findings into more applied, innovative research settings involving patients and populations with the ultimate objective of reducing incidence and mortality to the disease. A SPORE must include the following elements:

1. A strong institutional commitment. An institution receiving this award must incorporate the SPORE into

its institutional priorities. It must provide a plan which addresses how the institutional commitment will be maintained and sustained and how it will maintain accountability for promoting scientific progress. A SPORE application can originate from an institution with or without an existing P30 core grant. If a P30 already exists, lines of authority should be clearly indicated such that the SPORE does not interfere with the P30 chain of authority.

2. A qualified program leader. A leader must be selected as the principal investigator who can oversee, conduct planning activities and provide direction to SPORE with a translational research emphasis.

3. A substantive gastrointestinal cancer patient population. The SPORE must be a recognized leader in the treatment of these cancers and must have access to a patient population that can participate in and benefit from the innovative applied clinical and population research activities of the SPORE.

4. Research projects. Each SPORE application must include at least three approved research projects which together represent reasonably diverse experimental approaches. Each research project must be headed by basic and clinical co-investigators. This should facilitate exploiting the translational potential of the research. The research must be oriented toward translational activities using human materials and human subjects which address new, innovative possibilities in gastrointestinal research. This program will not support basic research that is without translational potential or significance nor will it support clinical research studies that are not "translated" from basic research. At least one research project must be on prevention or early detection and screening. It is expected that a SPORE will have a balanced approach to these cancers that encompasses the areas of prevention, etiology, screening, diagnosis and treatment. This balanced approach may be either through research being conducted in their institution, or through collaborative associations they have developed or plan to develop with other SPOREs or with other investigators in the biomedical research community.

5. Specialized resources. The SPORE must have a dedicated activity to human gastrointestinal cancer tissue collection. This resource must benefit the specific research activities of the SPORE as well as the research activities of other scientists within and outside of the parent institution who are concentrating on translational research issues. The SPORE must be willing to participate in any national prioritization for distribution of tissues through NCI supported tissue networks. A plan must be proposed for prioritizing distribution of tissues to SPORE scientists and others based on the most innovative ideas in translation gastrointestinal cancer research. This plan should be flexible enough to accommodate and complement broader national priorities as they are developed.

6. Career development. The SPORE must demonstrate an increased commitment to career development. A minimum of $100,000 in direct costs per year must be dedicated to the salaries and research activities of new, independent investigators who wish to pursue translational research careers on gastrointestinal cancers and who would be expected to leave the SPORE with the necessary research experience to develop independent research programs within or outside of the parent institution.

7. Developmental research funds. The SPORE must allocate a significant proportion of its budget and efforts to the conduct of pilot projects that continually explore new innovative ideas in collaboration with scientists within the institution and with other institutions. It is important that SPOREs use developmental funds to stimulate projects that take maximum advantage of new research opportunities.

8. Annual meeting of SPORE. GI SPOREs are expected to participate in an annual meeting with the Organ Systems Coordinating Branch of NCI.

If a SPORE is located in an institution that is already an NCI-designated cancer center, the program director of the SPORE must be a senior leader in the cancer center and the SPORE must be a major programmatic element. However, there must be a separate and distinct commitment of financial resources and/or positions in the institution to GI cancer research.

Letter

ORI And Plotkin: Release Report On Investigation

To the Editors:

The extraordinary circumstance of the Office of Research Integrity's recent public announcement of its "no misconduct" conclusion in the case of Dr. David Plotkin (a collaborating physician in NSABP clinical trials at Los Angeles Memorial Cancer Research Foundation, **The Cancer Letter**, June 16), and ORI's refusal to release the report that--presumably--contains evidence substantiating that conclusion give rise to a number of troubling questions.

According to the June 9 Chicago Tribune, ORI asserts it cannot release what it describes as its "exhaustive" report without Dr. Plotkin's permission. According to the Tribune, Dr. Plotkin's attorney says his client "had not agreed to release the report." Elsewhere, Dr. Plotkin is described in the June 7 Pittsburgh Post Gazette as "grateful and greatly relieved" by ORI's findings. Dr. Plotkin is quoted in

The Cancer Letter as saying he is "more than thankful" and has "been exonerated" by ORI.

Here are the most pressing questions for ORI and Dr. Plotkin:

1. Why does ORI deem it in the public interest to issue a press release about its conclusions in the Plotkin investigation while at the same time, ORI denies the public the right to examine the evidence supposedly substantiating those conclusions? What statutory, regulatory or other authority permits ORI to make sparse, selective public releases of information related to "no misconduct" conclusions, while at the same time ORI refuses to release the evidence that suposedly substantiates those conclusions?

2. If Dr. Plotkin is so certain that he has been "exonerated," why does he not approve release of the ORI report (if his approval really is necessary)? Indeed, why have Dr. Plotkin and his attorney not demanded an immediate release of the allegedly exonerating report?

As a former Congressional staff investigator who is thoroughly familiar with the Plotkin case, I know that the investigative issues in the case are significant, and are not resolved by ORI's vague allusions to "incomplete records" and "occasional differences in interpretation of data." If ORI, as its press release claims, really did conduct an "independent...thorough investigation," if ORI really did "exonerate" Dr. Plotkin, then ORI and Dr. Plotkin both should insist on prompt release of the ORI report.

The public interest, including the interests of the scientific community and breast cancer patients, most especially those research patients recruited at Dr. Plotkin's site, demand nothing less.

Suzanne Hadley
Rockville, MD

Small Business Technology Transfer Solicitation Released

Small Business Technology Transfer Program
Application Receipt Dates: Aug. 1, Dec. 1, 1995; April 1, Aug. 1, Dec. 1, 1996

The purpose of this notice is to inform the public about the opportunities that the STTR program offers to small business concerns as well as to scientists at research institutions, including colleges and universities. The applicant organization must be the small business concern. At least 40 percent of the project is to be performed by the small business concern and at least 30 percent of the project is to be performed by the research institution. The STTR program consists of the following three phases:

Phase I: The objective of this phase is to determine the scientific, technical, and commercial merit and feasibility of the proposed cooperative effort and the quality of performance of the small business concern, prior to providing further federal support in Phase II.

Phase II: The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application.

Phase III: The objective of this phase, where appropriate, is to pursue with non-STTR funds the commercialization of the results of the research or R&D funded in Phases I and II.

The amount and period of support for STTR awards are as follows:

Phase I: Awards may not exceed $100,000 for direct costs, indirect costs, and fixed fee for a period normally not to exceed one year.

Phase II: Awards may not exceed $500,000 for direct costs, indirect costs, and fixed fee for a period normally not to exceed two years, that is, generally, a two-year Phase II project may not cost more than $500,000 for that project. A Phase I award must have issued in order to be eligible to apply for a Phase II award.

Both Phase I and Phase II applications will be accepted on the application receipt dates identified above. It is estimated that fiscal year 1996 funds of about $12 million will be set aside by NIH to make grant awards under the STTR program.

Inquiries: Copies of the NIH STTR Solicitation are available from: SBIR/STTR Solicitation Office, 13687 Baltimore Ave., Laurel, MD 20707-5096, tel: 301/206-9385, fax: 301/206-9722, Email: a2y@cu.nih.gov

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