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PO Box 9905 Washington DC 20016 Telephone 202-362-1809

As Bristol's Final Defenses Fall, IVAX Prepares Launch Of Generic Paclitaxel

Within the next two weeks, IVAX Pharmaceuticals of Miami is expected to start shipping generic paclitaxel to oncologists in the U.S.

The appearance of the generic will mark the fall of the elaborate defenses Bristol-Myers Squibb erected around the drug that contributed about $1.48 billion to the company's revenues last year.

Bristol's market exclusivity for the drug sold under the brand name Taxol expired in January 1998. Yet, for nearly three years the company fought off generics through legal maneuvers that appeared to be designed to delay the other players' entry on the paclitaxel market.

The last of these defenses fell last March, when a federal judge

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In Brief:

UPCC Wins $26 Million Center Grant From NCI; Massey Center Opens New Outpatient Clinic

UNIVERSITY OF PENNSYLVANIA CANCER CENTER received a $26 million Cancer Center Support Grant from NCI. The five-year grant is the largest ever received by the university from NIH and is a 62 percent annual increase over the prior award, the university said. UPCC has been continuously funded by the NCI CCSG mechanism since the early 1970s. The grant renewal received "outstanding," the highest possible status, and full approval and funding of its 13 research programs and 16 core facilities, which provide specialized services to support cancer research. The center also was re-approved as an NCI-designated comprehensive cancer center. "We are extremely proud to receive this recognition from our peers and from NCI," UPCC Director **John Glick** said. The center plans to open the Rena Rowan Breast Center this fall, encompassing one floor of the Penn Tower building. . . . **VIRGINIA COMMONWEALTH UNIVERSITY** has opened a new outpatient cancer care facility operated by the NCI-designated Massey Cancer Center. VCU's Massey Cancer Center at Stony Point is a $6.6 million, 20,000-square-foot addition to an outpatient facility that has offered suburban access to physicians from VCU's Medical College of Virginia Hospitals for seven years. Last year, the Stony Point outpatient facility had more than 100,000 patient visits to its family practice and specialty physicians. "Current approaches to cancer treatment may result in patients making frequent visits to their cancer center for repeated rounds of chemotherapy or radiation therapy," said **Gordon Ginder**, director of the Massey Cancer Center. "We wanted to

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FTC Probing Bristol, ABI Dispute Over Taxol Patent

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invalidated Bristol's key patent claims (**The Cancer Letter**, March 3). According to court papers, later in the spring, Bristol learned that a small California-based firm, American BioScience Inc., was about to receive a patent involving paclitaxel.

There are two possible interpretations of ABI's appearance on the scene.

The first version of events assumes that the ABI patent infringement claims were a genuine surprise to Bristol. Under this assumption, the ABI patent would have been a gift from the gods to Bristol.

After the ABI patent issued, BMS could report the potential infringement dispute to the FDA "Orange Book," thereby compelling the agency to preserve the status quo for as long as 30 months.

The Federal Trade Commission is investigating another, less charitable, scenario, court papers show. "The Commission recently commenced an investigation of the conduct of Bristol and ABI involving Taxol to determine whether [their] conduct may restrict competition and harm consumers," the agency said in a recent court filing.

The current flurry of litigation can be traced to Aug.1, the day ABI told Bristol that it received U.S. Patent No. 6,096,331 covering "Methods and Compositions Useful for Administration of Chemotherapeutic Agents." Primarily, ABI claimed that the sizes of vials used by BMS to package Taxol violated the newly-issued patent.

On Aug. 10, a Bristol attorney responded that the company did not receive enough documents from ABI and didn't have enough time to evaluate its patent claims. "Under the circumstances, Bristol must respectfully decline to list the patent," Bristol attorney Louis Solomon, of the New York firm of Solomon, Zauder, Ellenhorn, Frischer and Sharp, wrote to ABI.

Even if the patent claims were trivial, at that point, BMS had the opportunity to report the potential infringement to the Orange Book and spend as long as 30 months hashing out the patent dispute. Meanwhile, Taxol would continue to contribute over $4 million a day to Bristol's revenues.

A submission to the Orange Book at that time would have been unlikely to open Bristol to anti-trust action from the government, experts say. No matter how far-fetched, claims made to the federal government are protected by the Noerr-Pennington doctrine. One down side would have been in public relations, with Bristol appearing "greedy," observers said.

Informed by Bristol that it would not list the patent, ABI filed a suit in the U.S. District Court for the Central District of California, and a day later, on Aug. 11, Judge William Rea issued a temporary restraining order that, among other things, forced Bristol to list the ABI patent in the Orange Book.

Bristol complied immediately. Not only was the company acting to buttress the exclusivity of Taxol, but it was under a court order to do so.

Yet, this was an odd legal situation. ABI was claiming that Bristol's failure to list its patent would cause irreparable damage to the company.

"If ABI patent is not listed in the Orange Book, FDA will continue to process requests from other drug companies to approve Taxol product," the ABI filing said. "Approval of infringing Taxol for sale will destroy ABI's exclusive control of the intellectual property embodied in its Taxol patent."

The ABI suit claimed that Bristol did not have the option to decline to list the ABI patent. "ABI's ability to exploit its Taxol patent will be severely and immediately impaired by [Bristol's] failure to comply with its legal obligations to list the Taxol patent in the Orange Book."

In its response to ABI's motion, Bristol described the unusual nature of the dispute and asked the court to sort through the dilemmas contained in the case.

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World Wide Web: http://www.cancerletter.com

Editor & Publisher: Kirsten Boyd Goldberg
Editor: Paul Goldberg
Editorial Assistant: Shelley Whitmore Wolfe

Editorial: 202-362-1809 Fax: 202-362-1681
PO Box 9905, Washington DC 20016
E-mail: kirsten@cancerletter.com or paul@cancerletter.com

Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724

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"In a typical scenario, the NDA holder and the patent owner are the same or related entities," the company said in an opposition filing of Aug. 16. "The language of the listing statute and implementing regulations make clear sense in that context."

In this case ABI stated that it would sue Bristol if the pharmaceutical company fails to license the patent. By demanding that Bristol protect Taxol from IVAX and others, ABI was in effect protecting its stake in the drug.

The suit presented the following dilemmas for Bristol:

—The company hasn't had an opportunity to study the patent. "[When] the NDA holder is not the patent owner or is unrelated, the NDA holder may not have the knowledge needed to comply with the listing requirements," the document states.

—"The NDA holder should not be put in the position of submitting a patent for listing and then perhaps being required to defend an infringement suit against the very same patent at a later time. This would create a Hobson's choice for the NDA holder: it risks violating the statute by refusing to submit a patent for listing that it does not own or have rights to, yet if it lists and thereafter does not take a license to the patent, the very act of listing could be seen as acknowledging applicability, validity, or infringement."

Shortly after Bristol and ABI filed their first motions, IVAX recognized the threat of having to wait another 30 months and petitioned to join the suit.

"ABI's and [BMS] interests in this case are not adverse, but aligned. Indeed, if the temporary restraining order is not dissolved, and the injunctive relief ABI seeks is granted, [BMS] stands to reap hundreds of millions of dollars through further extension of an already improper monopoly on the blockbuster anticancer drug paclitaxel," IVAX said in a motion to intervene, dated Aug. 18.

In another motion, IVAX attorneys argued that ABI would not sustain irreparable harm, because it has no product.

"All ABI stands to lose—initially—if its patent is not listed in the Orange Book is whatever monetary damage might flow from ABI's inability to delay FDA approval of a generic paclitaxel product and the entry of such product into the market before ABI can obtain judicial relief," attorneys for the generic said in another filing.

ABI and Bristol opposed the move by IVAX to join the litigation. ABI and Bristol were "engaged in good faith, arms-length negotiations in [an] attempt to resolve the narrow, but nevertheless important, disputes at issue, without the need for burdening the court, further litigation or discovery," Bristol attorney Solomon wrote in a court document.

At the same time, the case attracted the attention of FTC. The agency's *Amicus Curiae* brief states that FTC has initiated an investigation of the interactions between Bristol and ABI.

The agency urged the judge not to approve a permanent settlement agreement in which BMS was obligated to list the ABI patent in the Orange Book.

"A factual finding by this court that the `331 patent satisfies the statutory and regulatory requirements for Orange Book listing may raise significant barriers to a generic company's challenge to that listing," the FTC brief said. "The commission also urges the court to consider the pendency of the commission's investigation before entering the order proposed by the parties."

On Sept. 7, the court dismissed ABI's complaint against Bristol. If an innovator chooses not to list a patent in the Orange Book, only the federal government has the standing to compel it to do so, the judge ruled.

"There is no private right of action to remedy an alleged failure of BMY to comply with its obligations under the Food, Drug and Cosmetic Act," Judge William Matthew Byrne wrote in a ruling Sept. 7. "An action to enforce the FDCA or to restrain violations thereof may only be brought by and in the name of the United States."

In another blow to Bristol, the judge ordered the company to remove the ABI listing from the Orange Book. An appeals court upheld the ruling and ordered the company to "delist" the patent.

The California ruling eliminated Bristol's final opportunity to protect its de-facto exclusivity for paclitaxel. Moreover, the company was facing an FTC investigation.

On Sept. 11, the company asked the U.S. District Court for the Southern District of New York for a "declaratory judgment" to guide it through the complexities of patent and antitrust law.

On the same day, the company attempted to list the ABI patent in the FDA Orange Book. This was a long-shot effort since FDA law gives innovators 30 days to list infringing patents.

As a result of the California litigation, the deadline for listing was overshot by 12 days.

On Sept. 15, FDA declined to "relist" the patent. Also, the agency moved rapidly to open the doors for

Bristol's generic competitors. On the same day, FDA gave final approval to the IVAX version of paclitaxel.

As the first generic to file an Abbreviated New Drug Application, IVAX will have market exclusivity for the generic for six months. On Sept. 19, four days after approving the IVAX paclitaxel, the agency approved another generic version of the drug, produced by Mylan Pharmaceuticals.

After the disappointment in the California suit, ABI sued IVAX, alleging patent infringement, and went to court in Washington, seeking to compel FDA to list its patent. However, the U.S. District Court for the District of Columbia dismissed the company's petition, essentially echoing the California ruling. An appeals court affirmed that ruling.

In addition to other problems, Bristol is facing a suit from IVAX, in which the Miami company claims that the dispute in California courts was not genuine.

"Bristol conspired with ABI to plot and implement a scheme pursuant to which Bristol hoped to be enabled to list the `331 patent in the Orange Book, thus effectively blocking final FDA approval [of the IVAX] version of Taxol for yet another two and a half years, without subjecting itself or ABI to antitrust liability," the suit states. IVAX is alleging conspiracy in restraint of trade and violations of Florida's antitrust law by Bristol.

Bristol spokesman Nancy Goldfarb said the IVAX allegations are without merit. "This is just another attempt by IVAX to fuel a climate of misinformation and innuendo rather than concentrate on bringing to market essential therapies for patients with cancer," she said to **The Cancer Letter**.

Professional Societies:

ACS Defends Dialogue, Calls Story "Misleading"

In internal communications, officials of the American Cancer Society and the National Dialogue on Cancer said a recent article in **The Cancer Letter** made assertions that were "patently false to the degree that they do not merit a formal response."

The communications, which responded to a story published in the Sept. 22 issue, were circulated to the society's senior employees and participants of the Dialogue, an ACS-funded effort to develop an overarching cancer agenda.

In one of the two memos, LaSalle Leffall, chairman of the Dialogue's Steering Committee, said the story "is built on a good deal of speculation, grossly misleading, and less than credible."

"One of almost 100 national organizations that make up the National Dialogue Cancer [sic.], the American Cancer Society was targeted once again in this issue of **The Cancer Letter**," Leffall wrote in the memo dated Oct. 10 and addressed to Dialogue participants.

"Given the valuable work we are all doing for and with our own entities, the millions of prospective cancer patients and hundreds of thousands of cancer survivors we are dedicated to serve, it is my hope that **The Cancer Letter** and all other similar documents will find it possible to get behind and support our collective efforts in order that we might reach our ultimate goal at the earliest possible time," Leffall wrote.

Leffall's memo was circulated with a memo from Harmon Eyre, the ACS chief medical officer. Copies of the two documents were obtained by **The Cancer Letter**.

"These memos fail to point out specific errors in the story," said Kirsten Boyd Goldberg, publisher of **The Cancer Letter**. "The story was well-reported and accurate. We stand by it."

The story, which is posted on **The Cancer Letter** web site (http://www.cancerletter.com/headlinenews.html) reported that:

—Centers for Disease Control and Prevention recently gave a $100,000 grant to the ACS to support the Dialogue. Citing legal opinions, the story said the contribution raises questions about some of these funds being used for lobbying.

Government agencies are prohibited from lobbying. The Dialogue, which is not a legally defined entity, operates a spin-off committee that is developing a plan for rewriting the National Cancer Act. The two entities are not completely isolated from each other, and are funded primarily by ACS.

Legal experts quoted in the story pointed to a structural problem: the apparent absence of a firewall separating the legislation committee from the Dialogue.

—The CDC contribution to the Dialogue was added to a multi-million-dollar sole-source grant. Citing assessments from public health experts, the story argued that the work done under this grant could have been performed by other entities. At least one project funded through the agreement would have been unlikely to survive peer review, experts said.

—The relationship and financial dealings between CDC and ACS are significant because ACS has been a persistent lobbyist for the Atlanta-based

government agency, and since the leaders of the cancer legislation committee publicly called for the elevation of the agency's status and budget.

—The rewriting of the National Cancer Act as well as the activities of the Dialogue on Cancer are being carried out behind closed doors.

In a memorandum addressed to senior management of the ACS national office and chief executives of the society's divisions, Eyre said the society has not "redirected federal funds to support inappropriate lobbying activities."

"Of course, these assertions are patently false to the degree that they do not merit a formal response," Eyre wrote. "However, knowing that you might receive inquires about this matter, I felt it important to share a few important facts for the record."

Eyre's memorandum states:

—"The ACS has tremendous interest in the collaborative power of the Dialogue with its 125 member organizations. The ACS also participates in NCLAC, which is a separate and distinct effort to bring together a diverse group of organizations and individuals in the cancer community. NCLAC exists to evaluate the wide variety of policy options lawmakers could consider to help advance the fight against cancer. To that end, the ACS has agreed to provide source funding to both organizations. However, the Society has created separate financial project numbers for expenses related to each initiative, as well as separate budgets and funding sources. No CDC grant funds received by the ACS has been used to support NCLAC.

—"The two projects are staffed by different teams of Society executives. I manage our involvement in the National Dialogue on Cancer, with assistance from Allan Erickson, who serves as a consultant on this special project. The NCLAC project itself is managed by independent consultants, and our involvement comes through our national government relations team under the direction of National Vice President Dan Smith.

—"As a recipient of government grants, the ACS is required annually to have these grants audited by an independent accounting firm. The independent auditors insist upon full compliance with the government grant management process. The National Home Office has a finance team staffer dedicated to the tracking, reconciliation and overall management of these federal grant funds.

—"Perhaps most importantly, the CDC will not reimburse the Society for the use of the grant monies in question until *after* they have been spent—and spent on the purpose for which they were specifically intended. The CDC requires rigorous documentation of the way in which grant dollars are spent before it will release funds; and only then will release the dollar amount that was actually spent, even if that amount is less than the amount of the grant."

The memorandum emphasized accounting structures and did not address the question of propriety of the sole-source cooperative agreement between CDC and ACS or the question of appropriateness of developing the National Cancer Act in closed meetings.

The memorandum offered no discussion of a project that gave ACS $300,000 last year to develop and carry out health information campaigns.

These campaigns disregarded evidence-based methods for designing health messages, failed to define target populations, and did not monitor outcomes, public health experts said.

Cancer Policy:
Report Urges Enhancement Of Cancer Data Systems

To improve the quality of cancer care in the U.S., existing state and federal systems that collect data on patient outcomes need to be expanded, and federal funding for data analysis and research should be increased, the National Cancer Policy Board said in a new report.

"Like the U.S. healthcare system, the data systems available to assess the quality of care on a national or regional basis are fragmented," the report said.

The report, "Enhancing Data Systems to Improve the Quality of Cancer Care," is a follow-up to the board's 1999 report, "Ensuring Quality Cancer Care." The new report is available at http://books.nap.edu/catalog/9970.html.

Executive Summary

Following are excerpts from the report's Executive Summary:

The board's review of current cancer care data systems suggests that we are far from the ideal. Relatively few healthcare systems are monitoring the quality of cancer care. Serious barriers impeding such efforts include:

--a lack of recognized measures of quality;

--an absence of benchmarks with which to measure progress and success;

--reliance on hospital-based data retrieval, while cancer care is shifting to ambulatory care settings;

--reliance on retrospective medical chart reviews for data, a method that is labor intensive, inefficient, and prone to error relative to the prospective electronic capture of information possible through computer-based patient record systems;

--methodologic difficulties (e.g., adequacy of sample sizes for comparison, availability of data with which to control for differences in patient mix); and

--concerns about protecting the privacy and confidentiality of patient in-formation.

Advances in information technology and the evolution of fully integrated systems of care may ultimately resolve some of the problems associated with existing data systems. Computer-based patient records and electronic communication have the potential to greatly improve the quality, comprehensiveness, and timeliness of data. And data systems built to meet the needs of disease management programs could capture information on an individual's full episode of care, regardless of where in the system care was provided. Such developments are, however, likely years away from widespread application and are in part dependent on resolving policy issues concerning the maintenance of confidentiality of patient information.

In the short term, three national cancer-related databases hold great promise to further quality improvement efforts: 1.the National Program of Cancer Registries of the Centers for Disease Control and Prevention; 2.the Surveillance, Epidemiology, and End Results program of the NCI; and 3.the National Cancer Data Base, sponsored by the American College of Surgeon's Commission on Cancer (ACoS-CoC) and the American Cancer Society.

NPCR and SEER are cancer surveillance systems with a primary mission of providing population-based estimates with which to understand the occurrence and distribution of cancer. These surveillance systems can also become powerful tools for assessing quality of care when linked to other data sources or when used to select individual cases for special studies. Surveillance databases have great potential to provide population-based estimates of quality-of-care problems. Despite the value of these databases, sustaining them is difficult, let alone expanding their use for quality measurement. Most states do not have the re-sources to augment their current workload to conduct studies of quality care, which fall outside their primary mission of cancer surveillance; many states struggle merely to ensure that basic cancer surveillance continues.

The ACoS-CoC and the American Cancer Society have long supported the examination of quality of cancer care through the most extensive national data collection effort dedicated to this purpose, NCDB. NCDB has tremendous potential to provide detailed information regarding quality to the facilities that report to it, thereby encouraging improvements in performance. As a source of national information on quality, however, NCDB has limitations because of its lack of complete coverage. Only facilities with cancer programs approved by ACoS-CoC must report data to NCDB, and most of these are hospitals. Cases that tend to be missed in NCDB are those diagnosed and treated in unapproved facilities and ambulatory care settings. While NCDB is not nationally representative, estimates are that roughly 80 percent of incident cancer cases are reported to NCDB, making it a powerful resource for internal quality assessments within sites of cancer care serving the majority of Americans.

Of all available systems, NCDB includes the most extensive set of treatment-related items. NPCR and SEER include first course treatment, but little else. Gathering data on chemotherapy and adjuvant radiation therapy is challenging because the individuals collecting much of the data for data systems, cancer registrars, are generally hospital based. They abstract needed information from the hospital chart. Procedures occurring outside of the hospital (e.g., in community-based, private practice office settings) are usually not recorded in the hospital chart, and because there are generally insufficient resources to track such care, treatment data from cancer registries and databases is often too incomplete to use for quality studies.

What steps can be taken to enhance data systems so that they can be used to monitor and improve the quality of cancer care?

The board recommends that steps be taken in three areas: 1.Enhance key elements of the data system infrastructure: quality-of-care measures, cancer registries and databases, data collection technologies, and analytic capacity; 2.Expand support for analyses of quality of cancer care using existing data systems; 3.Monitor the effectiveness of data systems to promote quality improvement within health systems.

Enhance Key Elements of the Data System Infrastructure

Recommendation 1: Develop a core set of cancer

care quality measures.

a. The secretary of the Department of Health and Human Services should designate a committee made up of representatives of public institutions (e.g., the DHHS Quality of Cancer Care Committee, state cancer registries, academic institutions) and private groups (e.g., consumer organizations, professional associations, purchasers, health insurers and plans) to:

1) identify a single core set of quality measures that span the full spectrum of an individual's care and are based on the best available evidence; 2) advise other national groups (e.g., National Committee for Quality Assurance, Joint Commission for the Accreditation of Healthcare Organizations, Quality Forum) to adopt the recommended core set of measures; and 3) monitor the progress of ongoing efforts to improve standard reporting of cancer stage and comorbidity.

b. Research sponsors (e.g., Agency for Healthcare Research and Quality, National Cancer Institute, Health Care Financing Administration, Department of Veterans Affairs) should invest in studies to identify evidence-based quality indicators across the continuum of cancer care.

c. Ongoing efforts to standardize reporting of cancer stage and comorbidity should receive a high priority and be fully supported.

d. Efforts to identify quality of cancer care measures should be coordinated with ongoing national efforts regarding quality of care.

Recommendation 2: Congress should increase support to the Centers for Disease Control and Prevention for the National Program of Cancer Registries to improve the capacity of states to achieve complete coverage and timely reporting of incident cancer cases. NPCR's primary purpose is cancer surveillance, but NPCR, together with SEER, has great potential to facilitate national, population-based assessments of the quality of cancer care through linkage studies and by serving as a sample frame for special studies.

Recommendation 3: Private cancer-related organizations should join the American Cancer Society and the American College of Surgeons' to provide financial support for the National Cancer Data Base. Expanded support would facilitate efforts underway to report quality benchmarks and performance data to institutions providing cancer care.

Recommendation 4: Federal research agencies (e.g., NCI, CDC, AHRQ, HCFA) should support research and demonstration projects to identify new mechanisms to organize and finance the collection of data for cancer care quality studies. Current data systems tend to be hospital based, while cancer care is shifting to outpatient settings. New models are needed to capture entire episodes of care, irrespective of the setting of care.

Recommendation 5: Federal research agencies (NIH, FDA, CDC, and VA) should support public-private partnerships to develop technologies, including computer-based patient record systems and intranet-based communication systems, that will improve the availability, quality, and timeliness of clinical data relevant to assessing quality of cancer care.

Recommendation 6: Federal research agencies (NCI, AHRQ, VA) should expand support for training in health services research and training of professionals with expertise in the measurement of quality of care and the implementation and evaluation of interventions designed to improve the quality of care.

Expand Support for Analyses of Quality of Cancer Care Using Existing Data Systems

Recommendation 7: Federal research agencies should expand support for health services research, especially studies based on the linkage of cancer registry to administrative data and special studies of cases sampled from cancer registries. Resources should also be made available through NPCR and SEER to provide technical assistance to states to help them expand the capability of using cancer registry data for quality improvement initiatives. NPCR should also be supported in its efforts to consolidate state data and link them to national data files.

Recommendation 8: Federal research agencies should develop models for the conduct of linkage studies and the release of confidential data for research purposes that protect the confidentiality and privacy of healthcare information.

Monitor the Effectiveness of Data Systems to Promote Quality Improvement Within Health Systems

Recommendation 9: Federal research agencies should fund demonstration projects to assess the application of quality monitoring programs within healthcare systems and the impact of data-driven changes in the delivery of services on the quality of health care. Findings from the demonstrations should be disseminated widely to consumers, payers, purchasers, and cancer care providers.

Funding Opportunities:

SmithKline Beecham Seeks Abstracts For Fellows Forum

Oncology fellows are invited to submit abstracts for presentation at SmithKline Beecham's Fifth Annual Oncology Fellows Forums, scheduled to take place next February and March.

The meetings allow medical and gynecologic oncology fellows to participate in an interactive scientific forum moderated by oncology faculty. Fellows are invited to submit basic science or clinical research abstracts to be considered for presentation. Faculty will select the top four presenters at each meeting to receive a $1,000 travel grant to attend a national oncology meeting of their choice in 2001.

The deadline for gynecologic oncology submissions is Dec. 1, and the forum is scheduled for Feb. 1-4. For medical oncology submissions, the deadline is Dec. 8, and the forum is scheduled to be held March 1-4.

For further information, see http://www.stimedinfo.com/1592gyn.htm for the gynecologic forum, or http://www.stimedinfo.com/1591med.htm for the medical oncology forum, or contact Christy Kass, at phone: 973-376-5655.

RFA Available

RFA RR-00-006: Centers of Biomedical Research Excellence

Letter of Intent Receipt Date: Dec.1, 2000

Application Receipt Date: Jan. 12, 2001

National Center for Research Resources invites grant applications for the Institutional Development Award Program to promote health-related research and increase the competitiveness of investigators.

Inquiries: Sidney McNairy, associate director, Research Infrastructure, National Center for Research Resources, NIH, 6705 Rockledge Dr., Bethesda, MD 20892-7965, phone 301-435-0788; fax 301-480-3770; e-mail sidneym@ncrr.nih.gov

In Brief:

NIH Scientists Engineer Mice That Get Burkitt's Lymphoma

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offer our suburban patients the option of receiving their care in a setting closer to home." . . . **NIH SCIENTISTS** have genetically engineered mice to develop Burkitt's lymphoma, a rare cancer. "We in effect created a 'mini-gene' that reproduces the cancer as it occurs in people," said **Herbert Morse III**, chief of the immunopathology lab at the National Institute of Allergy and Infectious Diseases. The results of this work, supported by NIAID and NCI, are detailed in the current issue of the Journal of Experimental Medicine. "This new animal model may allow researchers to find ways to treat Burkitt's patients who don't respond to the standard treatment," Morse said. "It will also help us understand why the cells 'go bad' to cause this malignancy." . . . **MOHAMED ABDEL-RAHMAN** is the first recipient of the Lois M. Jones Endowment for Cancer Research Fellowship at the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute. He conducts research on sporadic solid tumors. . . . **MING YOU** was selected for the new Barbara J. Bonner Chair in Lung Cancer Genetics Research at Ohio State University Comprehensive Cancer Center. She will be a tenured professor in the Division of Human Cancer Genetics of the College of Medicine and Public Health's Department of Molecular Virology, Immunology and Medical Genetics. She conducts research to identify human and mouse lung cancer susceptibility genes, and translate the findings into experimental drugs. You is the principal investigator for Ohio State's grant under the seven-institution NCI Genetic Epidemiology of Lung Cancer Consortium. . . . **ROSALYNN CARTER**, vice chairman of the Carter Center and chairman of the Carter Center Mental Health Task Force, received the Rhoda and Bernard Sarnat International Prize in Mental Health, presented by the Institute of Medicine. The prize consists of a medal and $20,000 and was presented Oct. 17 at the IOM Annual Meeting. Carter received the award for her dedication and effectiveness in educating and mobilizing the public to the needs and opportunities in the mental health field. The award also recognizes her for commitment to research and treatment of mental illness, as well as for pioneering efforts to reduce the stigma of mental disorders. . . . **JUDY ROLLINS**, adjunct instructor at Georgetown University School of Medicine, is the first recipient of the International Society of Nurses in Cancer Care/Bristol-Myers Squibb Clinical Nursing Practice Grant. She was selected for her research comparing stress and coping for children with cancer in the U.S. and the U.K. . . . **CLARIFICATION:** A story in the Oct. 6 issue of **The Cancer Letter** on new SPORE grants funded by NCI inadvertently left out the Harvard School of Public Health as participating with the Dana-Farber Cancer Institute and Harvard Cancer Center.

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