THE CANCER LETTER INTERACTIVE

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NCI To Appoint Expert Group To Consider Standards For Outcomes Measurement

In an effort to improve research in the quality of cancer care, NCI plans to form a working group to study the measurement of cancer outcomes.

The field of measuring the quality of health care in general, and cancer care in particular, is in early stages of development. A number of competing quality of life measurement tools and a few emerging patient satisfaction instruments are being applied in clinical trials and observational studies. However, like incompatible computer software, the outcomes

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In Brief:

Carroll Named Deputy Director At Huntsman; Pamer Leads Infectious Disease Service, MSKCC

WILLIAM CARROLL was appointed deputy director of the Huntsman Canceer Institute at the University of Utah. Carroll is the director of the Center for Children, a collaboration between Huntsman and the Primary Children's Medical Center, as well as a professor of pediatrics at the university. He will continue his clinical care of children with cancer and his research. He also will work with Joseph Simone, executive director of the Huntsman Cancer Care Program, on a research collaboration with Intermountain Healthcare. . . . **ERIC PAMER** was appointed chief of the Infectious Disease Service in the Department of Medicine at Memorial Sloan-Kettering Cancer Center. Pamer was an associate professor of medicine at Yale University. He has conducted research on the biology of antigen processing in cells infected with *Listeria*. His work is directed toward finding ways to enhance the immune system in cancer patients. Pamer received his M.D. degree from Case Western Reserve University in 1982 and completed residency and fellowship training at University of California, San Diego. He also was a research fellow at the Scripps Clinic and Research Foundation. . . . **CEDARS-SINAI MEDICAL CENTER's** Maxine Dunitz Neurosurgical Institute has begun a Pediatric Program for Neurosurgery. The program is led by pediatric neurosurgeon **Moise Danielpour**, one of only a few pediatric neurosurgeons in the world who performs in utero surgery for myelomeningocele spinal cord defect. He specializes in treatment of pediatric brain tumors and other central nervous system disorders. Danielpour is a co-investigator in NIH-sponsored trials for assessment of the role of intrauterine closure of myelomeningocele defect in maintaining neurological function, correction of Chiari II

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NCI Sees Role To Improve Research In Quality Of Care

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generated using one method often can't be compared to outcomes using another.

"It's going to be an interesting and controversial endeavor, because there are those who feel strongly that unless we start by identifying a gold standard, we will never be able to move forward and compare things," Joseph Lipscomb, chief of the NCI Outcomes Research Branch, said to **The Cancer Letter**. "Others feel that the field isn't ready for that yet and we ought to focus more on developing criteria and establishing a research program."

NCI plans to select experts in measurement theory, oncology, and health services research for the Cancer Outcomes Measurement Working Group later this year. The panel would begin its deliberations in early 2001 as part of NCI's "Improving the Quality of Cancer Care" initiative.

NCI's Four-Point Research Plan

Under the initiative, approved by HHS Secretary Donna Shalala last fall, NCI proposed a four-point research plan that has the following objectives:

—Develop core process and endpoint measures for cancer care.

—Strengthen the methodological and empirical research base for quality assessment in cancer.

—Enhance quality of care research in the restructured NCI clinical trials program.

—Improve the quality of cancer communications.

In the year since NCI announced the initiative, the Division of Cancer Control and Population Sciences, working with other NCI divisions, has begun to develop specific plans for research in each of these areas, Deputy Division Director Robert Hiatt said in a recent presentation to the National Cancer Advisory Board.

NCI was spurred to take action on quality of care issues by a report of the National Cancer Policy Board of the Institute of Medicine. The policy board's report, issued in April 1999, found that no uniform standards exist for measuring the quality of cancer care, and that evidence collected piecemeal suggests the quality of care is uneven at best (**The Cancer Letter**, April 9, 1999). The report, "Ensuring Quality Cancer Care," emphasized the role of the federal government in working with the private sector to establish measurements of quality and to hold health-care providers accountable.

Quality of care is defined as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge," according to a 1990 IOM report. NCI's role in this field is to "enhance the state-of-the-science for defining, monitoring, and improving the quality of cancer care," Hiatt said to the NCAB at its Sept. 12 meeting.

Existing data for quality of care analysis have several shortcomings, Hiatt said. More patient-centered endpoints are needed. "There is a real morass in this field," he said. "Measures that are available haven't been believable to physicians."

There are similar challenges in developing good process measures of the quality of cancer care. Measures need to be feasible to collect and rapidly available. Currently there is no national population-based system to monitor quality of care. "There is a disconnect between measures for national benchmarks and surveillance, and measures for practitioners and health plans," Hiatt said.

Earlier this month, NCI issued a Request for Applications to form a research consortium to conduct cancer outcomes research and surveillance (**The Cancer Letter**, Sept. 1). The consortium will initially conduct studies of new lung and colorectal cancer patients to identify uniform outcome measures and the design and conduct of analyses.

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Founded Dec. 21, 1973, by Jerry D. Boyd

The Institute plans to set aside $40 million over the next five years to fund grants for five or six research teams for each cancer site, as well as a statistical coordinating center, that would form the Cancer Care Outcomes Research and Surveillance Consortium (CanCORS).

Information on the program is available at the DCCPS Web site: http://www-dccps.ims.nci.nih.gov/ARP/cancors.html.

Outcomes Working Group

The outcomes working group will be charged with evaluating the current measures of quality of life for the major disease sites—breast, prostate, colorectal, and lung cancer. The group will be asked to consider recommending or developing "core" measures, Lipscomb said.

"This group will take on a very dramatic challenge to look at what has been done in outcomes measurement, and this may lead us to a gold standard, or it may lead us to a research program," he said.

The Outcomes Research Branch also plans to develop a new Program Announcement in the spring of 2001 calling for investigator-initiated studies in "basic" outcomes research, including modern measurement applied to cancer endpoint assessment, Lipscomb said.

The branch also plans to evaluate practice guidelines from professional organizations, provider groups, third-party payers, and researchers in peer-reviewed literature. The goal would be to identify areas of agreement and disagreement, and gaps, in order to shape the research agenda, Lipscomb said.

Quality of Cancer Care Committee

NCI is leading a federal government-wide effort to make cancer a working model for quality of care research and application. This is underway through a Quality of Cancer Care Committee, which is part of the HHS Quality Improvement Initiative.

The committee, chaired by NCI, includes officials from the federal agencies that have a role in cancer care and research, including the Department of Veteran's Affairs, Department of Defense, Agency for Heathcare Research and Quality, Health Care Financing Administration, Centers for Disease Control and Prevention, the National Center for Health Statistics, Food and Drug Administration, Health Research Services Administration, and the Indian Health Service.

The charge to the committee is to:

—Describe quality of cancer care research supported or conducted by federal agencies.

—Determine agency needs for evidence on the quality of care.

—Identify gaps between research and needs and use to stimulate interagency projects and additional research.

—Establish systematic process for the interaction of research and application arms of the federal government to ensure that the best possible evidence is used for decisions on delivery, coverage, and reimbursement of cancer services.

The committee is developing research projects involving NCI and the other agencies. None of these have begun, but NCI expects to have some studies funded in its fiscal 2001 budget, Hiatt said to the NCAB.

Some of the projects being considered include:

—VA: A Quality Enhancement Research Initiative (QUERI) project for a major cancer, probably colorectal.

—HCFA: Translating effective colorectal cancer screening interventions to HCFA's Peer Review Organizations.

—FDA: Sponsor analyses and research to investigate in-depth the relationship between quality of life endpoints and symptom-based measures of outcome, ultimately to strengthen the information base for evaluating drug efficacy and advertising claims.

—HRSA: Improving prevention and screening services through Bureau of Primary Health Care.

Reimbursement:

IND-Exempt Trials May Need Special Review, HCFA Says

The final "National Coverage Decision" that mandates Medicare reimbursement for patient care costs for participants in clinical trials states that trials that are exempt from FDA Investigational New Drug requirements may have to go through specially designed qualification procedures.

The decision in effect establishes two tiers of eligibility requirements:

—Trials that have been sponsored or reviewed by government agencies would automatically qualify for Medicare reimbursement of patient care costs.

—Trials that have not been reviewed would have to meet additional criteria. However, until these criteria are developed, these trials, too, will be automatically qualified for reimbursement.

IND-exempt trials include trials of approved drugs that are not intended to support a new indication or labeling change and if the trials are not expected to significantly increase the risks associated with the use of the drug. Many drug company-sponsored trials are exempt from IND requirements.

The decision states:

"Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status."

The full text of the decision is posted on HCFA's web site: http://www.hcfa.gov/quality/8d2.htm. An earlier version of the plan didn't require self-certification for IND-exempt trials. The coverage decision became effective on Sept. 19.

Observers said the change is not expected to trigger significant opposition from patient and physician groups.

The decision provides automatic coverage for trials that have been sponsored or reviewed by government agencies. These include trials funded by federal agencies or through their cooperative groups, as well as trials conducted under IND reviewed by the FDA. The list of sponsoring agencies includes NIH, HCFA, Centers for Disease Control, the Agency for Healthcare Research and Quality, Department of Defense, and Veterans Administration.

Since IND-exempt trials are not reviewed by any of these agencies, they will be subjected to different criteria before qualifying for coverage. According to the HCFA decision, the government agencies will meet to come up with these criteria.

"These criteria will be easily verifiable, and where possible, dichotomous," the document states. "Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs. This panel is not reviewing or approving individual trials. The multi-agency panel will meet periodically to review and evaluate the program and recommend any necessary refinements to HCFA…

"Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development."

No date has been set for the agencies' first meeting. Also, the document does not state whether patient and physician groups would be involved in developing these prospective criteria. However, sources said that Administration officials have assured patient groups that they would be invited to serve on the panel.

According to the NCFA document, routine costs of a clinical trial include "all items and services that are otherwise generally available to Medicare beneficiaries that are provided in either the experimental or the control arms of a clinical trial."

Under this definition, routine costs in clinical trials include:

—Items or services that are typically provided absent a clinical trial (e.g., conventional care);

—Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

—Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service—in particular, for the diagnosis or treatment of complications.

The following items are specifically excluded from coverage:

—The investigational item or service;

—Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and

—Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

The decision is binding on Medicare carriers, fiscal intermediaries, peer review organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, and Medicare+Choice organizations.

NCI Programs:

Institute To Pilot Text Chat On CancerNet And CIS Sites

Later this year, a new NCI program will test the feasibility of offering people looking for cancer

information on its Web site the opportunity to chat online with a live operator.

Called "instant messaging" or "text chat," the technology now offered on some e-commerce sites could improve access to information on NCI's Web sites, the Institute said.

The Cancer Information Products and Systems Program, Cancer Information Service, and Office of Clinical Research Promotion are partnering to create a pilot that will test and evaluate the potential for instant messaging.

Later this year, links on the CancerNet and CIS Web sites will open a window for a live text conversation with an information specialist. Users of this service will be able to receive assistance with tasks such as searching for a clinical trial or ordering an NCI publication.

Cancer Policy:

Satcher Calls For Wider Use Of Smoking Prevention Efforts

Smoking rates among teens and adults could be cut in half within the decade if the U.S. would fully implement anti-smoking programs using effective approaches that are already available, Surgeon General David Satcher said recently.

Satcher released a new Surgeon General's report on "Reducing Tobacco Use" at the 11th World Conference on Tobacco or Health in Chicago last month. The report provides an analysis of the effectiveness of various methods to reduce tobacco use—educational, clinical, regulatory, economic, and social.

"During the past four decades we have made unprecedented gains in preventing and controlling tobacco use," Satcher said at the conference. "However, the sobering reality is that smoking remains the leading cause of preventable death and disease in our nation, and those who suffer the most are poor Americans, minority populations, and young people. Although our knowledge remains imperfect, we know more than enough to address the tobacco control challenges of the 21st century."

The report calls for the widespread use of methods that have proven to be effective in substantially reducing the number of people who will become addicted to nicotine; increasing the success rate of young people and adults trying to quit tobacco use; decreasing nonsmokers' exposure to environmental tobacco smoke; reducing disparities related to tobacco use and its health effects among different population groups; and decreasing the future health burden of tobacco-related disease and death.

Key actions that Satcher outlined to reduce tobacco use include:

—Implementing effective school-based programs, combined with community and media-based activities, which can prevent or postpone smoking onset in 20 to 40 percent of U.S. adolescents. Unfortunately, fewer than 5 percent of schools nationwide are implementing the major components of school guidelines recommended by CDC.

—Changing physician behavior, medical system procedures, and insurance coverage to encourage widespread use of state-of-the-art treatment of nicotine addiction. The report shows that brief physician advice to quit smoking can double or quadruple normal quit rates, while a combination of behavioral counseling and pharmacological treatment can boost success up to 10 times.

—Passing and enforcing strong clean indoor air regulations, which contribute to changing social norms and may decrease tobacco consumption among smokers and increase smoking cessation. The report calls on states to pass laws that will not restrict local governments from passing even stronger measures.

—Improving tobacco warning labels in the U.S., which are weaker and less prominent than those required in other countries such as Canada and Australia. The report shows that consumers receive very little information regarding the ingredients, additives, and potential toxicity of tobacco products.

—Increasing tobacco prices and excise taxes. Evidence presented in the report suggests that a 10 percent increase in price will reduce overall cigarette consumption by 3 to 5 percent. However, both the average price of cigarettes and the average cigarette excise tax in the U.S. are well below those in most other industrialized countries.

—Changing many facets of the social environment to reduce the broad cultural acceptability of tobacco use. The report concludes that comprehensive approaches combining community interventions, mass media campaigns, and program policy and regulation are most effective in changing social norms and reducing tobacco use.

"Failure to effectively use every intervention strategy at our disposal could mean turning back the clock on the efforts we've made since the 1960's to reduce cigarette smoking, one of the most notable public health accomplishments of this century,"

Satcher said. "We must respond aggressively to the serious challenges we still face: most importantly, the tobacco industry's continuing campaign to advertise and promote tobacco products. We need fair but aggressive measures to regulate these marketing activities, especially those that influence young people."

Satcher noted that the industry spent $6.7 billion in 1998—or more than $18 million a day—to market cigarettes, despite the overwhelming evidence of the harm they cause.

A summary of the report is available at: http://www.cdc.gov/tobacco. Copies of the Executive Summary can also be ordered via fax by calling 800-CDC-1311.

NIH Programs:

NIH Funds 11 New Grants In Women's Health Research

NIH said it will fund 11 awards to support development of new research in women's health.

The program, Building Interdisciplinary Research Careers in Women's Health, will increase the number of researchers working on women's health issues and will mentor junior researchers in an interdisciplinary scientific setting by pairing them with senior investigators.

The Office of Research on Women's Health at NIH, which leads the BIRCWH Initiative, will award a total of $5.5 million to 11 universities. In addition to ORWH, nine NIH Institutes and the Agency for Healthcare Research and Quality will co-sponsor this program.

Junior faculty members, selected as Interdisciplinary Women's Health Research Scholars, will have the opportunity to augment their research skills in these interdisciplinary career development programs. They will be matched with a seasoned senior investigator, who will mentor them for a period of two to five years.

The universities participating in the new program are Baylor College of Medicine, University of Alabama at Birmingham, University of California, Los Angeles and San Francisco, University of Connecticut Health Center, University of Kentucky, University of Medicine and Dentistry of New Jersey, University of North Carolina at Chapel Hill, Virginia Commonwealth University, Washington University in St. Louis, and Yale University School of Medicine.

Funding Opportunties:

AACR Seeks Nominations For Annual Awards, Lectures

The American Association for Cancer Research seeks nominations for its annual awards and lectures.

—AACR-Pezcoller International Award for Cancer Research is given annually to a scientist anywhere in the world who has made a major scientific discovery in the field of cancer, who continues to be active in the field, and whose ongoing work holds promise for future substantive contributions to cancer research. The Award recognizes extraordinary basic or translational cancer research.

The Award will be presented to a single investigator for his or her highly original work. In extraordinary circumstances, two individuals may be selected to share the Award when their investigations are clearly related and have resulted in prizeworthy work. The Awardee will be selected by an international committee of AACR members appointed by the AACR President with the agreement of the Council of the Pezcoller Foundation. The Award consists of a prize of US $75,000 and a commemorative plaque.

The Foundation and the AACR are soliciting nominations for the 2001 Award. Nominations can be made by any scientist who is now or has been affiliated with an institution engaged in cancer research. Institutions or organizations are not eligible for this award, and candidates may not nominate themselves.There is no official application form for this award.

The nomination package should consist of the following:

The candidate's curriculum vita, an indication of the most important references in the candidate's curriculum vita and list of publications, and a letter of recommendation in English (500 words, maximum) describing the candidate's major scientific achievements and explaining the impact of these achievements on progress in cancer research.

Nominators are asked to maintain the confidentiality of the nomination process and to refrain from informing the candidate about the nomination. Nominators should submit the original plus 12 copies of their nominations and supporting materials to: AACR-Pezcoller International Award for Cancer Research, c/o American Association for Cancer Research Inc., Public Ledger Building Suite 826, 150 South Independence Mall West, Philadelphia, PA 19106-3483.

Other AACR Awards:

—AACR-American Cancer Society Award to honor outstanding achievements in the fields of epidemiology, biomarkers, and prevention.

—AACR Joseph H. Burchenal Clinical Research Award to recognize outstanding achievements in clinical cancer research.

—AACR Bruce F. Cain Memorial Award to recognize an individual or research team for outstanding preclinical research that has implications for the improved care of cancer patients.

—AACR G.H.A. Clowes Memorial Award to recognize outstanding basic cancer research, laboratory or epidemiological.

—AACR Cornelius P. Rhoads Memorial Award to give recognition to an individual on the basis of meritorious achievement in cancer research. The awardee must be a young investigator; therefore, the Board of Directors of the Association has stipulated that the recipient must not have reached his or her 41st birthday by the time of the award (March 24, 2001).

—AACR Richard and Hinda Rosenthal Foundation Award to recognize research which has made or gives the promise of soon making a notable contribution to improved clinical care in the field of cancer. The award is restricted to individuals who are engaged in the practice of medicine, who reside in the Americas, and who will not be more than 50 years of age at the time of the award (March 24, 2001).

2001 AACR Lectures:

—DeWitt S. Goodman Lecture, by a scientist who has made significant contributions to the general field of cancer prevention.

—Charlotte Friend Memorial Lecture, given by a scientist recognized for outstanding achievements in cancer research.

There are no official application forms for these awards and lectures. The nominator need submit only a brief letter of nomination and (if possible) a curriculum vitae for each candidate. Nominators are asked to maintain the confidentiality of the nomination process and to refrain from informing the candidate about the nomination.

The deadline for receipt of nominations for the 2001 Awards is Oct. 2. Forward the original nomination letter and any accompanying materials to: American Association for Cancer Research, Public Ledger Building, Suite 826, 150 S. Independence Mall West, Philadelphia, PA 19106-3483 USA, (Attn: Preston Moritz).

RFAs Available

RFA AR-00-009: Planning Grant for Clinical Research Training in Minority Institutions

Letter of Intent Receipt Date: Oct. 23, 2000

Application Receipt Date: Dec. 19, 2000

The Office of Research on Minority Health joins NCI, National Center for Research Resources, National Center for Complementary and Alternative Medicine, National Eye Institute, National Institute on Aging, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Drug Abuse, and the National Institute of Nursing Research to invite minority institutions with professional schools in one or more of the health care disciplines to apply for a planning grant to develop a Master of Clinical Research or a Master of Public Health in a clinically relevant area. The RFA will use the NIH R21 award mechanism.

Inquiries: For NCI—Sanya Springfield, chief, CMBB, OCTR, ODDES, NCI, 6116 Executive Blvd., Suite 700, Bethesda, MD 20892-8347, phone 301-496-7344; fax 301402-4551; e-mail springfs@mail.nih.gov

RFA CA-01-015: Planning Grant for Collaboration on Nutritional Modulation of Genetic Pathways Leading to Cancer

Letter of Intent Receipt Date: Dec. 8, 2000

Application Receipt Date: Feb. 14, 2001

The RFA invites applications for P20 planning grants that will lead to collaborative interdisciplinary research teams to resolve complex gene-nutrient interrelationships that are related to cancer prevention. All approaches to planning are encouraged, as long as they address the following essential features: a cancer focus, institutional commitment, organizational capabilities, facilities, and interdisciplinary coordination and collaboration. Phase I will use the NIH P20 Planning Grant mechanism. NCI intends to commit approximately $600,000 in FY 2001 to fund up to six awards in response to this RFA. An applicant may request a project period of up to six months.

Inquiries: John Milner, Nutritional Science Research Group, Division of Cancer Prevention, NCI, 6130 Executive Blvd., Room 212, MSC-7328, Rockville, MD 20852, phone 301-496-8573; fax 301-402-0553; e-mail milnerj@mail.nih.gov

Program Announcements

PA PAR-00-137: Cancer Communication and Interactive Media Technology

Letter of Intent Receipt Date: Oct. 24, 2000

Application Receipt Date: Nov. 28, 2000

This NCI program announcement, which utilizes the R25 and Fast-Track (both the phase I SBIR and phase II SBIR are included in the Fast-Track applications) grant mechanisms in tandem, is designed to promote and support collaborations between non-profit organizations and for-profit small businesses on research projects that address 1) translation of cancer research into interactive applications designed for specific population groups; 2) development of organizational infrastructures within health care settings or training programs that promote the use of media technologies to enhance communication between primary care professionals, oncologists and their patients; 3) development of intervention strategies, tailoring models and tools to better inform the public

about cancer prevention and control; or 4) development of traditional or distance-learning core competencies, training modules, evaluation modules and tools needed to develop or expand a master's degree program in health communication and media technology.

Inquiries: Connie Dresser, Division of Cancer Control and Population Sciences, NCI, Executive Plaza North, Rm 232, Bethesda, MD 20892-7365, phone 301-435-2846; fax 301-480-2087; e-mail cd34b@nih.gov

PA PAR-00-139: Post-Baccalaureate Research Education Program

Application Receipt Date: Dec. 13, 2000

The Minority Access to Research Careers Program Branch of the Division of Minority Opportunities in Research of the National Institute of General Medical Sciences announces the establishment of the MARC Branch, a new institutional initiative. This Post-baccalaureate Research Education Program encourages underrepresented minorities who hold a recent baccalaureate degree in the biomedically-relevant sciences, to pursue a research doctorate. In this PA, the term science means the biological, chemical, computer, physical, and behavioral sciences, including mathematics, which have relevance to biomedical research.

Inquiries: Adolphus Toliver, Division of Minority Opportunities in Research, National Institute of General Medical Sciences, 45 Center Drive, Rm 2AS.37, MSC 6200, Bethesda, MD 20892-6200, phone 301-594-3900; fax 301-480-2753; e-mail tolivera@nigms.nih.gov

In Brief:

Oncology Nursing Society Names 15 To Advisory Panel

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malformation and prevention of hydrocephalus. . . . **ONCOLOGY NURSING SOCIETY** has established a Consumer Advisory Panel to advise the ONS board on consumer issues related to cancer nursing. Members of the panel are: Lois Anderson, York, PA; Kathleen Barry, Seattle; Pamela Brown, Morgantown, WV; Bobbi de Cordova-Hanks, Jacksonville, FL; Margorie Diggs Freeman, Durham, NC; M. Venus Gines, Snellville, GA; Peter Halbin, Cleveland; Barbara Lasser, Huntington Beach, CA; Claire Levenberg, Chicago; Cynthia Levinson, Austin, TX; Carolene Marks, San Francisco; Patricia McCollom, Ankeny, IA; Judy Niedzwiedz, Sacramento; Eric Rosenthal, Wynnewood, PA; and Margaret Souza, Brooklyn. . . . **CITY OF HOPE** Cancer Center was awarded a $960,000 grant from the California Department of Health Services for a proposal to develop a technology transfer program and provide medical education in cancer genetics. Principal investigator of the program is **Jeffrey Weitzel**, director of City of Hope's Department of Clinical Cancer Genetics. The grant will enable City of Hope's cancer genetics team in Duarte, CA, to share clinical information with physicians, genetic counselors, and patients at its network of cancer prevention and screening programs across the state. . . . **CONGRESSIONAL FAMILIES** Action for Cancer Awareness Program gave its Lifetime Award to Rep. John Porter (R-IL) and Sen. Connie Mack (R-FL) for their significant contributions to cancer legislation. The program also presented the Spouse Award to **Tamra Bentsen** and **Jill Biden**; the Advocate Award to **Ruth Ann LaMott** and **Barbara Raehl** for forming the Navigator Program at Traverse City, MI, Munson Medical Center that helps guide cancer patients after a diagnosis of breast cancer; and the Media Award to **Shirley Ruedy**, health columnist at the Cedar Rapids, IA, Gazette. . . . **NATIONAL COALITION FOR CANCER RESEARCH** also honored Porter and Mack earlier this month with its Legacy Award. The coalition also presented its Congressional Champion Award to **Rep. Ken Bentsen** (D-TX), **Sen. Edward Kennedy** (D-MA), **Rep. Deborah Pryce** (R-OH), **Sen. Arlen Specter** (R-PA), and **Rep. C.W. Bill Young** (R-FL). . . . **IAN SMITH**, a medical correspondent for NBC News, and a medical columnist for Time magazine and the New York Daily News, has joined the Cancer Research Foundation of America's Board of Directors. The foundation is based in Alexandria, VA. . . . **LINDA THRANE** was appointed executive director of the Council for Biotechnology Information, a Washington, DC, based coalition of eight life-science companies including Aventis CropScience, BASF, Bayer, Dow Chemical, DuPont, Monsanto, Novartis, Zeneca Ag Products, as well as the Biotechnology Industry Organization and the American Crop Protection Association. The mission of the council is to share information about the benefits of crops and foods derived through biotechnology. Thrane was vice president of public affairs at Cargill Inc. and previously was an editorial writer at the Minneapolis Star Tribune. . . . **CANCER MEETINGS**: **The Cancer Letter's** list of upcoming oncology-related meetings worldwide is located on the Web at http://www.cancerletter.com/events.html. Meeting notices, items for the "In Brief" section and Funding Opportunities may be sent via email to: news@cancerletter.com.

THE CANCER LETTER

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September 2000

Business & Regulatory Report

Formerly "Cancer Economics"

Product Approvals & Applications:

FDA Approval Of Two Generic Versions Of Taxol Likely To End BMS Exclusivity

In a move that may end the eight-year market exclusivity run for Taxol (paclitaxel), FDA has approved two generic versions of the drug that contributes an estimated $1.7 billion in revenues to **Bristol-Myers Squibb**.

IVAX Corp. (AMEX: IVX) of Miami, the first contender for Taxol market, said it has begun its selling program, and that the shipping will begin in early October. IVAX did not reveal the price of its version of the drug.

Under FDA rules, the IVAX first-to-file position for generic paclitaxel

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Oncology Mangement:

M.D. Anderson, SWOG To Use Web-Based Software To Expand Access To Trials

iKnowMed of Berkeley, CA, said it has has signed separate agreements with **M.D. Anderson Cancer Center** and **Southwest Oncology Group.**

Under the agreement with M.D. Anderson, iKnowChart, iKnowMed's Web-based knowledge tool physician software, will be utilized to enhance the quality of patient care, expand access to clinical trials and improve overall efficiency.

M. D. Anderson will work with iKnowMed technology on two key projects.

First, M. D. Anderson will use iKnowChart for its integrated, comprehensive electronic patient charting solution for the main facility in Houston. Via Internet technology, iKnowChart enables physicians to record and view all patient care information including care plans, treatments and protocols. It also allows caregivers to enter orders for treatments and tests, view laboratory results, update a patient's chart, analyze outcomes data, and correspond with referring physicians.

iKnowMed technology is currently used to send M. D. Anderson proprietary treatment guidelines to approved and credentialed M. D. Anderson affiliated community practices. Through iKnowChart, the credentialed community affiliates are able to access online the M. D. Anderson treatment guidelines, demonstrating their concordance with the M. D. Anderson standard of care.

"iKnowChart offers our physicians the best available tools to assist

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Clinical Trials:
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Deals & Collaborations:
Abbott To Supply Quest Diagnostics With Assay Tests
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PO Box 9905
Washington DC 20016
Telephone 202-362-1809

FDA Approves Generic Taxol By IVAX, Mylan Laboratories

(Continued from page 1)

injection 6 mg/mL (packaged in 30 mg/5 mL, 150 mg/25 mL, and 300 mg/50 mL multiple-dose vials) entitles the company to 180 days of marketing exclusivity.

Six months from now, other generics are expected to attempt to carve out a slice of the paclitaxel market. Earlier this month, **Mylan Laboratories Inc.** (NYSE: MYL) of Pittsburgh received tentative approval from FDA to manufacture and market paclitaxel, which will be available in 30 mg/5ml (6 mg/ml) vials.

Over nearly three years after expiration of the standard market exclusivity granted to innovator companies by FDA, Bristol pursued an aggressive strategy aimed at extending exclusivity. Legal maneuvers escalated in recent weeks. The most recent player in the dispute, **American BioScience Inc.** of Santa Monica, CA, recently sued BMS, IVAX and FDA to protect its paclitaxel patent rights.

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Applied Imaging Corp. (Nasdaq: AICX) of Santa Clara, CA, said it has received 510(k) clearance from FDA to market its MDS system for detecting micrometastatic cells. The MDS, a scanning microscopy platform, has been cleared for in vitro diagnostic use as an aid to pathologists in the detection and classification of specific rare cancer cells in bone marrow specimens.

"This rapid FDA clearance of the first clinical application for the MDS represents the achievement of a significant milestone for the company," said Jack Goldstein, chairman and CEO of Applied Imaging. "Our clinical data showed that pathologists using the MDS detected 46% more patients with metastatic cells than they detected by unaided microscopic examination. This substantial improvement will allow us to market the MDS system to thousands of cancer centers worldwide, presenting us with a dramatically expanded opportunity for the company's products."

The company said it plans to pursue additional applications of the technology to genetically characterize cancer cells by conducting simultaneous fluorescent and brightfield studies, techniques for the automated analysis of DNA and RNA probes.

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Cell Pathways Inc. (Nasdaq:CLPA) of Horsham, PA, said it received last evening the expected FDA "non-approvable letter" for its NDA seeking approval of Aptosyn (exisulind) for the treatment and prevention of adenomatous polyps in Familial Polyposis (FAP) patients.

The letter states the deficiencies the FDA has identified regarding the safety and efficacy data submitted with respect to FAP. The company will advise the FDA that it intends to amend the NDA and will request a meeting to address the deficiencies and the possible requirement for additional clinical data.

Aptosyn is Cell Pathways' lead drug from a novel class of compounds under development by the company, called Selective Apoptotic Anti-Neoplastic Drugs. SAANDS inhibit a novel form of cyclic GMP phosphodiesterase and selectively induce apoptosis (programmed cell death) in abnormally growing precancerous and cancerous cells.

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Cell Therapeutics Inc. (Nasdaq: CTIC) of Seattle said Trisenox (arsenic trioxide) injection was approved by FDA for acute promyelocytic leukemia, a malignant disorder of the white blood cells which can affect patients of any age. In the US, APL represents 10-15% of the more than 10,000 patients diagnosed with acute myeloid leukemia each year.

"For patients with APL whose disease has recurred following initial treatment, the use of salvage therapy is highly toxic and rarely curative," said Carolyn Paradise, vice president, clinical development at cti. "Results of the clinical trials using Trisenox demonstrated that a significant number of those

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patients who suffered multiple relapses were able to achieve a complete remission, or a disappearance of all visible leukemia cells. The majority of patients who achieved complete remission were still alive and disease-free with a median follow-up time of 16 months. This new treatment represents a significant advance for patients with this disease."

A trial involving 40 patients with relapsed/ refractory APL unresponsive to standard therapies was conducted at nine institutions, including Memorial Sloan-Kettering Cancer Center and other leading cancer centers across the U.S.. Seventy percent of these patients achieved a complete remission, with the majority achieving molecular eradication of the genetic abnormality associated with APL. Complete remission was achieved on average within two months after initiation of Trisenox.

"We are impressed at both the high rate of complete remission and the relapse-free survival in this high risk population of APL patients whose previous treatment failed to eradicate their disease," said Steven Soignet, investigator of Developmental Chemotherapy Service at Memorial Sloan- Kettering.

Most patients experienced some drug-related toxicity. Acute toxicities associated with arsenic trioxide therapy are well defined and when monitored and treated appropriately are manageable. Serious adverse events reported include APL-differentiation syndrome symptoms (fever, weight gain, shortness of breath, and musculoskeletal pain) in 23% of the patients, and hyperleukocytosis (increased levels of white blood cells) in 50% of the patients.

Common toxicities include gastrointestinal (nausea, vomiting, diarrhea, and abdominal pain), fatigue, edema, hyperglycemia, dyspnea, cough, rash or itching, headaches, and dizziness. These adverse effects have not been observed to be permanent or irreversible nor do they usually require interruption of therapy. Another important adverse event was QT prolongation - a change in the time it takes for the heart to relax after each beat.

One serious case of QT prolongation evolved into an abnormally rapid heartbeat. This episode resolved spontaneously, and the patient was retreated with TRISENOX without recurrence of the event. In contrast to the side effects prevalent with use of standard chemotherapy, hair loss, mucositis (mouth sores and ulcers) were uncommon.

Trisenox is administered intravenously in two phases: induction therapy consisting of daily injections of 0.15 mg/kg until the bone marrow is cleared of leukemic cells, for up to a maximum of 60 days, and consolidation therapy using the same dose for 25 days beginning three weeks after bone marrow remission is evident.

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Coulter Pharmaceutical Inc. (Nasdaq: CLTR) of South San Francisco and **SmithKline Beecham** (NYSE: SBH) of Philadelphia announced the re-submission of a Biologics License Application FDA for Bexxar (tositumomab, iodine I 131 tositumomab).

The companies are seeking marketing approval of Bexxar for the treatment of patients with relapsed or refractory, low-grade or transformed low-grade B-cell non-Hodgkin's lymphoma. Bexxar has been designated a Fast Track Product by the FDA because one of the targeted indications for the therapy is transformed, low-grade non-Hodgkin's lymphoma, a life-threatening disease representing an unmet medical need. Because Bexxar is designated as a fast track product, the companies said they will request a Priority Review.

Bexxar is a radioimmunotherapy involving an antibody conjugated to iodine 131 (I-131) that attaches to a protein found only on the surface of B-cells, including non-Hodgkin's lymphoma B-cells. The properties of the I-131 radioisotope allow an appropriate patient-specific dose to be easily determined and administered, the companies said. Bexxar is believed to work through multiple mechanisms of action resulting from immune system activity of the monoclonal antibody and the therapeutic effects of the I-131 radioisotope.

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InKine Pharmaceutical Co. Inc., (Nasdaq: INKP) of Blue Bell, PA, said FDA has approved Visicol tablets (brand of sodium phosphate) for cleansing of the bowel as a preparation for colonoscopy.

The approval occurred in ten months from NDA submission and includes full labeling of the product as agreed to by FDA and InKine. The drug will be available next January, the company said

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Novartis Pharmaceuticals Corp. of East Hanover, NJ, said that the supplemental new drug application for Femara (letrozole tablets) as first-line therapy in postmenopausal women with advanced breast cancer has been designated for priority review by FDA.

Femara, an aromatase inhibitor, is indicated for second-line therapy of advanced breast cancer in

postmenopausal women with disease progression following antiestrogen therapy. Priority review status is granted by the FDA to products that are considered to be a potential therapeutic advance over existing therapies.

Actions taken on drugs given a priority review generally are made within six months. Novartis submitted the supplemental new drug application for Femara to the FDA on July 11. Regulatory submissions for this indication have also been filed globally in Europe, Canada, Switzerland and Japan, the company said.

According to the company, the filing is based on results of a study of more than 900 women evaluating Femara and tamoxifen in patients with metastatic breast cancer.

FDA approved Femara in 1997 for advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy.

Clinical Trials:

Polymer Platinate Begins Testing In Phase I Trial

Access Pharmaceuticals Inc. (Amex: AKC) of Dallas said it is commencing a phase I trial of polymer platinate AP 5280. This study will be conducted at two European sites, the company said.

The initial pase I study protocol is designed to determine the maximum tolerated dose, where the dose-limiting toxicity is identified using the standard once every 3 weeks platinum dosing regimen.

Polymer platinate AP 5280, a compound consisting of platinum bound to a polymer, is designed to improve the effectiveness of platinum-based therapy while at the same time reducing side-effects, the company said. By attaching the platinum to a polymer, AP 5280 is designed to deliver more platinum to the tumor while reducing systemic toxicity.

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Berlex Laboratories Inc. of Mountville, NJ, and **Techniclone Corp.** (Nasdaq: TCLN) of Tustin, CA, announced the initiation of a phase I study of Oncolym (I-131 labeled Lym-1 antibody) in relapsed and refractory diffuse large B-cell lymphoma.

The study is a dose escalation and dosimetry study to determine the maximum tolerated single dose of Oncolym. Berlex Laboratories, and its affiliates, obtained worldwide rights for Oncolym from Techniclone Corporation. Berlex is responsible for all clinical development and for marketing and commercialization, while Techniclone retains the manufacturing rights.

Berlex is awaiting FDA approval to launch Campath (Alemtuzumab), a human monoclonal antibody under investigation for the treatment of B-cell chronic lymphocytic leukemia.

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EntreMed Inc. (Nasdaq: ENMD) of Rockville, MD, announced commencement of the first phase I trial of 2- Methoxyestradiol (2ME2) combined with cytotoxic chemotherapy. 2ME2, an orally active compound, is a naturally occurring antiproliferative and antiangiogenic agent.

The objective of the study is to determine the safety profile of the simultaneous administration of 2ME2 and the potent cytotoxic docetaxel (Taxotere) in patients with advanced breast cancer. The Company recently received authorization from the Institutional Review Board at Indiana University in Indiana to begin the combination study, and the first patient with breast cancer is now receiving treatment.

Another phase I safety evaluation of 2ME2 as a single agent commenced last March, also at Indiana University. That trial is conducted by Kathy Miller and George Sledge. Miller is the principal investigator of the combination trial of 2ME2 and Taxotere. In this study, the safety profile of five dose levels of 2ME2 and Taxotere will be assessed, the company said.

Additional information on the 2ME2 single agent study or the combination study of 2ME2 with Taxotere is available at (317) 278-3730.

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ImmunoGen Inc. (Nasdaq: IMGN) of Cambridge, MA, said that huC242-DM1/SB-408075, its lead Tumor-Activated Prodrug for the treatment of colorectal and pancreatic cancers, has entered a second Phase I/II clinical trial. The Company's partner, **SmithKline Beecham**, is conducting the study. As a result of treating the first patient in the study, ImmunoGen has received a $2 million cash payment.

This dose-escalating, multi-dose study is designed to establish the safety of huC242-DM1/SB-408075 when administered weekly and is being conducted at the University of Chicago Cancer Research Center under the direction of Richard Schilsky.

The study will enroll refractory colorectal and pancreatic cancer, and possibly non-small-cell lung cancer patients. Another phase I/II clinical trial is

ongoing at the Institute for Drug Development of the Cancer Therapy and Research Center, San Antonio, Texas.

Thus far in its agreement with SB, ImmunoGen has achieved five milestones and received payments totaling $14 million, the company said.

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Pharmacyclics Inc. (Nasdaq: PCYC) of Sunnyvale, CA, announced the initiation of two phase I trials with the company's Xcytrin (motexafin gadolinium) Injection. The studies, sponsored under an IND held by NCI, are being conducted at the Ohio State University Comprehensive Cancer Center/James Cancer Hospital and Solove Research Institute under a Cooperative Research and Development Agreement between Pharmacyclics and the NCI.

The first phase I study is designed to determine the safety of two different dosing regimens of Xcytrin during preoperative radiotherapy after induction chemotherapy in patients with stage IIIA (N2) non-small cell lung cancer.

Patients enrolled in one of the phase I studies will be given three cycles of Taxol (paclitaxel) and carboplatin followed by Xcytrin plus radiation therapy and, ultimately, surgery to resect any residual tumor, the company said. Xcytrin will also be given three hours before surgery so researchers can measure the drug level in the tumor after it has been removed. The trial is designed to test the strategy of treating the potential distant metastases with chemotherapy while Xcytrin plus radiation shrinks the tumor so that it can be surgically removed, the company said.

The second phase I study is designed to examine the use of Xcytrin in combination with stereotactic Gamma Knife radiosurgery in patients with primary brain tumors known as glioblastoma multiforme. Stereotactic Gamma Knife radiosurgery is a technique that delivers a single, high-dose of radiation precisely to the tumor. Patients enrolled in this study will receive standard external beam radiotherapy for five weeks, after which they will get Xcytrin plus stereotactic Gamma Knife radiosurgery directed to the tumor. Two dose levels of Xcytrin will be studied.

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StressGen Biotechnologies Corp. (TSE: SSB) of Victoria, BC, said it has initiated a phase II trial of HspE7, an immunotherapeutic, as a treatment for advanced cancer of the uterine cervix caused by the human papillomavirus.

In the trial, StressGen will employ proprietary heat shock fusion protein immunotherapy, HspE7, which the company developed to treat HPV-related diseases such as cervical cancer and anal dysplasias. The study requires each patient to receive multiple injections of HspE7.

HspE7, a recombinant fusion product, is composed of heat shock protein 65 (Hsp65) from Mycobacterium-bovis BCG and the protein E7. The E7 protein is derived from HPV and is involved in the malignant transformation of anal and cervical epithelial cells, the company said.

E7 is a tumor-specific antigen and thus represents a precise target for the immune system attack on abnormal cells. HspE7 is based on Stressgen's proprietary fusion protein platform technology. StressGen also has an active phase II HspE7 study in women with HPV-related cervical dysplasia (CIN), and plans to initiate a phase III trial in HPV-related anal dysplasia (AIN).

Deals & Collaborations:

Abbott To Supply Quest With Immunoassay Tests

Abbott Laboratories (NYSE: ABT) announced the signing of a two-year, $60 million supply agreement with **Quest Diagnostics Inc.** (NYSE: DGX).

Under the agreement, Abbott will provide Quest Diagnostics with immunoassay tests and systems for hepatitis, cancer, cardiac conditions and therapeutic drug monitoring. In addition, Quest will use Abbott's PSA test. Abbott's homocysteine test, introduced in 1998, is the first automated test to measure levels of homocysteine, an amino acid, identified as a risk factor for cardiovascular disease.

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Advanced Magnetics Inc. (Amex: AVM) of Cambridge, MA, said that by mutual agreement with Cytogen, the companies have terminated their agreement under which **Cytogen Corp.** (Nasdaq: CYTO) was to acquire Advanced Magnetics in a stock transaction.

The two companies have entered into product marketing and supply agreements that cover products in Advanced Magnetics' pipeline. Cytogen will receive exclusive U.S. marketing rights to Combidex Magnetic Resonance Imaging contrast agent for the detection of lymph node metastases and U.S. marketing rights to Code 7228, Advanced Magnetics' next-generation imaging agent, for oncology indications. FDA recently issued an approvable letter with respect to Combidex, subject to certain conditions.

Under the agreements, Advanced Magnetics has received 1.5 million registered shares of Cytogen's stock and will receive an additional 0.5 million registered shares upon achieving future milestones, the companies said. In addition, Advanced Magnetics will receive payments for product manufacturing as well as royalties on sales. Advanced Magnetics will continue to be responsible for all clinical development and regulatory matters relating to the products.

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Coulter Pharmaceutical Inc. (Nasdaq: CLTR) of South San Francisco, said it has acquired rights to a class of ultra-potent anti-cancer compounds from Kyowa Hakko Kogyo Co., Ltd. of Japan. Coulter intends to enhance the potency of these agents by incorporating them into Coulter's proprietary tumor activated prodrug (TAP) and tumor specific targeting (TST) technologies. The resulting drug candidates will be designed to target the potent anti-cancer power of these agents directly to tumor cells to maximize efficacy while minimizing side-effects to normal tissues.

The compounds, Duocarmycin B2 and KW-2189 directly attack the DNA of cancer cells, causing cell death, the company said. Drug candidates using these compounds have already been created by Coulter and have shown activity against multi-drug resistant human tumor cell lines, the company said.

Under the agreement, Coulter acquired exclusive worldwide rights to all uses of the agents. Coulter is developing its TAP technology to enhance the specificity of chemotherapeutic agents for tumor cells. TAP prodrugs are designed to remain stable in circulation until being activated preferentially at the tumor site. As a result, relatively larger quantities of cytotoxic agents are expected to reach and enter malignant cells compared to normal cells. This approach is designed to permit an increase in maximum tolerated dosages, potentially overcoming drug resistance in some cancer cells.

In addition to TAP, the company is developing tumor specific targeting (TST) technologies including peptides, non-peptides and internalizing antibodies. These targeting approaches are designed to bind the TST compound selectively to tumor target cells. Upon binding, the TST compound is internalized into the cell and the ultra potent payload is released from the targeting entity. Once released, the ultra potent drug acts on its intracellular target and kills the tumor cell.

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Cytoclonal Pharmaceutics Inc. (NASDAQ: CYPH) of Dallas announced the issuance of a patent for a new gene coding for Taxus geranylgeranyl diphosphate synthase, a pivotal enzyme in paclitaxel synthesis.

The technology is covered in U.S. Patent No. 6,043,072. The isolation of the new gene, coupled with the discovery of previous Taxol genes proprietary to Cytoclonal, are part of the company's program with Bristol-Myers Squibb to generate a cost-effective production system for paclitaxel using fermentation and genetic engineering.

Cytoclonal has been developing a method for making paclitaxel through fermentation and genetic engineering. Microbial fermentation and genetic engineering are a part of the company's program with **Bristol-Myers Squibb** to generate an optimized production system for paclitaxel. These methods have been the basis for cost-effective production of a variety of drugs, including antibiotics.

The Taxus geranylgeranyl diphosphate synthase gene and other paclitaxel-related genes were isolated by Rodney Croteau of Washington State University, under contract with Cytoclonal.

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Cytogen Corp. (Nasdaq: CYTO) of Princeton, NJ, has signed a binding letter of intent with **Draxis Health Inc.** (Nasdaq: DRAX) (TSE: DAX) of Mississauga, Ontario, to market and distribute BrachySeed implants for prostate cancer therapy in the U.S.

Under the 10-year agreement, Draxis' wholly owned sub-sidiary, Draximage, will supply radioactive iodine and palladium seeds to Cytogen in exchange for royalties on sales and certain milestone payments. Cytogen said radioactive iodine BrachySeed to be available in the U.S. late this year.

In August, FDA granted marketing approval for BrachySeed, a second-generation implant therapy. The Companies believe that the patented BrachySeed product demonstrates a number of important innovations over currently available technology, including double encapsulation for additional patient safety and near perfect dosimetry to reduce "cold spots," areas within the target organ not reached by the radiation, that may occur when seeds do not provide symmetrical and spherical fields of radiation.

While brachytherapy has been available since the 1970s, it has only started to gain prominence and greater acceptance within recent years, coinciding with the development of advanced technologies to aid seed placement. Brachytherapy is the fastest growing

treatment for early stage prostate cancer and offers a number of potential benefits compared to alternative treatments such as prostatectomy, including: rapid patient recovery, lower costs and reduced incidence of complications such as impotency and incontinence.

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ILEX Oncology Inc. (Nasdaq: ILXO) of San Antonio said it has entered into an agreement with BASF Pharma of Ludwigshafen, Germany, for an exclusive, worldwide license to BSF 23651, an orally active anti-cancer compound.

A synthetic pentapeptide analog of dolastatin, BSF 223651 has a mechanism of action similar to taxanes, yet appears to be active against taxane-resistant tumor models, the company said. The compound is ready for an Investigational New Drug filing and is expected to begin human clinical trials shortly.

In another development, ILEX and BASF Pharma are finalizing an agreement giving ILEX an option for an exclusive worldwide license to Elinafide, an anti-cancer compound, which is in clinical development, the companies said.

BSF 223651, a tubulin interactive, anti-mitotic compound, has shown significant activity in a variety of solid tumor models in early preclinical testing. BASF Pharma has tested another dolastatin analog, cemadotin, which demonstrated clinical activity in wide-ranging phase II studies, the companies said. As a second generation dolastatin, BSF 223651 is chemically modified to provide improved pharmacologic properties, including a potentially enhanced therapeutic window over cemadotin and other first generation dolastatins, the company said.

Elinafide has demonstrated anti-neoplastic activity in ovarian cancer, breast cancer and mesothelioma in phase I trials conducted by BASF Pharma, the companies said. ILEX said it plans to conduct additional phase I studies to further expand the compound's therapeutic window.

BASF Pharma represents the global pharmaceutical operations of BASF Aktiengesellschaft, Germany. Within BASF Pharma, Knoll AG is its largest organization.

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Roche Holdings AG and **Bristol-Myers Squibb Co.** announced a European clinical research partnership to facilitate the development of clinical trials of Herceptin (trastuzumab), marketed outside the U.S. by Roche and the BMS drug Taxol (paclitaxel).

The collaboration will include studies in breast cancer as well as other solid tumors where scientific evidence suggests that this drug combination has potential for clinical activity.

Under the agreement, the companies will establish a central review committee for clinical trial proposals involving the two products. The committee will review study proposals submitted by European investigators.

In a related development, Roche has signed an agreement with **SmithKline Beecham** to acquire global rights to Kytril (granisetron hydrochloride), an antiemetic used in chemotherapy.

The deal requires the approval of regulatory agencies reviewing SB's merger with Glaxo Wellcome including the Federal Trade Commission. Under the agreement, SB will acquire from Roche exclusive rights in the U.S. and Canada for Coreg (carvedilol), a drug for congestive heart failure and hypertension.

Coreg is co-promoted in the US by Roche and SB. Roche will remain the sole supplier of carvedilol in all markets outside North America. The Kytril deal is valued at $1.23 billion, the company said. The Coreg deal is valued at about $400 million, Roche said.

Roche's oncology portfolio now includes the breast cancer therapy Herceptin, MabThera (Non-Hodgkin's lymphoma), NeoRecormon (anemia in cancer patients), Roferon-A (leukemia, Kaposi's sarcoma, malignant melanoma), Bondronat (tumour-induced hypercalcemia), and Xeloda (breast cancer).

Oncology Management:

Internet-Based Software To Be Tested By SWOG

(Continued from page 1)

them in making medical decisions, capturing outcomes and benchmarking care at a number of sites," said Mitch Morris, senior vice president and chief information officer of M. D. Anderson.

The deal with SWOG involves a $1.3 million grant from NCI. The purpose of the project is to enhance cancer treatment by streamlining the clinical trial process, the company said.

Under the grant, physicians from SWOG-affiliated oncology centers will utilize iKnowChart, iKnowMed's Internet-based patient charting technology, to recruit patients for oncology clinical trials and more effectively manage compliance with research protocols by capturing information at the point of care.

SWOG physicians will use iKnowChart to screen patients for more than 40 clinical trials representing a variety of different cancers, and use iKnowChart technology to facilitate the management of 20 clinical trials. iKnowMed and SWOG agree that results from the project will provide a platform for enhancing patient recruitment in clinical trials and improving operational efficiency of the clinical trial process throughout the country.

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InfoCure Corp. (Nasdaq: INCX) of Atlanta said **US Oncology Inc.** (Nasdaq: USON) has begun the installation of VitalWorks' electronic medical records system at its affiliated practices.

The VitalWorks system, based on the VitalWorks CHARTStation product, was recently installed at the Rocky Mountain Cancer Center in Thornton, CO. "VitalWorks' EMR technology coupled with the focused efforts of management and staff from both our organizations is what is making this endeavor so successful," said Lloyd Everson, president of US Oncology. "The project has the potential to change the way we deliver care resulting in further improvements in the quality, efficiency and overall effectiveness of cancer care delivery in the U.S. US Oncology is committed to helping lead the way."

US Oncology has over 850 affiliated physicians in 26 states. The rollout of VitalWorks' EMR system is planned to continue throughout the US Oncology network.

InfoCure provides of healthcare practice management and clinical software products and services to targeted healthcare practice specialties, including oncology, anesthesiology, dermatology, emergency medicine, pathology, podiatry, radiology, and enterprise-wide medical entities.

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Hartford Life of Simsbury, CN, has become the first major stop-loss insurer to offer the services of the Strategic Health Cancer Network.

Through the Network, negotiated provider rates as well as greater access to some of the premier cancer care facilities in the U.S. will be available to more than one million plan participants and their dependents whose employers carry stop-loss coverage from Hartford Life.

The Network is an alliance of **Strategic Health Development Corp.** and the **National Comprehensive Cancer Network.**

"Cancer is one of this nation's most prevalent diseases," said Ray Marra, vice president and director of Hartford Life's Integrated Medical Solutions group. "Its treatment can be among the most costly, with the outcomes being far from guaranteed. The Network provides all parties the information needed to make critical decisions in a well-informed and timely manner."

Use of the Network is a value-added feature available with all Hartford Life stop-loss plans. It is entirely voluntary and there are no additional costs to access the network. More information may be obtained at http://www.stoploss.thehartford.com.

"Participating providers have an unparalleled dedication and commitment to fighting cancer," said Lizabeth Zlatkus, executive vice president and director of Hartford Life's Group Benefits Division. "We're delighted to be able to make this feature available and hope it will make a positive difference to those battling the disease."

Strategic Health Development Corp. provides 24-hour care management services.

* * *

Nelson Braslow was named chief medical officer and executive vice president of **Response Oncology Inc.** (Nasdaq: ROIX), of Memphis, TN.

The position was being attended on an interim basis by William West, chairman and former CEO. Braslow is the former senior medical director, medical management at Blue Cross of Northeastern Pennsylvania.

In another appointment, **Larry Box** was named vice president, operations. Box is the former vice president, infusion services, at Medshares Health Care Services Inc.

* * *

Myriad Genetics Inc. (Nasdaq: MYGN) of Salt Lake City said that it plans to launch a predictive medicine test for hereditary colon cancer and uterine cancer.

The test, named Colaris, is used to assess an individual's risk of colon cancer based on the presence of a mutation in either of two genes. The same mutations also substantially increase a woman's risk of endometrial cancer.

Individuals who receive a positive Colaris test result have an 80% lifetime risk of colon cancer, and women who test positive have a 40 to 60% risk of uterine cancer, the company said.

The test will be sold in the US by Myriad's 40-person oncology product sales force, the company said. Worldwide rollout will follow introduction in the US.

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