THE CANCER LETTER INTERACTIVE

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

Vol. 28 No. 12
March 22, 2002

Senators Tie Medicare Oral Drug Payment To Ending Markup On Infused Drugs

No allies were in sight when oncologists and patient groups went to Capitol Hill to discuss reimbursement for office-based services last week.

In a surprising twist, Senate members linked the issue cancer groups like—obtaining Medicare reimbursement for orally administered cancer drugs—to the issue that has haunted these groups for over a decade—eliminating oncologists' markup on drugs infused in oncologists' offices.

"We need to correct Medicare's payment for these drugs and ensure that providers are paid the right amount to administer these drugs," said Sen. John Rockefeller (D-WA), chairman of the Senate Finance

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In Brief:

Bass & Howes Bought By DDB Seattle; Surgical Oncologists Honor Thompson

BASS & HOWES INC., a public policy firm with offices in Washington, DC and New York City, has been acquired by DDB Seattle, a division of DDB Worldwide Communications Group. DDB's Issues & Advocacy group is merging with Bass & Howes to create DDB Bass & Howes. Clients include The NARAL Foundation, The David and Lucile Packard Foundation, Genentech, The Alliance to Save Energy, The National Breast Cancer Coalition, Pfizer Inc., and New York State Energy Research and Development Authority. **Candy Cox** will serve as the managing partner of DDB Bass & Howes, while the former Bass & Howes principals will assume partner roles under the following titles: **Joanne Howes**, director of client services government affairs; **Nanette Falkenberg**, director of client services policy and programs; and **Marie Bass**, director of business development and special projects. **Arlene Fairfield** of DDB will serve as the director of advertising and public relations. Last year, DDB Seattle's Issues & Advocacy group was responsible for $33 million of the firm's billings. Bass & Howes Inc. posted capitalized billings of more than $13 million. . . . **HHS SECRETARY Tommy Thompson** was given the James Ewing Layman's Award by the Society of Surgical Oncology, at the society's annual meeting March 16 in Denver. The award was bestowed for Thompson's career record of supporting efforts to improve the lives and treatment of cancer patients, including building and expanding the University of Wisconsin Comprehensive Cancer Center, securing funding for the expansion of biological sciences at the university, coordinating the State of Wisconsin's cancer efforts with the Wisconsin Cancer Care Networks,

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In Surprising Twist, Senate May Link AWP, Oral Drugs

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Committee's Subcommittee on Health, at a hearing March 14.

"This will assure access to services that we need, such as chemotherapy treatments, and to make sure that they are not compromised. Another way to ensure that our correction of Medicare's payments for drugs does not adversely affect access to cancer therapies, is to use part of the savings that we achieve to cover all oral cancer drugs."

Rockefeller and Sen. Olympia Snowe (R-ME) are authors of a bill, S. 913, introduced last May, to provide Medicare reimbursement for oral chemotherapy. Based on Rockefeller's remarks last week, the Senate bill may now be amended to link oral chemotherapy and AWP. The corresponding House bill, H.R. 1624, sponsored by Rep. Deborah Pryce (R-OH), contains no linkage with AWP.

Rockefeller said the bill could avoid the logjam expected to stymie the Prescription Drug Bill. "We're here today to highlight possible solutions so that Congress can take action on this problem this year," Rockefeller said. "It's an easy thing to do and we can do it without passing the entire Prescription Drug Bill, which is something we also want to pass but we can't say we do one or do other—we do both and then we pass the whole Prescription Drug Bill."

THE CANCER LETTER

Member, Newsletter and Electronic Publishers Association

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Subscription $305 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Founded Dec. 21, 1973, by Jerry D. Boyd

The AWP controversy has been resurfacing regularly since 1991. However, in recent years, opposition to the reimbursement system has been building momentum, and now the AWP controversy may well overshadow the issue of securing Medicare reimbursement for Gleevec, a targeted drug for chronic myeloid leukemia and gastrointestinal stromal tumors, as well as for other oral drugs.

This linkage caused an odd political problem for the American Society of Clinical Oncology. In testimony last week, society President Larry Norton had to spend more time deflecting attacks on AWP than advocating for Medicare reimbursement of oral drugs.

Using what has become a standard estimate, Rockefeller said oncologists are overpaid between $800 million and $1 billion a year because Medicare uses a reimbursement schema based on Average Wholesale Prices of oncology drugs, a method that is widely acknowledged as unrealistic.

AWP is analogous to the manufacturer's suggested retail price, an inflated price that hardly anyone pays. Under current regulations, oncologists are reimbursed at AWP minus 5 percent. Excessive payments based on AWP allow oncologists to earn profits on many of the drugs they infuse, and cover under-reimbursed expenses associated with running an oncology practice.

Oncologists say that they need to make the profit on drugs, because Medicare reimbursement for cancer care is grossly inadequate. While everyone agrees that oncologists are underpaid for treating Medicare patients, there are differences of opinion about the magnitude of this shortfall.

Government agencies say that an overall increase of about $50 million would fix the problem. The American Society of Clinical Oncology offers no firm estimate of the shortfall, arguing that the federal agencies have failed to conduct a detailed study of what the costs are.

At last week's hearing, Rockefeller was not alone in claiming that oncologists are overpaid. "There is nothing desirable about the Medicare reimbursement system that's stuck in the past," Snowe said at the hearing. "This is a system in dire need of modernization, both in terms of the amount the program spends to purchase prescription drugs, and also the drugs that are considered acceptable for reimbursement."

Sen. Bob Graham (D-FL) echoed Rockefeller's and Snowe's remarks. "I urge all involved parties to

commit to finding a resolution and to do so this year," Graham said at the hearing. "We have a short Congressional year in 2002, but we simply cannot continue to knowingly overpay for prescription drugs and underpay practice expenses.

"Those resources can and should be used instead to finance expanded coverage of oral cancer drugs, such as the legislation that Committee and Sen. Snowe have introduced, also to expand to self-injectable drugs and to appropriately compensate providers for their expenses," Graham said.

The mood in the House similarly favors action in cutting reimbursement. Last fall, some of the same issues were raised at a hearing of the House Committee on Energy and Commerce (**The Cancer Letter**, Oct. 5, 2001). At the House committee hearing, the issue of oral drugs was not raised.

It appears that the Bush Administration matches the Clinton Administration in eagerness to act on the AWP issue. The President's budget proposal for next fiscal year assumes a decrease in payments to oncologists as part of savings in Medicare, said Tom Scully, administrator of the Centers for Medicare and Medicaid Services.

If Congress fails to act, the Administration would, Scully said.

"We really want to get this fixed," he said. "We have a proposal that's a plug in our budget for what we have assumed we'll do this summer if Congress doesn't act. But we would greatly prefer to work with Congress to do it legislatively. We think it's a much neater and cleaner."

Scully said the Administration hasn't decided on a reimbursement schema. However, in calculating the budget, the Administration is relying on Average Manufacturer's Price, a price used by Medicaid. "It's a much lower price, so it generates substantial savings, but potentially you could have problems with physician access to the drugs," Scully said.

Elaborating on this statement, Scully acknowledged that manufacturers may not be eager to sell drugs at such prices. "It's clearly a number we use in Medicaid," Scully said. "It's audited. The manufacturers under Medicaid law give them to us, and we could use it. The manufacturers aren't going to like it very much, but that's not our number one concern, to be honest."

Scully said the Administration has the authority to cut the payments to oncologists, making up for the profits built into AWP. However, Congress would have to get involved in increasing the physicians' fees, to make them more realistic.

"I believe that the assumption of the budget did not include add-backs for practice expenses," Scully said. "But we've publicly said in a number of forums that we would support doing that in the context of an AWP reduction."

While Scully estimated the required adjustment as $50 million, ASCO President Norton said the problem is complicated, and drastic solutions could be disastrous.

"Oncology is not like any other practice in internal medicine," said Norton, an oncologist at Memorial Sloan-Kettering Cancer Center. "The doctors have to buy the drugs, they have to buy the IV tubing, they have to buy the needles, they have to pay for the nurses, they have to pay for the social workers. They have to do all this before the first patient walks in the door. These are all out-of-pocket expenses.

"The government's own estimate has been that doctors are now being reimbursed at 25 percent or less of the actual cost of the administration of the medications. That additional—the money that's coming out of pocket is coming back and to some extent—and we don't know to what extent—from the AWP issue and we support what everybody said here before, that AWP has to change," Norton said.

"But it has to change commensurate with a change in the reimbursement for the actual cost of administering the chemotherapy or else we can be in real trouble here. And I think—I really want to emphasize that this is a very, very serious issue, that all the cost we're talking about—the nursing cost, the monitoring for toxicities, that the phone calls involved, nutritional counseling, social work counseling, family counseling—all these critical issues right now are working to some extent."

The absence of numbers left Rockefeller unimpressed.

"I'm going to say to Dr. Norton, I'm sort of running out of patience of, you know, we've got to be paid more, but we don't know what the data is," Rockefeller said. "And so I'd just like to say to you that I'd like to have you present to the Finance Committee in about a month, how much more you have to be paid in order not to have a catastrophe.

"You ought to be able to come up with some data that tells us how much we can—how much more we have to pay you in your judgment so that you will not, you know, present to us a catastrophe. And I don't think that's a particularly unfair request and it's

a request that I'm making and I hope that you will have it to this committee within a month."

The question of proper reimbursement for oncologists is vital to patients, said Ellen Stovall, executive director of the National Coalition for Cancer Survivorship.

"I'm worried that Mr. Scully and CMS are using a calculus that is really off based," Stovall said at the hearing. "If there is no methodology that starts at the bottom and works its way back, we really have no idea what we're paying for out there."

In 1999, Congress directed the General Accounting Office to conduct such a study, but the agency's report did not examine the expenses of oncology practices (**The Cancer Letter**, Oct. 5, 2001).

Since GAO failed to address the question, Stovall went to the Institute of Medicine and suggested a study. "They said they would," said Stovall, co-chairman of the IOM National Cancer Policy Board.

"They are very interested in helping us get a picture of what's going on out there in the community," Stovall said. "We really don't know what we're paying for and I think as citizens all of us deserve to know where our money's going from CMS, and I don't think we have a clue."

Books:

Surgeons, Women, Cancer And The Battles Of The Breast

Advances in medicine are not driven entirely by science, physician and historian Barron Lerner, author of The Breast Cancer Wars, said March 13 in a seminar in Washington for health journalists, held by the National Press Foundation.

"Scientific knowledge has been constructed as an objective entity for so long, but scientific data is filtered through a social context," Lerner said.

It is no coincidence that William Halstead's disfiguring mastectomy operation—the standard breast cancer treatment for 60 years—began to be challenged at the beginning of women's liberation in the 1960s and 1970s, Lerner said.

Some of the foremost challengers were women journalists-turned-activists, including Rose Kushner, a Kensington, MD, writer. After finding a lump in her breast, Kushner didn't go to a doctor's office. She went to the National Library of Medicine and read articles on breast cancer biology and treatment. She refused to have the anguishing "one-step" procedure, in which a patient went under anesthesia for a biopsy and did not know until she awoke whether her breast would still be there.

Kushner was turned down by nine surgeons until she found one at Roswell Park Cancer Institute who agreed to perform only a biopsy. Kushner later served on an NIH Consensus Conference panel that, among other things, recommended that physicians end the "one-step" procedure.

Lerner, an associate professor of medicine and public health at the Columbia Presbyterian Medical Cancer, said his goal in writing a book chronicling the treatment, early detection, and prevention of breast cancer in the 20th Century was "to place the science and medicine in a social and historical context."

The book was published last summer by Oxford University Press.

The book also helped Lerner understand his family history. His mother was diagnosed with breast cancer in 1977, when Lerner was 16. His memories of her treatment and recovery were "fragmented," in part because of her reticence to talk about the experience.

"I came to believe that my mother had lived because she dutifully discovered her cancer at an early stage and because of the aggressive treatment she had received," Lerner wrote. "I also assumed that the happiness of surviving cancer was necessarily tempered by the negative consequences of having had the disease. After all, my mother had never resumed several of the activities and friendships that she had enjoyed before becoming ill.

"As a medical student in the 1980s, I learned how my family's collective memories about my mother's illness drew on both reality and myth," Lerner wrote. "My research for this book further demonstrated this point.

"In contrast to what we had come to believe, chemotherapy and other therapeutic interventions actually 'cured' only a fraction of those who received them. Other women would have recovered even without such treatment. Similarly, tumor biology—not just how promptly a woman discovered her cancer—played a major role in determining how long she would survive.

"Finally, it hardly required extensive research to realize how women diagnosed with breast cancer in the 1990s seemed to make friends rather than lose them." Breast cancer in the U.S. "has become a national phenomenon, perpetually discussed in magazines and on television and the Internet. Survivors meet each other at races, support groups,

and corporate-sponsored galas."

Long before the era of galas, breast cancer was a battlefield, and Lerner writes engagingly about the skirmishes and their participants. Halstead, for example, was deeply commited to scientific knowledge and pursued research that supported his surgical procedure. He pioneered the use of surgical gloves—initially not to limit infections, but to protect his nurse's hands from the irritation caused by mercuric chloride used during surgery. He later married the nurse, Caroline Hampton.

It's important to remember how shocking it was to the medical profession, used to private scientific debate, when surgeons George Crile Jr., of Cleveland, and Oliver Cope, of Boston, "went public" with their doubts about the Halstead procedure by talking to women's magazines.

These physicians were vilified by colleagues like Jerome Urban, of Memorial Sloan-Kettering, who once said, "Lesser surgery is done by lesser surgeons."

Physicians who harnessed the power of emerging areas of science, such as sophisticated statistical methodology, were more successful in advancing their treatment methods, Lerner said. The book chronicles the rise of Pittsburgh surgeon Bernard Fisher, whose "sonorous and authoritative" advocacy of randomized clinical trials "represented a true threat to business as usual in the world of surgery."

Fisher and other RCT advocates successfully invoked science to rhetorically denigrate critics and push the new agenda to the forefront—just as Halstead did in his day, Lerner wrote.

Will the breast cancer wars ever end? Just one skirmish, the war over mammographic screening, has taken place for 30 years and there is no end in sight, Lerner said.

"Having eight randomized controlled trials [of mammographic screening] is an amazing amount of data," Lerner said. "There are problems with the trials. The trials are old now, but were well thought out at the time, yet still there is sincere disagreement. It's reasonable to expect that disagreement to persist.

"My view is, six of the eight trials show some benefit especially for 50 and over. So for women 50 and over, there's no reason to change anything.

"I tell patients that there's a debate going on and some of the faith that people had in mammography is waning."

Lerner noted that the American Cancer Society has always supported aggressive early detection and treatment, while some statisticians have spoken out opposing screening guidelines. "None of these people ever publishes an article in which they change their minds," Lerner said. "I'd like to see that happen just once.

"When I interviewed Art Holleb, [longtime ACS medical director] and I suggested that maybe some people didn't share the [ACS] view on mammograms, he looked at me like I was crazy," Lerner said.

The society "still sees itself as the major force behind the war on cancer," Lerner said. "There has been success in early detection with cervical cancer and colon cancer. It's probably pretty hard for an organization to step back and say, 'You know that war on cancer? We've had more success with some cancers than other cancers.'

"It's interesting to me that to some extent, the groups that have been content to have the PSA choice take place between the man and his doctor have been less content to have the mammography choice between the woman and her doctor," Lerner said.

Media interest in breast cancer can be directly traced to the American Cancer Society starting its annual Science Writers' Conferences, Lerner said. Though the conferences were aimed at promoting the society's views and highlighting its funded research projects, some of the journalists who attended the conferences went on, as Kushner had, to learn the science, read journals, go to other scientific meetings, and challenge the accepted medical dogma.

"Journalists have been valuable at times in giving voice to the critics of the system," Lerner told the journalists at the seminar.

Lerner's book serves as a valuable history of the patient advocacy movement, which never has been a simplistic story of women patients versus male surgeons. While Kushner and others directly challenged the medical profession and fought for change, other breast cancer survivors took a more conservative approach. Marvella Bayh, for instance, served as a spokesperson for the American Cancer Society until her death in 1979.

It is often thought that current breast cancer activists learned techniques from the AIDS activists of the 1980s. That's not entirely the case, Lerner said. "A lot of the technique of the AIDS activists was based on what Rose Kushner did," he said.

According to Lerner, the key elements of each skirmish in the breast cancer wars involve:

—The ability of science to generate answers.

—The involvement of patients in making decisions.

—Debate about which direction to take scientifically and clinically, whether that involves prevention, early detection, or treatment.

Originally, Lerner wanted to write a history of breast and prostate cancer, but dropped prostate cancer early in the project.

"The prostate cancer story follows the breast cancer story by about a 10- or 20-year lag," Lerner said.

Oncologists be forewarned.

The Breast Cancer Wars: Hope, Fear, and the Pursuit of a Cure in Twentieth-Century America, by Barron Lerner, Oxford University Press, may be purchased at: http://www.amazon.com/exec/obidos/ASIN/0195142616/cancerlettercom.

Reports:

Evidence Too Weak To Link Agent Orange And Cancer

Evidence is too weak to establish whether an association exists between exposure to the herbicides used during the Vietnam War and the development of a form of leukemia in veterans' children, according to a report from the Institute of Medicine of the National Academies.

Based on a review of all available research, as well as corrected data from an Australian study, the committee that wrote the report revised its earlier finding of a possible association.

The prior IOM review founded its conclusion in part on a report from the Australian Institute of Health and Welfare that looked at the incidence of acute myelogenous leukemia in the children of Australian veterans of the Vietnam War. The Australian study was later found to have contained a miscalculation that led its authors to incorrectly conclude that these children faced a significantly greater risk of AML than children in the general population did.

The revised analysis found that the incidence of the illness was within the range that might be expected in the general population. The committee also considered new evidence from German and Norwegian studies of AML in the offspring of parents who had occupational exposure to pesticides. Neither study found a significant difference in incidence from unexposed populations.

"On the whole, there is insufficient evidence at this time to determine whether a connection exists between AML in children and their parents' military service in Vietnam or Cambodia," said committee chairman Irva Hertz-Picciotto, professor of epidemiology, University of California, Davis. "Our review of available studies, combined with the revised analysis from Australia, indicates that the evidence is too weak to draw any conclusions or even make tentative ones."

The ability of researchers to pinpoint the health risks faced by veterans or their children is hampered by inadequate information about herbicide exposure levels of troops in Vietnam. Most information comes from studies of civilians who were exposed to herbicides on the job or in industrial accidents. It also is difficult to say which troops may have been exposed.

U.S. forces sprayed Agent Orange and other defoliants over parts of south Vietnam and Cambodia beginning in 1962. A 1969 scientific report concluded that one of the primary chemicals used in Agent Orange could cause birth defects in laboratory animals. The military halted all herbicide spraying in Vietnam in 1971.

The committee's work was sponsored by the U.S. Department of Veterans Affairs.

The report, "Veterans And Agent Orange: Herbicides/Dioxin Exposure And Acute Myelogenous Leukemia In The Children Of Vietnam Veterans," is available at http://www.nap.edu.

* * *

MAMMOGRAPHY SCREENING: An international working group has concluded that randomized clinical trials have provided sufficient evidence for the efficacy of mammography screening of women between 50 and 69 years.

The reduction in mortality from breast cancer among women who chose to participate in screening programmes was estimated to be about 35 percent, said the working group convened by the International Agency for Research on Cancer of the World Health Organisation.

The group, consisting of 24 experts from 11 countries, met in Lyon on March 5-12.

For women aged 40-49 years, there is only limited evidence for a reduction, the group concluded. The working group found that many of the earlier criticisms of the trials were unsubstantiated, and the remaining deficiencies were judged not to invalidate the trials' findings.

The effectiveness of national screening programs varies due to differences in coverage of the female population, quality of mammography, treatment and other factors, the group said. Organised screening programmes are more effective in reducing the rate

of death from breast cancer than sporadic screening of selected groups of women. The working group also concluded that there is insufficient evidence that clinical breast examination or self-examination reduce mortality from breast cancer.

The report is available at http://www.iarc.fr.

* * *

MARKETING TACTICS from inside the tobacco industry are dissected in the March 11 issue of Tobacco Control, a journal edited by **K. Michael Cummings**, chairman of cancer prevention, epidemiology and biostatistics at Roswell Park Cancer Institute. The supplement is devoted to disclosures from corporate documents. Articles from the journal are available at http://roswell.tobaccodocuments.org.

* * *

CANCER CLUSTERS, a topic plagued by a wide disparity between public perceptions and scientific findings, is explored in a new report, "Cancer Clusters: Findings Vs. Feelings," by the American Council on Science and Health. The report discusses the potential cancer clusters in Toms River, New Jersey, and Long Island, New York. The report is available at http://www.acsh.org/publications/booklets/clusters2002.html.

Funding Opportunities:

DOD Breast Cancer Research Program Announcements

Department of Defense Breast Cancer Research Program for fiscal year 2002 has released its program announcement. The program has $150 million this year to support innovative research directed toward the eradication of breast cancer.

This program is administered by the U.S. Army Medical Research and Materiel Command through the Office of the Congressionally Directed Medical Research Programs.

For the FY02 BCRP, there are two program announcements:

FY02 BCRP Program Announcement I: All Program Announcement I mechanisms require a pre-proposal submission, which is due by **April 3, 4 p.m. Eastern**. This announcement will call for proposals in the following mechanisms:

- Clinical Translational Research (CTR) Awards
- Biotechnology Clinical Partnership Awards
- Collaborative-CTR Awards
- Breast Cancer Center of Excellence Awards
- Historically Black Colleges and Universities/ Minority Institutions Partnership Training Awards

New this year: *Biotechnology Clinical Partnership Awards* are intended to support the establishment of partnerships between the biotechnology industry and academic institutions, and are expected to accelerate the delivery of novel breast cancer therapeutics and chemopreventives.

FY02 BCRP Program Announcement II will call for proposals in the following mechanisms: Electronic proposal submission due as indicated:

- Innovator Awards: submission by June 13, 2002.
- Exploration Awards: submission by June 13, 2002
- Idea Awards: submission by June 11, 2002
- Physician-Scientist Training Awards: submission June 12, 2002
- Clinical Research Nurse Training Awards: submission June 12, 2002
- Predoctoral and Postdoctoral Traineeship Awards: submission June 12, 2002
- Undergraduate Summer Training Program Awards: submission June 12, 2002

New this year:

Exploration Awards are intended to fund an initial innovative concept or theory (with no preliminary data) that could give rise to a testable hypothesis. Critical to this award is innovation, which will be the major evaluation criterion.

Physician-Scientist Training Awards are intended to support the training of new breast cancer clinical research physicians.

Clinical Research Nurse Training Awards are intended to support nurses at all levels (BSN, MSN, and Ph.D.) focusing on breast cancer research in an interdisciplinary breast cancer research environment.

For further information about the BCRP, BCRP awardees, previous BCRP Program Announcements, and other CDMRP-sponsored programs and events, see http://cdmrp.army.mil.

NIH Program Announcement

PA-02-072: Methodology and Measurement in the Behavioral and Social Sciences

NCI and participating Institutes and Centers invite applications on methodology and measurement in the behavioral and social sciences. Methodology and measurement issues include the processes that underlie research design, data collection techniques, measurement, and data analysis techniques in the social

and behavioral sciences. Research that addresses methodology and measurement issues in diverse populations, issues in studying sensitive behaviors, issues of ethics in research, issues related to confidential data and the protection of research subjects, and issues in developing multidisciplinary, multimethod, and multilevel approaches to behavioral and social science research is particularly encouraged. The primary mechanism of support will be the investigator-initiated research R01 grant. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-02-072.html.

Inquiries: For NCI—Michael Stefanek, Division of Cancer Control and Population Sciences, 6130 Executive Blvd., Rm 4066, Rockville, MD 20852, phone 301-496-8776; fax 301-435-7547; e-mail ms496r@nih.gov

In Brief:

Karlan Named Director, Women's Institute At CSMC

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funding for NCI, and extending preventive cancer care and treatment to more Americans, the society said. . . **BETH KARLAN**, gynecologic cancer surgeon and research scientist at Cedars-Sinai Medical Center, has been named director of the Women's Cancer Research Institute. Karlan holds appointments as director of the Division of Gynecologic Oncology and the Gilda Radner Ovarian Cancer Program at CSMC. . . . **ROSALYN BLUMENTHAL**, director of the Tumor Biology at the Garden State Center in New Jersey, was selected Eminent Scientist of the Year 2002 by the Internal Research Promotion Council and World Scientists Forum for her work in women's health cancers, especially endometriosis. . . . **EMERY BRESNICK**, associate professor of pharmacology at the University of Wisconsin Comprehensive Cancer Center, received the 2002 Romnes Fellowship, named after the late H.I. Romnes, former chair of the board of AT&T and former president of the Wisconsin Alumni Research Foundation Board of Trustees. Bresnick is known for his program on elucidating physiological mechanisms that control gene transcription in the context of chromosome segments, termed domains. He is also known for his discoveries on how intercellular communication results in changes in gene activity that control the development of complex organisms. . . . **DAVID SCHWARTZ**, professor of genetics at UWCCC, received the Kellett Mid-Career Award. Schwartz is recognized as one of the leading figures in the Human Genome Project. He is regarded for his contributions to genomics, including the development of pulsed-field electrophoresis, optical mapping technologies and the systems required to analyze the complex genetic data.

THE CANCER LETTER

Vol. 17 No. 3
March 2002

Business & Regulatory Report

Drug Development:

FDA Turns Down Corixa's Bexxar, Says Further Clinical Trials Needed

FDA earlier this month informed **Corixa Corp.** (Nasdaq: CRXA) that its Biological License Application for Bexxar (tositumomab, iodine I-131 tositumomab) failed to provide sufficient evidence of the safety and clinical benefit of the agent, the company said.

Additional clinical trials will be needed, the agency said in a letter

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Oncology Management:

Amgen Signs Agreement To Provide Supportive Care Agents To US Oncology

Amgen (Nasdaq:AMGN) of Thousand Oaks, CA, said it has signed a multi-year agreement with **US Oncology Inc.** (Nasdaq:USON) of Houston covering Aranesp (darbepoetin alfa) for anemia, Neulasta (pegfilgrastim) and Neupogen (Filgrastim) for chemotherapy-induced neutropenia.

"Aranesp, Neulasta, and Neupogen are important tools that give our member physicians a wide variety of effective options for treating anemia and neutropenia and improve patient outcomes and quality of life," said Michael Louviere, vice president, Oncology Pharmaceutical Services division of US Oncology.

Clinical trials showed that Neulasta is safe and well-tolerated, the company said. The most common adverse event following combination chemotherapy in patients (n=465) with lymphoma and solid tumors was bone pain reported in 26 percent. In most cases, bone pain was controlled with non-narcotic analgesics. The most serious adverse event was low oxygen in the blood, reported in one patient. While not reported in patients receiving Neulasta, rare events of adult respiratory distress syndrome, splenic rupture, and sickle cell crisis have been reported in patients receiving the parent compound, Neupogen, the company said.

In the phase III trial of Neupogen therapy following combination chemotherapy in patients (n = 207) with small cell lung cancer, bone pain was reported in 22 percent of patients, the company said. In most cases, bone pain was controlled with non-narcotic analgesics such as acetaminophen.

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Corixa Failed To Show Bexxar Addresses Unmet Need: FDA

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received by the company March 12.

Corixa sought accelerated approval for Bexxar, an investigational radioimmunotherapy, for low-grade or transformed low-grade non-Hodgkin's lymphoma. Rejecting the application, the agency said Corixa failed to demonstrate that the agent addresses an unmet medical need.

Only therapies that address such needs are eligible for accelerated approval by FDA, a regulatory mechanism that does not require sponsors to demonstrate that patients benefit from the therapy, and instead show that a "surrogate endpoint" may translate into benefit. Accelerated approval is frequently granted on the basis of phase II studies, but the sponsors are required to conduct further trials that would demonstrate patient benefit.

Now, the company can either amend the application, withdraw it, or request a hearing to challenge the agency's decision.

"We are extremely disappointed with the FDA's decision and intend to promptly pursue resolution with our partner, GlaxoSmithKline and the Agency," Corixa Chairman and CEO Steven Gillis said in a statement. "We are formally requesting a meeting with the FDA and hope to reach mutual agreement on the specific steps still necessary for approval."

THE CANCER LETTER

Member, Newsletter and Electronic Publishers Association

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

Business & Regulatory Report

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

Editorial: 202-362-1809 Fax: 202-318-4030
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Business & Regulatory Report is a supplement to The Cancer Letter and available separately for $185 per year. ISSN 1053-9611.

According to regulatory filings, Corixa filed a Biologics License Application for Bexxar in June 1999, but in August, FDA responded with a Refusal to File letter. The company resubmitted the BLA in September 2000, and in March 2001 the agency responded with a complete review letter that requested additional clinical and manufacturing information.

Corixa acquired Bexxar in December 2000, when it acquired the agent's sponsor, Coulter Pharmaceutical Inc. Coulter has previously licensed the agent from the University of Michigan.

In the U.S., the company is codeveloping Bexxar with GlaxoSmithKline.

A competing product, Zevalin, received FDA approval in February. Corixa is in patent litigation with Zevalin's sponsor, IDEC Pharmaceuticals Inc. Patents in question cover imaging, composition of matter and methods-of-use in the treatment of non-Hodgkin's lymphoma.

If Bexxar is approved, its administration would require medical personnel treating NHL to handle radioactive materials. Since few oncologists and hematologists are licensed to administer radioimmunotherapies, they will need to engage a nuclear medicine specialists.

In a separate development, ODAC on Feb. 27 endorsed Corixa's proposed design for a second phase III trial for its melanoma vaccine, Melacine. The company proposed a design that would evaluate Melacine versus observation in HLA A2 and/or HLA C3 positive, resected stage II melanoma.

Melacine is approved for marketing in Canada.

HHS Plan Cuts FDA Target Review Time By Two Months

HHS Secretary Tommy Thompson last week delivered to Congress a plan for reauthorization of the Prescription Drug User Act, the legislation that enables the government to charge pharmaceutical and biotech companies for FDA review of their applications.

The law, which was originally passed in 1992, comes up for reauthorization later this year. The existing version of the law sunsets on Oct. 1, and unless a new law is passed, about 1,000 FDA medical reviewers could end up looking for other jobs.

The 25-page document Thompson brought to the Hill March 13 is the result of six months of negotiations between pharmaceutical industry groups and the agency.

During the current year, user fees contributed $177 million to the agency's budget. Under the new proposal, industry contributions would increase to $260 million within five years.

"Despite its overall success, this program is at risk of being seriously underfunded, due to unforeseen changes in drug submission patterns and other factors," Thompson said in a statement. "The new proposal addresses these problems and establishes a financial structure that should put the program on a sound footing for the foreseeable future."

The new plan requires FDA to complete review of 90 percent of standard New Drug Applications within 10 months of submission. The agency's current target is to act on 90 percent of NDAs within a year of submission. The performance goal for priority applications remains unchanged: six months for 90 percent of applications.

The new plan requires the agency and the sponsors to develop strategies for managing toxicity of newly approved drugs. The plan goes beyond listing toxicities on the label, and requires sponsors to develop risk management plans tailored for specific drugs.

To monitor risk management, the agency would use PDUFA funds to hire 100 "safety officers."

"This proposal would provide FDA with significantly expanded resources for risk management activities related to medicines—especially after they enter the marketplace," Thompson said. "These risk management activities are essential for maximizing the benefits of medicines, minimizing their risks and continue to protect the health of the American people."

PDUFA funds account for 51 percent of FDA budget. Under the new law, the industry will contribute 60 percent.

While Republican leadership of the House Committee on Energy and Commerce will try to resist amendments, Democrats are expected to press for giving the agency greater power for post-approval management and some curbs on direct to consumer advertising, Capitol Hill Sources said.

"We cannot allow reauthorization of PDUFA to be turned into a Christmas tree. If we do this, we increase the likelihood that hard-working FDA employees will be presented with RIF notices later this summer," Rep. Billy Tauzin (R-LA), chairman of the House Energy and Commerce Committee, said at a recent hearing. "We cannot allow this to happen. Let's deal with PDUFA now, and then turn our attention to other FDA reforms. It is my every intent to see the Committee consider other FDA matters later in this session, so let's produce a clean PDUFA reauthorization now."

Oncology Management:

Amgen, ION Sign Agreement To Provide Three Drugs

(Continued from page 1)

Aranesp was approved by FDA in September 2001 for anemia related to chronic renal failure, for patients on dialysis and not on dialysis, and is under review by the FDA for use in cancer chemotherapy, the company said.

In a related development, Amgen said it has signed a multi-year agreement with **International Oncology Network** of Baltimore for Aranesp (darbepoetin alfa) for anemia, and Neulasta (pegfilgrastim) and Neupogen (Filgrastim) for chemotherapy-induced neutropenia.

Amgen said it would work with ION to develop physician and patient educational services around the ION cancer care services.

"This agreement is the latest evidence that physicians are eager to embrace our products to improve patient care," said George Morrow, executive vice president of worldwide marketing and sales at Amgen.

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National Comprehensive Cancer Network unveiled its 2002 Breast Cancer Practice Guidelines.

The Guidelines in Oncology are the recognized standard for clinical policy in the field of oncology, the network said. They are monitored and updated with up-to-date cancer care information.

The Breast Cancer Treatment Guidelines have been revised twice in the past year, the network said. A full update was completed in December 2001 and updated again in January 2002 based on data at the 2001 San Antonio Breast Cancer Symposium.

Major changes in 2002 include elaboration on the role of sentinel node biopsy, and updates in systemic therapies including the role of hormonal therapy with the aromatase inhibitors in postmenopausal women and LH-RH agonists in premenopausal women for metastatic disease, the network said.

Trial results that led to the January 2002 update include the ATAC (Arimidex and Tamoxifen alone or in combination) trial results, which demonstrate that Arimidex (anastrozole) provides superior disease-free survival and a favorable toxicity profile compared to

tamoxifen as adjuvant therapy for hormone receptor-positive breast cancer in postmenopausal women, the network said.

The ATAC results were compiled after a median of 33.3 months follow-up and a median duration of treatment of 30.7 months, the network said.

The revised guidelines state that anastrozole may be considered as an option to tamoxifen after discussion of the available data between the physician and patient.

Tamoxifen has been on the market for over 20 years, the network said.

"Since new developments in cancer research are truly happening all the time, we revise our Practice Guidelines continuously," said Rodger Winn, chairman of the NCCN guidelines steering committee.

"The NCCN new Internet version of the guidelines allows our panels to respond to treatment advances almost immediately," Winn said.

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Oncology Care Systems Group of Concord, CA, owned by **Siemens Medical Solutions** (NYSE: SI) of Iselin, NJ, and Erlangen, Germany, said it has signed an agreement with **BrainLAB** to supply customers with integrated micro multileaf collimator systems.

The BrainLAB m3 micro-MLC will be used on the Siemens Primus linear accelerators, the company said.

The integration of both systems will result in improved functionality, user friendliness and safety in day-to-day treatments, the company said.

Under the agreement, Siemens will offer a software interface for the m3, along with its Primus accelerator, the company said.

BrainLAB will provide the m3 system, along with the BrainSCAN treatment planning system, which enables image fusion, auto contouring capabilities and optimization tools in order to supply inverse treatment planning for intensity modulated radiation therapy.

The m3 micro-MLC provides fine resolution beam shaping, and has a well-established track record in stereotactic radiosurgery and IMRT applications and is part of the intensity modulated radio surgery offering, the company said.

When it is combined with the Siemens linear accelerator and the Primeview graphical user interface, the result in an integrated micro-MLC solution for delivering IMRT, which sculpts a dose of radiation around a tumor, thus decreasing the side effects to normal tissues adjacent to the tumor.

Clinical Trials:

MGI Pharma Begins Trial Of Irofulven For Solid Tumors

MGI Pharma Inc. (Nasdaq:MOGN) of Minneapolis said it has begun a phase I trial of its anti-cancer compound, irofulven, in combination with the anti-tumor agent cisplatin for advanced solid tumors.

The primary objective of the 40-patient, international, multi-center, dose-escalating trial is to determine the maximum-tolerated dose of the two drugs when used in combination, the company said. Secondary objectives are to determine the safety, anti-tumor activity, and the pharmacokinetic profile of irofulven and cisplatin when administered in combination. Both drugs will be administered on an every-other-week dosing schedule, the company said.

"This is an important first clinical step in determining the future role of irofulven in combination with platinum agents, like cisplatin, which have exhibited broad utility in the treatment of solid tumors," said Eric Raymond, head of the Clinical Pharmacology Unit in the Department of Medicine at Institut Gustave Roussy in Villejuif, France, and principal investigator for the MGI trial. "While irofulven and cisplatin are both DNA-interactive agents, they feature contrasting mechanisms of anti-tumor action. Preclinical studies of the drugs in combination have demonstrated synergistic activity and an absence of cross-resistance in common drug-resistant cell lines. The clinical anti-tumor effect of the irofulven-cisplatin combination may be synergistic as well."

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Northwest Biotherapeutics Inc. (Nasdaq:NWBT) of Bothell, WA, said its investigational new drug application for its third dendritic cell-based immunotherapy, DCVax-Lung, has been cleared by FDA.

A phase I trial to evaluate the safety of the drug for non-small cell lung cancer will begin later this year, the company said.

The Northwest Biotherapeutics development efforts are based on two proprietary approaches: DCVax, a dendritic cell-based immunotherapy platform and HuRx, a fully human monoclonal antibody platform, the company said.

DCVax-Prostate, is an investigational prostate cancer treatment entering a phase III trial, the company said. It received FDA clearance for a phase

II trial evaluating its DCVax-Brain as a possible treatment for glioblastoma multiforme.

HuRx is a human monoclonal antibody program that is being co-developed with Medarex, Inc, the company said. HuRx-Prostate, the lead HuRx product candidate, is being manufactured for anticipated phase I trials.

Deals & Collaborations:

Biotherapies Sells Unit To Genesis Bioventures

Biotherapies Inc. of Ann Arbor said has completed the sale of the diagnostic unit, **Biomedical Diagnostics**, begun as a joint venture with **Genesis Bioventures** (Amex: GBI).

Biotherapies started the business enterprise with GBI in 1998 to accelerate development of diagnostic technology for breast cancer, the company said. Biotherapies had developed a test that measured a protein called Mammastatin in the blood. The observation that Mammastatin was missing from the blood of most breast cancer patients suggested the need for a screening product to identify breast cancer and breast cancer risk, the company said.

The transaction transfers complete ownership of Biomedical Diagnostics to GBI and provides a license to the Mammastatin Serum Assay technology and any prostate or ovarian diagnostic developments to GBI, the company said. Biotherapies receives $14 million in capital and equity, along with a royalty commitment of 10-20 percent (dependent on the level of net revenue).

"The transaction allows us to maintain our focus and provides us with additional resources to develop the Mammastatin therapy," said Paul Ervin, scientific director and CEO of Biotherapies. "The sale will also provide a continuing revenue stream to support the development of additional products."

"We had always planned to leverage the diagnostic product to help development of the therapeutic," said Ervin. "Therapeutic development is more difficult and expensive because of the need for FDA approval. We have essentially leveraged this technology twice to aid in therapeutic development — once with the establishment of Biomedical Diagnostics when we received a license fee, and now with the sale of Biomedical Diagnostics."

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BSD Medical Corp. (OTC Bulletin Board: BSDM) of Salt Lake City said it has acquired the rights to the FDA approvals of **Clinitherm Inc.** for various applications of hyperthermia therapy, and also acquired the rights to broaden the FDA approvals already granted to the company.

BSD Medical and Clinitherm said they are the only companies granted FDA approval for interstitial hyperthermia therapy. The acquired approval applies to a microwave antenna that features variable heating lengths and uniform heating patterns developed by the University of California, San Francisco. BSD Medical had exclusive rights to the antenna through a license agreement with UCSF. UCSF demonstrated clinical response in a phase III study treating brain cancers with the antenna design, the company said.

BSD Medical said its strategy in cancer therapy is to deliver FDA approved hyperthermia systems capable of treating cancer anywhere in the body and has been developing four products now nearing release for cancers that can be accessed through interstitial and external approaches.

Interstitial hyperthermia systems are used to treat tumors in combination with popular interstitial and intracavitary radiation therapy (brachytherapy), using tiny microwave antennae inserted through the same catheters used to deliver radioactive seeds, the company said. The technique can treat prostate cancer, breast cancer and head and neck cancer. Superficial hyperthermia systems are used to treat tumors within a few centimeters of the surface of the body such as melanoma or recurrent breast cancer. Deep hyperthermia is used to treat cancer sites in the pelvis, abdomen and chest, the company said.

In another development, BSD Medical said it had acquired the rights under a patent license from NIH for the coupling of MRI treatment monitoring with the BSD high-end system used for deep hyperthermia therapy, the BSD-2000/3D. The concept was patented by NIH, but BSD Medical has developed it and made it practical for medical use.

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Debio Recherche Pharmaceutique of Martigny, Switzerland, said it has entered into an agreement with **Shearwater Corp.** of Huntsville, AL, a subsidiary of **Inhale Therapeutic Systems**, Inc. of San Carlos, CA, to develop and commercialize hydrogel technology to deliver macromolecular drugs and proteins as polyethylene-glycol conjugates.

The contract between the companies provides for patents under the Debio R.P. name that are derived from research financed by Debio R.P. in exchange for royalties payable to Shearwater on sales of

products containing PEG hydrogels from the collaboration, the companies said. Shearwater said it has also been granted a license to make and use the PEG hydrogels outside the drug delivery field in exchange for royalties payable to Debio R.P. The first patent resulting from collaboration work on one type of injectable PEG hydrogel was granted in the U.S.

The platform technology assigned to Debio R.P. consists of a new family of hydrogels, one of which releases proteins in situ as PEG-conjugates, the company said.

"This feature clearly confers significant advantages over other types of hydrogels, such as better tissue penetration, possibility for tumor targeting and an increased therapeutic index, particularly for the release of proteins with a short duration of action," said Piero Orsolini, CEO of Debio R.P.

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HopeLink Corp. of Sanfrancisco and **MEDePass Inc.** of Burlingame, CA, a California Medical Association subsidiary, said they would collaborate on a clinical trials information service for MEDePass subscribers.

The service will allow primary care and specialist physicians to identify trials for their patients, qualify their participation and monitor open trials and treatment, the companies said. The HopeLink Clinical Trial Service will rely on MEDePass Certificates to authenticate the identity and medical licensure status of physician users accessing the HopeLink service, ensuring that only licensed physicians can provide and access confidential patient information.

"Our partnership with HopeLink is an excellent example of the direction online medical communication must take if the promise of the Internet is going to be realized," said Catherine Roth, CEO of MEDePass. "Without assurance that a person is the physician he or she purports to be, it is impossible to offer services such as HopeLink's that can provide authenticated identities so that patients, physicians, and investigators can take advantage of the Internet to increase participation in clinical trials."

The California Medical Association is an advocacy organization that represents more than 34,000 California physicians from all regions, modes of practice and medical specialties, the companies said.

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NimbleGen Systems Inc. of Madison, WI, said it has opened **NimbleGen Systems LLC** of Iceland, which manufactures custom DNA arrays and related services worldwide.

"The Iceland facility allows us to penetrate several key markets with world-class products and services for the biopharmaceutical and academic research markets," said Mike Treble, president and CEO of NimbleGen. "NGS-I greatly expands our research, customer training, operating flexibility, manufacturing capacity and product lines. It is another indication that we have evolved into a company that can both develop and commercialize custom, high density DNA arrays, systems and related services."

The development of the Icelandic enterprise was a result of a collaboration with the **Iceland Genomics Corp.** subsidiary, **UVS**, a privately held biopharmaceutical company of Reykjavik.

"The collaboration between NimbleGen Systems and our company will help strengthen our comprehensive cancer research program, which we are working on with Icelandic hospitals, clinicians and the Cancer Society," said Gunnlaugur Gunnlaugsson, CEO of Iceland Genomics Corp.

David Cooper, senior vice president of services and chief medical officer, will head NimbleGen Systems Iceland, the company said. His corporate experience includes serving as chief science and operating officer of the Quest Diagnostics Nichols Institute, chief science officer of both Quest Diagnostics and diaDexus, the company said. In academia, Cooper held tenured faculty positions at: Duke, University of Pittsburgh and Lichfield. He founded the first division of molecular pathology in the U. S., was the first chairman of the Association for Molecular Pathology and was editor and founder of the journal, Molecular Diagnosis.

Iceland Genomics Corp. is a privately held biopharmaceutical company that promotes the advantages of the Icelandic population in the search for cancer treatments and cures, the company said.

The relationship with the Icelandic clinicians and hospitals gives the company preferential access to information and samples from cancer patients and their families in one of the world's best populations for genetic studies, the company said.

By genotyping affected families and analyzing the molecular features of tumors, the company is isolating genes involved in both inherited and sporadic cancers, and plans to use the genes as the basis of diagnostic tests, while at the same time validating the most promising of them as therapeutic targets and screening for drug leads directed against them.

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Ricerca LLC of Concord, OH, said it has begun

its oncology drug discovery program by licensing RAP-3 cancer-associated gene from **Genset S.A.** (Nasdaq: GENXY) (Euroclear: 5433) of Paris.

Ricerca said it would use RAP-3 as a drug target as well as developing the gene as a protein therapeutic. Income from the commercialization or licensing of drug products would be shared.

"RAP-3 is the first of several gene targets that Ricerca intends to license from Genset and other partners and for which the company will hold full drug development rights," said Prabhavathi Fernandes, CEO of Ricerca.

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Varian Medical Systems Inc. (Nasdaq: IMPH) of Palo Alto, CA, said it has entered into an alliance with Impath Inc. of New York for cancer treatment research and tumor registration clinical data management.

The partnership links the Varian VARiS information management software with the Impath Cancer Registry software for hospitals and cancer clinics, the company said. The software interfaces link radiation and medical oncology databases with tumor registries. Each company will continue to book revenue from its own products, and Varian will direct customers to Impath for tumor registry software.

Product Approvals & Applications:

Abbott Labs To Add New Data To Label For Vysis Assay

Abbott Labs. (NYSE: ABT) of Abbott Park, IL, said it received clearance from FDA to include new data from a multi-center longitudinal study in the labeling of its Vysis UroVysion DNA probe assay for bladder cancer recurrence.

The Vysis UroVysion Bladder Cancer Recurrence Kit is the only DNA-based test for monitoring recurrence of bladder cancer, the company said. The test is based on the detection of genetic changes in bladder cells utilizing a proprietary technology called Fluorescence in situ Hybridization.

The FISH-based test detects aneuploidy of certain chromosome and other genetic abnormalities in urine specimens for transitional cell carcinoma of the bladder, the company said. Test results are obtained from a noninvasive method for monitoring tumor recurrence in conjunction with cystoscopy.

"The FDA decision to allow the longitudinal study claim in the packaging is important because physicians need to be made aware of the study results and their statistical significance," said Kerry Flom, senior director, clinical affairs, Vysis Inc., a wholly owned subsidiary of Abbott Laboratories.

"Study findings clearly illustrate that among those test group patients with anticipatory positive results (FISH-positive and cystoscopy- negative), cancer recurred in an average of 6.9 months in 42 percent of patients compared to an average time of recurrence of 11 months in 19 percent of patients showing true negative results (FISH- negative and cystoscopy-negative)."

The original data from the trial showed that the UroVysion assay is both highly sensitive and highly specific, which is an important combination when diagnosing bladder cancer recurrence, according to Michael Sarosdy, South Texas Urology and Urologic Oncology Group, San Antonio, and principal investigator of the study.

"The new finding shows that the assay detects the presence of cancer cells in the urine even before a cancerous growth can be identified by visual inspection. For patients with a negative visual inspection followed for 18 months, a subsequent tumor was discovered more than twice as often for those whose UroVysion assay had been positive compared to those whose UroVysion assay had been negative. Thus, the UroVysion assay can serve to appropriately heighten suspicion and increase surveillance efforts in selected patients with a negative visual inspection," he said.

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Cytogen Corp. (Nasdaq: CYTO) of Princeton, NJ, said it has received a notice of compliance for ProstaScript, its radio-labeled monoclonal antibody prostate cancer imaging agent, from Health Canada.

ProstaScint is indicated for use newly diagnosed prostate cancer with high risk for lymph node metastases and for recurrent prostate cancer following a radical prostatectomy with suspected occult metastatic disease in both Canada and the U.S, the company said.

In Canada, ProstaScint is also indicated for recurrent prostate cancer that would benefit from local salvage radiation therapy, the company said.

"The expanded product label further validates the value of the information obtained from ProstaScint imaging in helping physicians and prostate cancer patients make more appropriate and informed treatment decisions," said H. Joseph Reiser, president and CEO of Cytogen Corp.

ProstaScint (capromab pendetide), developed

and marketed by Cytogen, is a radiolabeled monoclonal antibody that targets prostate specific membrane antigen, the company said. During a ProstaScint imaging procedure, the antibody is administered intravenously, traveling through the bloodstream and binding to prostate cancer cells, the company said. A gamma camera is then used to detect the radioactive isotope that been attached to the antibody, identifying the specific sites of cancer.

Patents:

Cervical Cell Collection Device Awarded Patent

Molecular Diagnostics Inc. (OTCBB: MCDG) of Chicago said it has been awarded a patent for its personal collection device, the InPath PCD, a personal cervical cell collection device used in self-collecting a cervical sample for analysis in a laboratory.

"While the device is not intended to replace a woman's need to visit her physician routinely where this is an option, in parts of the world where lack of physicians, or other sociological or religious obstacles preclude the woman from allowing such a collection, the device may dramatically improve the options for disease detection and treatment," said Eric Gombrich, vice president of Molecular Diagnostics Inc.

The device is in trials in China as part of a study managed in conjunction with the Cleveland Clinic Foundation, and the Beijing Cancer Institute, the company said.

The device, after collection of a sample, is deposited in a liquid preservative for transport to a laboratory for analysis, the company said. Testing options include the Molecular Diagnostics In-Cell HPV and Cocktail CVX assay, as well as conventional Pap testing, HPV DNA testing, Gonorrhea, Chlamydeous, and other molecular tests, the company said.

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Xcyte Therapies Inc. of Seattle said the Patent and Trademark Office has issued U.S. patent #6,352,694 for Xcellerate Technology, a core technology used in its products in cancer clinical trials.

The technology mimics natural mechanisms to stimulate T cells, the company said. Xcellerate is designed to activate a patient's T cells outside of the body by simulating natural events of the immune system to generate activated T cells, known as Xcellerated T Cells. Xcellerate is believed to increase T cell quantity, improve T cell quality and broaden T cell diversity, the company said.

"The issuance of this key patent represents an important milestone for Xcyte Therapies. It provides us with a strong proprietary position for our Xcellerate Technology to activate and grow T cells, which has demonstrated preliminary evidence of safety and efficacy," said Ronald Berenson, president and CEO of Xcyte Therapies. "We completed a phase I trial in metastatic renal cell carcinoma, which produced data indicating that Xcellerated T Cells were safe and well tolerated. collaborators. We plan to begin in a phase I/II trial shortly for hormone-refractory prostate cancer."

Awards:

PET-CT System Wins Product Of The Year Award

CTI PET Systems Inc. of Knoxville, TN, said it as won the Frost & Sullivan Product of the Year Award for development and commercialization of the first combination medical imaging system that merges positron emission tomography with computerized axial tomography for cancer diagnosis and monitoring, and radiation therapy planning.

The PET-CT system "demonstrates not only a novel application of existing technologies but also innovativeness that creates a new market niche within nuclear medicine," said Frost & Sullivan. Combining PET and CT "results in a dynamic imaging tool with the potential to revolutionize cancer care."

The PET-CT system was developed through research conducted by David Townsend, co-director of PET imaging at the University of Pittsburgh Medical Center and Ronald Nutt, a co-founder of CTI and president of CPS Innovations.

One of the most important uses for the PET/CT will be in directing more accurate treatment for tumors, the company said. "We now have the ability to direct therapy, including radiation therapy, in ways that are increasingly effective for the treatment of cancer," said Townsend. "This ability comes from the fact that the PET/CT provides oncologists with information about not only on where the tumor is located, but also how it is functioning."

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DOBI Medical Systems LLC of Mahwah, NJ, said it received the Most Innovative Product for 2002 Award for its ComfortScan Dynamic Optical Breast Imaging System from the New Jersey Technology Council at the 2002 Venture Fair. The system detects cancer through imaging angiogenesis.

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