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ImClone "Screwed Up," CEO Waksal Tells Conference; Stock Plunges

In his first appearance before investors since FDA said his company's application for approval of C225 was unacceptable, ImClone Systems Inc. president and chief executive Samuel Waksal acknowledged having "screwed up."

"What happened was that we put together a faulty [Biologics License Application] package, and we screwed up," Waksal said at JPMorgan H&Q health care conference in San Francisco Jan. 7.

ImClone's stock plunged after the New York-based company received a refusal-to-file letter from FDA on Dec. 28. The value dropped again

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In Brief:

Bush Signs HHS Appropriations; NCI Budget $4.188B After Administrative Rescission

PRESIDENT BUSH this week signed the Labor-HHS-Education appropriations bill providing $4.19 bilion for NCI, a 12 percent increase. The Institute was hit with a $2 million rescission for administrative costs that will reduce the actual amount to $4.188 billion, but "nobody here is complaining," an NCI source said. . . . **NATIVE AMERICAN WOMEN** diagnosed with breast or cervical cancer treatment through the Centers for Disease Control and Prevention's screening program will have their treatment paid by state Medicaid programs under a bill passed by the House last month. The bill, HR 1741, introduced by Reps. Tom Udall (D-NM) and J.D. Hayworth (R-AZ) and J.C. Watts (R-OK), corrects an omission from the original Breast and Cervical Cancer Prevention and Treatment Act passed by Congress last year that inadvertently made Native American women unable to receive the full benefits of treatment provided for under the Act. The Senate version of the bill passed in late November and awaits President Bush's signature to become law. Currently, 32 states offer coverage under the BCCPTA and 48 states have take administrative or legislative action toward enactment. . . . **RICHARD KLAUSNER**, senior fellow and special advisor for counterterrorismm at the National Academy of Sciences and former NCI director, was appointed to the Board of Scientific Advisors of the Van Andel Institute, in Grand Rapids, MI. "As director of NCI, he implemented innovative and new actions to help conquer one of humanity's greatest health challenges. It is this kind of bold leadership that will help guide the future of the Institute," said **David Van Andel**, chairman and CEO. . . . **ROSWELL PARK** Cancer Institute

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Shareholder Suits Claim ImClone Knew Of Problems

(Continued from page 1)

after **The Cancer Letter** published portions of the "refusal to file" letter in which the agency asked for additional clinical trials of C225 in advanced colorectal cancer (**The Cancer Letter**, Jan. 4).

Immediately following Waksal's remarks at the conference, ImClone's stock dipped again, hitting a low of $31.9 on Jan. 9, then bouncing back to $34.2 the following day. Overall, the company's stock lost 53.7 percent of its value since Dec. 5.

The company is facing at least a dozen class action suits filed on behalf of shareholders. The suits claim that the management of ImClone (Nasdaq: IMCL) knew, or should have known, that the BLA was in trouble, but didn't announce this to stockholders.

"There were a lot of questions that people have raised in all of this, and they said that we didn't communicate properly these issues with our shareholders, and that isn't the case at all," Waksal said at the conference Jan. 7. "We've been communicating, and communicating accurately all the while."

Waksal said the principal problem with the BLA was the company's failure to provide documentation demonstrating that the patients enrolled in ImClone's pivotal trial had met the eligibility criteria.

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Only advanced colorectal cancer patients whose disease progressed following treatment with a regimen containing CPT-11 were eligible for ImClone trial of CPT-11 plus C225.

"Without defining the refractory part of this, you don't have a clinical trial, because it's not well-controlled," Waksal acknowledged.

Demonstrating eligibility was indeed a fundamental issue in the high-risk approval strategy adopted by ImClone, experts say. The pivotal phase II trial the company presented as a basis for "accelerated approval" by FDA was testing the hypothesis that C225 works synergistically with CPT-11.

Trials of multi-drug regimens are commonly conducted by NCI-funded clinical trials cooperative groups. However, group trials are intended to shape medical practice, and are rarely used to generate data for approval of new drugs. By contrast, trials intended to support FDA approval are usually designed to isolate the impact of the new drug.

At the conference, Waksal reiterated his claim that the company was surprised to receive a refusal to file letter, a piece of correspondence that states that the application is poorly put together and cannot be reviewed.

"FDA didn't receive or could not comment, on any of the clinical information until after they received the package on Oct. 31, [2001]" he said.

Generally, the agency offers guidance on the structure of the trials long before companies submit applications for approval. FDA officials meet with companies before clinical trials begin, and at that point the agency reviews the trials for safety and comments on design.

Companies are free to disregard the agency's advice on design, but when they do, they are taking a risk.

"Trial design is usually discussed in pre-phase II meetings, at the end of phase I," said a senior pharmaceutical company executive involved in development of oncology drugs and their approval "You don't have to listen to FDA, but you would be a fool not to, if you want to use the trial for registration."

The FDA refusal to file letter said the agency had reservations about the design of ImClone's trial. The letter urges the company to conduct randomized trials, offering the company a choice of two designs:

—A randomized, controlled trial comparing CPT-11 and C225 with C225 as a single agent in patients refractory to CPT-11, or

—A three-arm trial of CPT-11 and C225 versus CPT-11 and C225 as single agents in patients not refractory to CPT-11.

C225 is a monoclonal antibody that targets the Epidermal Growth Factor Receptor expressed on the surface of some cancer cells. The agent's trade name is Erbitux, and its generic name is cetuximab.

Blaming the Consultants

In his presentation Jan. 7, Waksal offered his version of how ImClone's trials went wrong.

The problems were caused by the Independent Response Assessment Committee (IRAC), a group of two radiologists and two oncologists who reviewed the data from the trial's sites, he said.

"The data from all of the clinical sites was digitized and transferred to computers where [IRAC] sat with their cursors and reviewed the data in a blinded fashion," Waksal said. "During that review process, they were meant to document refractoriness. They were meant to measure and annotate every film, and show that these patients were—one—truly refractory, and—two—whether or not these were responders.

"If there were differences, they were meant to adjudicate between themselves, and they were meant to document that adjudication," Waksal said.

The committee ended up performing only one of these functions: documenting response, Waksal said.

"They only measured and documented when there was a response rate [Sic.]," he said. "All they did with the refractory question was say 'refractory' or 'stable disease.'"

This failure crippled the study, Waksal said.

"We did not provide that documentation," he said. "It doesn't exist."

Blaming the review committee is disingenuous, said Howard Ozer, director of Oklahoma University Cancer Center and Eason chair of oncology and hematology.

"It's not the IRAC's fault," said Ozer, who reviewed the FDA refusal to file letter for **The Cancer Letter**. "IRAC would have done whatever they were asked to do."

The committee was working for the company, which means that the company bears the ultimate responsibility, Ozer said.

Under normal circumstances, companies employ experts who make sure that the trials are being properly conducted.

"They would know when IRAC is screwing up, and they would immediately report back," Ozer said. "Companies do it in self-defense, so this kind of thing doesn't happen."

The agency's refusal to file letter indicates that IRAC received inconsistent instructions. According to the letter, at an Aug. 11, 2000, meeting with ImClone, the agency signed off on a set of criteria for assessing response.

"The procedure for this assessment was included in the charter for the IRAC," the letter states. "However, the license application also contains the Quintiles Technical Manual, which has a different set of criteria for assignment of response… It is unclear… which criteria were used…"

Also, the application does not contain the computer algorithm used to assess changes in the tumor, the letter states.

Quintiles Translational is a contract research firm that conducts clinical trials. It is unclear whether the firm was involved in preparing the ImClone BLA.

A Series of Mistakes

"This is a series of bad mistakes that the company made from the very beginning of the trial design, right on through to bringing the application to FDA for approval," Ozer said to **The Cancer Letter**. "I think they not only didn't do it right, but they didn't realize that they didn't do it right."

If the files for each patient enrolled in ImClone's pivotal trial indeed do not exist at a central location, they will be difficult to reconstruct, experts say.

"These are the kinds of things that are always difficult to get from sites, even when it's done prospectively," said Mace Rothenberg, a gastrointestinal cancer expert and associate professor of cancer research at Vanderbilt Ingram Cancer Center.

"It magnifies the problem if you try to go back and try to resurrect the scans from long-dead patients," Rothenberg said. "Often, scans are destroyed after the patient dies. The hard copies contain silver, so they are recycled. If you try to get a scan off a computer tape from a few years ago—good luck. It's not an easy matter."

The company would need more than the scans to document that the trial participants were refractory to CPT-11.

"You have to have dates for the scans, dates for the treatments, and dosage of the treatments in order to make that judgment," said Richard Kaplan, a gastrointestinal cancer expert and chief of the Clinical Investigations Branch of the NCI Cancer Therapy Evaluation Program.

Mistakes in defining eligibility had the potential to bias the study, boosting the apparent activity of CPT-11 and C225, experts say.

For example, the response rate can be inflated if patients whose disease becomes stable on CPT-11 are classified mistakenly as having progressive disease and receive ImClone's two-drug regimen. Such patients may actually be responding to CPT-11, after taking a break of a few months, experts say.

Also, physicians had an incentive to put their patients on C225, an agent featured on 60 Minutes and on the cover of Business Week.

"Here you have an incredibly hyped drug, you have patients demanding it, and you have doctors wanting to do the best they possibly can for their patients," said a member of the FDA Oncologic Drugs Advisory Committee, who spoke on condition that his name would not be used. "The end result is that it's very easy to fudge the numbers—little white lies, really—to try to get your patient on a trial like this."

Several experts were surprised to find that the response rate reported by the investigators in the pivotal study was lower than the response rate reported by IRAC.

The paper presented at last year's meeting of the American Society of Clinical Oncology reported that 23 of the 120 patients treated with CPT-11 and C225 responded to the therapy. Subsequently, IRAC concluded that 27 of the 120 patients had a response. This pushed up the response rate from 19.2 percent to 22.5 percent.

"Outside independent review panels almost invariably result in lower response rates, often by as much as 50 percent," said Rothenberg. "Therefore, it's surprising that not only did they confirm the response rate, but elevated it."

Who Knew What,When, And How

Class action suits filed on behalf of ImClone shareholders argue that company executives should have known that the C225 application was in trouble.

One of the suits, filed by the law firm of Milberg Weiss Bershad Hynes & Lerach, in the U.S. District Court for the Southern District of New York alleges that the company issued press releases on the progress of its BLA, highlighting "the positive impact that the drug's approval would have on the company's revenues."

These statements by ImClone were false and misleading, the law firm said in a press release inviting plaintiffs to join the class action suit.

"Defendants failed to comply with the FDA's requirements for filing the [BLA], and defendants knew, or should have known, that their deficient application would be rejected," the law firm said.

The law firm also alleged that "defendants filed their application, despite lacking the skill and expertise to make a proper filing, in order to convince Bristol-Myers Squibb Co. to purchase at least $1 billion in ImClone stock, of which approximately $150 million was tendered by ImClone insiders."

In addition to buying a 20-percent stake in ImClone, Bristol paid the biotech firm $200 million when the BLA was filed, and is obligated to pay another $800 million if additional milestones are reached.

It appears that Bristol didn't anticipate problems at FDA.

On Sept. 26, 2001, a week after the ImClone deal was announced, Collier Smyth, BMS vice president for medical affairs, wrote a letter to prominent oncologists: "We are optimistic that C225 will be approved by FDA in the near term, and thus be available to help oncologists extend and enhance the lives of patients with cancer."

Bristol didn't draw on the expertise of its Oncology Advisory Board, a panel of prominent academics, to assess the ImClone data before the deal was completed. The advisory board was briefed on C225 on Oct. 26, 2001.

According to the agenda of the committee meeting, an overview of C225 data was presented by John Mendelsohn, the scientist who led pre-clinical development of the agent.

Mendelsohn is also a member of the BMS advisory board, a member of the ImClone board of directors, and president of M.D. Anderson Cancer Center.

Mendelsohn was followed by Susan Arbuck, Bristol's vice president for oncology clinical research, who asked the board for suggestions for further development of the agent.

"We may have been lured into the same sense of security that Bristol was," a member of the advisory board said to **The Cancer Letter**. "In retrospect, it doesn't sound to me as a very accurate portrayal of ImClone's knowledge base."

Now, it's up to Bristol to make sense of ImClone's data, experts say. "I think what Bristol got was what in the housing market would be called a 'fixer-upper,'" said Ozer.

"Let's hope it's not a tear-down."

NCI Programs:

NCI Requests $5.69 Billion To Seize Opportunities In FY03

To fully seize the "extraordinary opportunities" in cancer research and translate findings into practical applications, NCI needs a budget of $5.69 billion in fiscal year 2003, according to the Institute's annual budget proposal.

The funding request, reflecting the professional judgment of NCI officials and the Institute's outside advisors, would require a $1.5 billion increase over the Institute's FY 2002 appropriation of $4.19 billion, passed last month by Congress.

Nearly $306 million of the proposed new funding would be spent to pay NCI's commitments to research projects already underway.

About $878 million would be used for fund items listed as "NCI's Challenge."

These include:

—Fund the top 35 percent of competing grant applications.

—Increase support to cancer centers for new technology development and informatics.

—Double the number of patients accrued to clinical trials and increase per-patient reimbursement.

—Improve the cancer surveillance system.

—Support research on the quality of cancer care.

—Expand research on cancer-related health disparities.

—Develop a "Cancer Informatics Infrastructure."

—Provide more funding for cancer research training and career development.

Extraordinary Opportunities

In addition, the proposal seeks $328.8 million for "extraordinary opportunities for investment." These areas, identified by NCI in previous years as funding priorities, include:

—Genes and the Environment

—Cancer Imaging

—Defining the Signatures of Cancer Cells: Detection, Diagnosis and Therapy

—Molecular Targets of Prevention and Treatment

—Research on Tobacco and Tobacco-Related Cancers

—Cancer Communication

The National Cancer Act of 1971 requires the NCI director to send a document to the President each year outlining the Institute's professional judgment of the funding needs in cancer research. Because the budget proposal is supposed to skip the usual review levels at NIH and the Department of Health and Human Services, the document has been known as the "Bypass Budget."

The Bypass On The Web

Over the past several years, NCI's Web usability experts have worked to translate the 100-page Bypass document into a true Web site, rather than a mere copy of the printed document in HTML format, NCI officials said. The result is an extensive, but nevertheless user-friendly site, with a simple address: plan.cancer.gov.

It may be faster to get answers to questions or follow one's parochial interests by going to the Web site, rather than flipping through the pages of the publication.

The site attempts to translate the peculiar terminology of the Bypass document into simpler terms. The site's heading is "Plans & Priorities for Cancer Research," while the official title of the printed document is "The Nation's Investment in Cancer Research."

Similarly, the Web editors prefer "scientific priorities" to the more fanciful "extraordinary opportunities."

Unfortunately, the site can't seem to escape the tyranny of NCI jargon so easily. Sometimes the Web editors use both their preferred term and the Bypass term. Case in point, a the redundant headline that appears on many pages: "Scientific Priorities for Cancer Research: NCI's Extraordinary Opportunities."

No doubt what the site is all about.

While the intended audience for the Bypass budget is the Administration, Congress, and the public, another group closely studies NCI's scientific priorities/extraordinary opportunities. Cancer researchers know that a research program that appears in the Bypass budget carries great weight in the Institute at grant renewal time.

Thus the headline ought to be: NCI's Priorities=Cancer Researchers' Opportunities.

"The Nation's Investment in Cancer Research, A Plan and Budget Proposal for Fiscal Year 2003," is available at http://plan.cancer.gov.

For advice on viewing or printing the document, see http://plan.cancer.gov/info_new.htm.

The printed document may be ordered by phone 800-4-CANCER, fax 301-330-7968, or by email cisocc@pop.nci.nih.gov.

Funding Opportunities:

RFP Available

RFP N01-CP-01003-13:Record Linkage Studies Utilizing Resources I Population-Based Tumor Registries

Response Date: March 20, 2002

NCI Division of Cancer Epidemiology & Genetics would like to contract with population-based tumor registries in order to collaborate in the conduct of record-linkage and subsequent analytical investigations. The tasks of the initiative include: developing a study plan; developing or applying appropriate record-linkage procedures to link a population file with the cancer registry files; evaluating results from the record-linkage study; providing results of the record-linkage study to the NCI in the form of a computer file with appropriate documentation of record format and variables used; developing record-keeping procedures to maintain filing systems of all relevant material; and monitoring performance and providing written technical and financial reports as required under a subsequent Master Agreement Order. Optional capabilities include providing biologic specimens and providing access to other existing computerized registries that have been or could be linked to the cancer registry. Offerors will be evaluated on their qualification as a population-based cancer registry including their knowledge of the opulation at risk; ability to provide completeness of ascertainment of incident cancer cases in the population; validity of classification and coding of all cancer cases; procedures used for case follow-up; ability to provide five-year cancer incidence data; ability to maintain data in a secure environment; and qualifications and experience of the registry and personnel. In addition, offerors will be evaluated on their technical response to a sample master agreement order on a hypothetical record-linkage study. The initial Master Agreement award is non-monetary and is exclusively for the purpose of establishing a pool of contractors who are qualified to perform services for epidemiologic studies of cancer using the resources of population-based tumor registries. The RFP may be accessed through the Research Contracts Branch Home Page by using the following internet address: http://rcb.nci.nih.gov/, then Click on Current Requests for Proposals. Proposals will be due approximately 45 days after release of the solicitation package. Any MA awarded as a result of this solicitation will be in effect from the effective date to July 30, 2005.

Inquiries: Kim Hall, contract specialist, phone 301-435-3781; fax 301-480-0241; e-mail kh175r@nih.gov or Sharon Miller, contracting officer, phone 301-435-3783; fax 301-480-0241; e-mail sm103r@nih.gov.; Department of Health and Human Services, NIH, NCI, Research Contracts Br., 6120 Executive Blvd. EPS Rm 604, Rockville, MD, 20852.

RFA Available

RFA: Chemoprevention of Tobacco- Related Cancers in Former Smokers: Preclinical Studies

The initiative encourages applications for research focused on validating surrogate biomarkers for tobacco-related cancers in animal models under experimental protocols that mimic the high risk of former smokers and identifying and prioritizing agents that prevent cancers in organ systems of tobacco-related cancers using protocols which mimic the higher risk of former smokers at the time of intervention.

The RFA supports research projects that address the development, validation and application of surrogate biomarkers and the development of agents which prevent cancer in late intervention protocols which mimic the risk and are applicable to former smokers. The target organs of interest include: lung, head and neck, bladder, esophagus, pancreas, cervix, and colon. The goals of the studies are to provide surrogate markers and agents for future clinical trials to prevent cancers in former smokers. The RFA is available at http://deainfo.nci.nih.gov/concepts/chemo_smokers.htm.

Inquiries: Vernon Steele, Division of Cancer Prevention, NCI, phone 301-594-0420; e-mail vs1y@nih.gov.

Program Announcements

PA: Competing Supplements to Develop and Use Organotypic Models of Cancer

The PA solicits competing supplements from NCI-funded investigators to design and use organotypic cell cultures as alternatives to other forms of model systems for cancer research. Examples of research supported by the PA may include, but are not restricted to: development of multi-cell culture systems to delineate the roles of the different types of transformed cells in a tissue or organ; definition of the interactions among specific cell types in a tissue or organ to study the contribution of normal or mutated phenotype of each to tumors that arise in that organ; use of normal, tumor-derived, or genetically engineered cell in various combinations to mimic stromal-epithelial interactions in cancer etiology; application of organotypic cultures to therapy- or prevention-related research objectives; exploration of novel approaches to design and implementation of new organotypic culture systems.

Inquiries: Suresh Mohla, Division of Cancer Biology, NCI, phone 301-435-1878; e-mail sm82e@nih.gov

PA: Cancer Therapy-Related Use of Genetically Engineered Mice

The PA solicits research that uses genetically engineered mouse models for cancer therapy-related applications. Projects funded require that a suitable

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model is available, and are not intended to support the derivation of new models. Projects may focus on credentialing existing models through systematic preclinical trials to discover how well the mice mimic the clinical course of human cancer in response to therapy or development of resistance. Examples of research to be funded are: preclinical trials of agents in relevant genetically engineered mice to determine whether the timing and penetrance of the tumor phenotype limits the use of GEMs for therapy-related research; preclinical trials to credential GEMs for how well they reflect the observed clinical course of human cancers; experiments to determine the pharmacodynamics and pharmacokinetics of specific agents in GEMs; preclinical trials that incorporate use of high-throughput technologies or small-animal imaging to monitor response to therapy; preclinical trials to determine efficacy of new single or multiple agents at different stages of tumor progression; preclinical trials that examine which aspects of trial design are appropriate for experiments with GEMs.

Inquiries: Cheryl Marks, Division of Cancer Biology, NCI, phone 301-594-8778; e-mail cm74v@nih.gov

PA: Innovative Toxicology Models for Drug Evaluation: Exploratory/Developmental Grants (R21,R33) and Phased Innovation Award (R21/R33) (Reissued)

The initiative encourages the discovery, standardization, and validation of models to determine or predict toxicological profiles of new agents under pre-clinical development. The toxicity models that will be discovered and validated will be designed to predict toxicological profiles or specific organ toxicities and will aid in the drug development process for new therapeutic agents. Projects could range from very early assay development to the standardization and validation of assays currently under evaluation.

Inquiries: Adaline Smith, Developmental Therapeutics Program, phone 301-496-8777; e-mail smithad@mail.nih.gov

Other Funding Notices

NOT-CA-02-008: Development of Dosage Forms and Delivery Systems for Antitumor Agents

Pharmaceutical Resources Branch of the Developmental Therapeutics Program, Division of Cancer Treatment and Diagnosis, NCI, seeks contractors to develop dosage forms for compounds, selected and provided by NCI, to be evaluated in cancer patients. In addition to solubility studies, the projects may require analytical work, particularly the development of a stability-indicating assay to monitor the integrity of the parent compound during the formulation studies. The principal investigator should possess a Ph.D. in pharmaceutics or medicinal chemistry and should also have at least three years experience in the development of injectable formulations. It is anticipated that three cost-reimbursement term (level of effort) type contracts will be awarded for five years. The RFP is available at http://rcb.nci.nih.gov/.

Inquiries: Diane Stalder, contract specialist, Treatment, Biology and Sciences Section, RCB, NCI, Executive Plaza South, 6120 Executive Blvd MSC 7220, Bethesda, MD 20892-7220, phone 301-435-3822; e-mail ds88b@nih.gov; fax 301-402-6699.

NOT-CA-02-005: Rapid Access to Intervention Development

Request Receipt Date: Feb. 1 and Aug 1

NCI requests applications for the RAID initiative. RAID will make available to academic investigators, on a competitive basis, the preclinical development contract resources of the NCI Developmental Therapeutics Program. The goal of RAID is the rapid movement of molecules and concepts from the laboratory to the clinic for proof-of-principle clinical trials, using NCI's contract research mechanisms. RAID will assist investigators who submit successful applications by providing any (or all) of the preclinical development steps that may be obstacles to clinical translation. These may include, production, bulk supply, GMP manufacturing, formulation and toxicology. Suitable agents will include small molecules, biologics or vaccines. Information is available at http://dtp.nci.nih.gov/.

Inquiries: RAID, Office of Associate Director, Developmental Therapeutics Program, NCI, Executive Plaza North Bldg., Suite 8022, 6130 Executive Blvd., Rockville, MD 20852, phone 301-496-8720; fax 301-402-0831; e-mail raid@dtpax2.ncifcrf.gov

NOT-CA-02-009: Continuing Receipt Dates for NCI Cancer Education Grant Program R25

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

NCI gives notice of the above continuing receipt dates for applications submitted in response to PA: PAR-00-033, and its Addendum Notice CA-00-012. The PA can be accessed at http://grants.nih.gov/grants/guide/pa-files/PAR-00-033.html. The addendum can be accessed at http://grants.nih.gov/grants/guide/notice-files/NOT-CA-00-012.html.

Inquiries: Maria Agelli, NCI, Centers, Training and Resources Program, Cancer Training Branch, 6130 Executive Blvd., Rm 520, MSC 7390, Bethesda, MD 20892-7390, phone 301-496-8580; fax 301-402-4472; e-mail ma215e@nih.gov

NOT-OD-02-019: Changes in Grantee/Contractor Reporting of Intellectual Property Utilization

Effective Jan. 1, 2002 requirements for reporting

of invention utilization will be changed to include the commercial name of any FDA-approved products, utilizing any subject invention, which have reached the market during the annual reporting period. The reporting procedure and new list of utilization questions are summarized in the Notice and are available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-019.html.

In Brief:

Roswell Park Wins Grants For Young Investigators

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received 28 awards through the New York State Breast Cancer Research and Education Fund. The awards include two Empowerment through Innovative Research and Education grants for preliminary research and two postdoctoral fellowships for the continued training of junior investigators. The grantees received $100,000 for each project. EMPIRE awardees are: **William Kraybill**, Department of Surgery; **Xinhiu Wang**, Department of Immunology. Postdoctoral fellowship grantees are: sponsor, **John Subjeck**, fellow, **Massoud Manjili**, Department of Molecular & Cellular Biophysics; sponsors, **Clement Ip**, **Bonnie Asch**, fellow, **Yang Dong**, Department of Experimental Pathology. Roswell Park also received a three-year, $300,000 award from the American Cancer Society for a preventive medicine training track in cancer prevention and control within the Department of Cancer Prevention, Epidemiology & Biostatistics at RPCI. The training program for resident physicians will be a component of the General Preventive Medicine Residency Program, Department of Social and Preventive Medicine at the University of Buffalo. The principal investigator for the grant is **Martin Mahoney**, research scientist, Department of Cancer Prevention, Epidemiology & Biostatistics at RPCI, and associate professor, Department of Family Medicine at UB. Participants will complete a two-year General Preventive Medicine Program at UB, including both a year of graduate study leading to a Master of Public Health degree and a practicum year. "Training the next generation of physicians with a specialization in cancer prevention and control is an investment in the future," said Mahoney. "These young doctors can facilitate the expansion of cancer surveillance to improve monitoring of progress in cancer control." . . . **CORRECTION: Robert Wittes** is not the editor-in-chief of the journal Oncology, as reported in the Dec. 7 issue of **The Cancer Letter**. Wittes served as editor-in-chief for many years, but the current editors-in-chief are **Martin Abeloff**, **James Armitage**, **Allen Lichter**, and **William Wood**.

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