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New Grant Program To Fund Partnerships Between Academia, Industry, Non-Profits

Advisors to NCI last week approved the Institute's plan to create a $20-million grant program that would support up to six partnerships between academia, industry, and non-profit organizations for discovery and development of cancer therapies.

The Academic Public-Private Partnership Program, or AP4, is designed to encourage academic researchers to work with industry and non-profit organizations to conduct basic research that could lead to the development of cancer therapies. Since emerging therapies are likely to target specific subtypes of cancers, the therapeutics market may become

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In Brief:

UCLA Forms Environmental Genomics Program With $1M Gift; ASBMT Installs New Officers

UCLA Jonsson Cancer Center and the School of Public Health received a $1 million gift to create the Ann Fitzpatrick Alper Program in Environmental Genomics. The program, which will be headed by **Robert Schiestl**, professor of pathology, environmental health, and radiation oncology, will explore how pollutants interact with genetics to cause a variety of cancers. Alper was an environmental activist who died of lung cancer. The gift from Art Alper is being augmented by the Kenneth Jonsson Family Foundation and the Jonsson Cancer Center Foundation, bringing the gift to $1 million. . . . **AMERICAN SOCIETY for Blood and Marrow Transplantation** has installed new officers. **Joseph Antin**, chief of the Stem Cell Transplant Program at Dana-Farber Cancer Institute, was elected president. **Nelson Chao**, professor of medicine and director, Division of Hematology, Duke University Medical Center, was elected vice president, to become president in 2005. **C. Fred LeMaistre**, has been elected treasurer. LeMaistre is director of the Texas Transplant Institute in San Antonio. The following directors were elected: **John DiPersio**, Washington University Medical School; **Jan Jansen**, Indiana Blood and Marrow Transplantation; and **Effie Petersdorf**, Fred Hutchinson Cancer Research Center. President-elect **Armand Keating**, head, Department of Medical Oncology and Hematology, Princess Margaret Hospital/Ontario Cancer Institute, will become president in 2004. He is also director of the Division of Hematology-Oncology at Mount Sinai Hospital, Toronto, and professor of medicine and director of the Division of Hematology, University of Toronto.

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Partnerships May Reduce Development Risk, NCI Says

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fragmented and less attractive to industry, NCI officials said.

"If we can develop these kind of partnerships, then we can reduce the risk to the private sector," said Anna Barker, NCI deputy director for strategic scientific initiatives. "The private sector has got to adopt cancer in a much more major way than they currently embrace cancer, and most of our diseases are going to evolve into orphans, if targeting pays off. Targeting has to pay off for us, actually, to hit our 2015 goals."

NCI Director Andrew von Eschenbach recently announced that the Institute's goal is to "eliminate the suffering and death from cancer by 2015" (**The Cancer Letter**, Feb. 14, 2003).

The NCI Board of Scientific Advisors approved the concept for AP4 at a meeting March 2. Under the proposal, NCI would set aside $1.125 million in fiscal 2004 to fund up to 15 one-year planning grants. The planning grant winners would compete in FY 2005 for the AP4 grants.

AP4 would give academic institutions up to $450,000 a year for five years, if the institution can line up $300,000 a year from industry or non-profit organizations.

Small companies are likely to be more interested in the program than "big pharma," said Edward Sausville, director of the Developmental Therapeutics Program, and program director for AP4. "It may not be terribly attractive to companies of a certain grain size, because, quite frankly, why should they bother? They have their own in-house discovery," he said in presenting the concept to the BSA.

"A Very Big Undertaking"

BSA members who served as primary reviewers expressed enthusiastic support for the concept, but said setting up these partnerships may present a challenge to academic institutions.

"The idea of bringing multidisciplinary groups together to speed drug discovery seems to me something no one could disagree with, and most would agree it's not simple to do," said BSA member Robert Young, president of Fox Chase Cancer Center. "This grant structure really provides a vehicle to explore the potential of getting academic institutions, for-profits, other governmental funding mechanisms, as well as disease advocacy groups together. There clearly is a lot of interest on the part of states in investing in programs which bring business into their state, and this has the potential of doing exactly that."

Young said the planning grant funding should be larger and last longer than a year. "Particularly getting multiple for-profits to agree on the intellectual property involved with these kinds of mechanisms may be a real challenge," he said.

"I think it's not clear-cut that it can work successfully," Young said. "I view it as an experiment. I think it's an experiment well worth carrying out."

BSA member Susan Horwitz, the Falkenstein Professor of Cancer Research at Albert Einstein College of Medicine, said the planning grant should continue for 18 months. "This is a very big job of setting these centers up," she said. "If you can do it in a year, that would be great, but I really feel this is a very big undertaking."

BSA member Shelton Earp, director of the Lineberger Comprehensive Cancer Center, said planning grants may not be necessary. "I think that putting this together will be somewhat difficult, but getting it together will be the real mark of institutional commitment and your partnership," he said. "You will sharpen the focus quickly about who is involved by not having a planning grant.

"Give it a year's lead-in time," Earp said. "The intellectual property problems are going to be very difficult and probably will not get solved until the last

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BSA member Richard Schilsky, associate dean for clinical research, University of Chicago, questioned the necessity of the AP4 program.

"If a center is successful in lining up one or more partners, then why shouldn't they just make a business deal and leave the government out of it?" Schilsky said. "If there are supposed to be multiple partners, and multiple for-profit partners, the probability of reaching a successful conclusion in [intellectual property] negotiations would be extremely unlikely. I'm unclear on what the NCI money is to be used for?"

Sausville said the NCI funds would be flexible, and could be used for research support, core resources, or almost anything the centers might propose. "That's not an insignificant chunk of change," he said. "Companies like the idea of participating in something that has the imprimatur of NIH peer review. Why not do a direct business deal? Sure, if they can, there's no need for us, then do it. Along the lines of the experimental nature, it would be interesting to see whether as a result of this we actually see some things happen."

William Kaelin, professor of medical oncology, Dana-Farber Cancer Institute, noted that his center has a research agreement with Novartis. "The one thing I've been constantly reminded by Novartis and companies like Novartis is that it's not that they have forgotten how to make drugs, or have lost interest in making drugs, it's simply that the only thing they really need from us are the targets, and they are really good at making drugs if we deliver the targets," Kaelin said.

"Getting back to [NCI's] 2015 milestone, a lot of what we need to be thinking about is, How do we deliver the next generation of targets?" Kaelin said. "Because, frankly, by historical standards, they should be on the blackboard now if we're going to have drugs to meet the 2015 deadline."

BSA member Mack Roach, professor in residence, radiation oncology, University of California, San Francisco, said the program didn't appear worth the money, considering that NCI budgets are likely to be tighter in coming years.

"When you have less money available, at a very difficult time, I feel a little uncomfortable being enthusiastic about an intellectual property nightmare in an underserved disease area," Roach said.

"Universities are going to have to think out of the box from the usual ways of dealing with government money and intellectual property," Sausville said.

William Wood, chairman of surgery at Emory University School of Medicine, said NCI should track how the partnerships are formed. "Many of the [concepts] we pass are a bit of an experiment, but I think it would be most unfortunate if this experiment goes unreported," he said. "Somehow, the lessons learned about how the partnerships are formed, which ones are successful, [need to be documented] if this is going to be maximally useful as an investment by the NCI."

NCI's Barker said she is looking at the overlap in some of the Institute's programs. "We have SPOREs, NCDDGs, SBIRs, RAID, centers, and now we have AP4," she said. "This is all directed at development, and we are really struggling with this transition from basic science into development, because academic medical centers are not development centers, generally. They are discovery centers.

"AP4 addresses that," Barker said. "I think it's going to call the question of how much discovery we have that's translatable. I think there's not nearly enough money in this, but that's my opinion. This is potentially something that, if it works as a model, we should put additional funds into it.

"I think this is an interesting model, and we will use it as potentially a synthetic approach to looking at these other models we're using, because there's lots of overlap here and lots of opportunity to bring tech transfer, intellectual property, some of these issues together to facilitate everything we're doing," Barker said. "This will be an interesting discovery process for us. We have a systems development problem here we really have to do something about."

"[AP4] will fit in to a larger array within our portfolio that Anna Barker has the responsibility for looking at overall, and managing," NCI Director von Eschenbach said. "We are looking for the outcome of the experiment, the best practices, and then, how one mechanism may result in the ability to downsize or eliminate or refocus other mechanisms."

The partnership program concept was approved with none opposed and two abstentions, by Wood and Roach.

The planning grant concept was approved with Wood and Earp opposed, and BSA member David Alberts, of Arizona Cancer Center, abstaining.

The edited text of the concept statements follow:

Academic Public-Private Partnership Program.

Concept for a new RFA, cooperative agreement, first-year set-aside $4.725 million, six awards for five years, total cost $19.731 million. Program director: Edward Sausville, Division of Cancer Treatment and Diagnosis, tel: (301) 496-8720, email: sausvile@mail.nih.gov.

The cost of discovering and developing a drug to the point of filing a New Drug Application to allow sale to the public is now estimated at more than $800 million, and requires up to 15 years of research, clinical trials, and marketing. At the same time, emerging science has revealed subtypes of human cancers using specific genetic markers that could potentially decrease the population of patients who might be the potential recipients of such rationally designed drugs, diagnostic, and imaging technologies. This raises the possibility of creating "orphan status" markets, traditionally f less interest to large pharmaceutical companies. This concern, that "big pharma" may actually lose interest in an "orphanized" cancer market, might be addressed by defining partnerships that would leverage the risks of cancer intervention discovery and development of the future. NCI desires to catalyze these continuing partnerships, particularly between academia and industry, to realize the promise of the molecular revolution in cancer biology.

In the fall of 2001, the Office of Scientific Planning and Assessment convened a committee of NCI staff charged with outlining an implementation plan which would make the public-private partnership concept a reality. OSPA identified a potential model for NCI activities in the Industrial/University Cooperative Research Center, an initiative originally developed by the National Science Foundation (www.eng.nsf.gov/iucrc/).

NCI proposes that its modification of this approach, to be called the Academic Public-Private Partnership Program (AP4), would constitute a novel mechanism for the NCI. AP4 features are envisioned to include:

—An academic director located in a university setting who conceives of and coordinates the center.

—Academic center-related participants need not be located in the same institution.

—Industry and/or non-profit partners who contribute financially to each center.

—Participation by state or local government is possible and would be encouraged.

—A Steering Committee of the membership of each center which approves ongoing and completed activities and recommends new projects, responding to current dynamic opportunities.

—A membership agreement which specifies how the center is governed, as well as the prospective management of intellectual property issues and publication procedures.

—Facile access to the development contract resources of the Developmental Therapeutics Program for promising lead compounds approved by the center Steering Committee. Criteria for NCI interest would follow the same guidelines as those compounds or biological constructs presented to the Drug Development Group.

The ideal partnership would be anchored at an academic center and include industrial partners, non-profit organizations, and disease-oriented charities, each with an interest in translating novel anticancer therapeutic, prevention, diagnostic, and imaging interventions from the laboratory to the clinic. Each center partner could focus on different functional areas of the intervention discovery and development process. Alternatively, partners could agree to pool their resources to support one aspect of a discovery and development program; the actual roles and goals of each center's corporate members would be articulated by the academic center director in the membership agreement which governs each center's operations. There would be an initial suite of selected research projects, of interest to the partners, to be conducted at the university, and upon which approval of the application would be partially based. Major criteria for review would encourage that the research approach take advantage of the latest technologies, allowing the center to change the way molecules and other intervention technologies are discovered and developed, and focus on diseases that are underserved.

The NCI program director would attend meetings, serve as a non-voting member of the Steering Committee, and facilitate accession of NCI resources, and lend research expertise and advice to the center. The SC would be vested with the authority to make go/no go decisions on current projects and bring new projects to the center. NCI envisions that project management would be dynamic: in the lifetime of a center, funds could be shifted freely from one project area to another at the discretion of the academic center director and with concurrence of the center membership according to processes articulated in the center agreement. The effort would thus differ fundamentally from traditional P01 or other grant arrangements funded by NCI, where defined projects are expected to continue for the life of the grant.

The centers would be catalyzed by a $450,000 per year (direct costs) investment from NCI, with a minimum of $300,000 per year (total) funds coming from center members. For centers with a combined partnership investment of at least $450,000, the NCI's annual contribution would increase to $600,000 (direct costs). Awards would be for a period of five years, subject to annual review and approval by the NCI program director. For centers where the annual evaluation is deemed unsatisfactory by the NCI program director, a subcommittee of the BSA would be formed to determine if funding should be discontinued. In the event of a recommendation to end funding, an arbitration panel consisting of NCI representation, the center academic director, and an arbitrator acceptable to both parties would make the final decision. Funding in year four would be at 75% of the initial level, and in year five at 50% of the initial level to encourage the centers to acquire additional

contributing partners and to prepare to become self-sustaining entities. A second five-year award of $100,000-$200,000 (direct) per year could be made to centers successful in meeting their established goals. After 10 years, the centers which continue to operate would be expected to be fully supported by industrial, non-profit, other federal agency, and/or state and local government partners.

Purpose of RFA: NCI is seeking approval to create partnerships between academia, industry, non-profit institutions, and government to stimulate novel cancer therapeutic, prevention, diagnostic, and imaging intervention-directed research which takes advantage of the latest discovery and development technologies with a focus on orphan diseases, using a multidisciplinary approach. This effort would begin with a one-year planning grant, which will be utilized by the proposed academic director to bring together potential partners and to put together the center application. Applicants to AP4 will emerge from those successful in the competition for the AP4 planning grant, which is the subject of a companion RFA. The actual center proposal would have a clearly articulated roster of committed partners along with a detailed description of how the partners would interact. Additional information in a successful center application would include:

—Definition of the partners who will participate with the academic center as members of the Steering Committee.

—Definition by the membership of the relationships between the investigators that would comprise the multidisciplinary components of the center.

—A membership agreement that would specify the organizational structure of the center, its decision making policies for taking on and termination projects, its administration, core and shared service functions.

—Additionally, the membership agreement which describes prospectively how intellectual property will be shared by center members and define a publication and patenting policy.

The research would occur at the academic centers with the advice and support of industrial and non-profit institute partners and the NCI. NCI anticipates that selected research projects would be of great interest to the pharmaceutical industry as a whole and would be initiated as basic research projects leading to novel interventions for human clinical trials. Applied tasks such as manufacturing issues, pharmacology, toxicology, or formulation research could be taken on by industrial partners, contracted out by charity partners, or by the development contracts of DTP after meeting criteria for NCI interest.

The impetus behind the creation of such a program is to promote public-private partnerships to advance our basic knowledge of the molecular biological events which lead to the cancer phenotype, and to apply that knowledge to the development of novel cancer interventions. The strategy addresses an important problem: how to discover new, more effective treatment, diagnostic, and prevention interventions for cancer and to bring together the necessary expertise over multiple disciplines to shorten the time required to develop and deliver these interventions to cancer patients.

Each center will select research projects of great relevance to the discovery of new agents for cancer therapy, prevention, and diagnosis. The main features of an AP4 center are envisioned to include:

—The center is based at a U.S. academic institution; the academic director is responsible for all coordination and operational aspects of the center.

—Membership includes at least two non-academic partners, ideally with non-overlapping or complementary interests. Local and state governments, non-profit organizations as well as large or small companies would be eligible for membership.

—A Steering Committee comprised of representatives from all center members. This committee will review and approve the continuation or discontinuation of projects, additional resources for projects, and recommend new research projects.

—A minimum of $300,000 in membership fees from participating industrial and non-profit concerns obtained per year would qualify the center for $450,000 in direct costs per year for the first three years from NCI. Centers which obtain at least $450,000 yearly membership fees would qualify for $600,000 in direct costs for the first three years from NCI.

—The center should be multidisciplinary, with representation, for example, from chemistry, biology, immunology, and screening technologies.

—A program administrator must be appointed who will be responsible for assuring that a center evaluation process, which includes standard feedback forms describing the progress of each project, is conducted as part of each SC meeting.

—Selected research projects are anticipated to be of interest to the pharmaceutical industry as a whole and are initiated as basic research which could culminate as interventions. The initial review, to secure funding, should showcase at least five projects coordinated by the academic director for the initial year of funding, with clear evidence of criteria for go/no go decisions and evidence of the ability to recruit new project areas for the full period of funding.

—AP4 is anticipated to be a dynamic initiative. Not all projects or investigators may be funded for the duration of the agreement. The SC is vested with the capacity to add, delete, or evolve the resources associated with particular projects. The NCI program director will offer perspective on these issues, but will not direct the work.

—Renewal of annual funding will occur according the usual criteria for multiyear commitments.

—Fast access to the development contract resources

of the Developmental Therapeutics Program (formulation, bulk synthesis, pharmacology, toxicology) for promising lead compounds approved by the center Steering Committee, provided that the agent selected meets criteria used by NCI evaluate its other drug development opportunities.

—IND-filing assistance through the Cancer Therapy Evaluation Program for an NCI-based clinical trial or a principal investigator-based trial will be afforded on a case-by-case basis. This may involve assistance in putting together INDs when held by the originating center or assumption of the IND if the agent is to be studied more broadly in NCI's existing early clinical trials groups.

—A membership agreement must be signed by all participants which includes membership rights and fees, publication rights, patent rights, and definition of the terms of royalty-free, non-exclusive licenses to members, and must follow "NCI Principles and Guidelines for Sharing of Biomedical Search Resources" to address the sharing of easily-transferable research findings.

Each center would be required to submit an annual report to the NCI DTP program director. These reports would be used as a basis for assessing annual performance and determining continued funding. The reports should include major accomplishments, the operating budget, completed center evaluation, research goals, and the process being used to communicate with center members.

Evaluation metrics should be determined by each center and should be included in the center application. Metrics could include an accounting of the center's success in attaining the goals outlined in the application.

Academic Public-Private Partnership Program Planning Grant. Concept for a new RFA, 15 one-year awards, total $1.125 million. Program director: Edward Sausville.

Only recipients of a planning grant will be eligible to submit an AP4 center application. Elements of a successful planning grant might include:

—A summary of the proposed projects, how the projects would impact the diagnosis, prevention, or treatment of cancer or a specific cancer, and how the areas of research are appropriate to an academic environment.

—A brief description of the capabilities of the university, including faculty and infrastructure.

—The organization of the center, policies, management plans, and operational procedures.

—Costs for the center.

—An outline for a meeting with potential partners designed to determine the research agenda and its viability.

—A description of the managerial experience of the proposed academic director, and the roles of other researchers in performing the proposed studies.

—Letters from potential center members stating that the proposed research agenda of the center in concordant with the organization and that the organization would consider joining if the center were formed.

A letter of intent would precede the application and be reviewed by the NCI program director. A $50,000 (direct) one-year planning grant, which would be competitive and peer-reviewed, would be utilized by the proposed academic center administrator to study the feasibility of developing the pharmaceutical/non-profit/academic interaction necessary to establish and support a center, and to actually prepare the application. The planning grant period should include a meeting that brings together potential members to explore opportunities, define how intellectual property issues would be handled, and establish a research plan. The ideal planning grant would arise from an academic center with a clear track record in cancer biology with an overall theme and/or disease identified, along with a range of potential partners to be sought in actualizing the program, and resources to be brought to the program by the institution—letters of commitment to join a center would be desirable, but not necessary, for the planning grant.

Pharmaceutical Industry:

BMS Settles FTC Charges Of Obstructing Generics

Bristol-Myers Squibb last week settled the Federal Trade Commission's charges that it engaged in anticompetitive acts to obstruct generic competitors.

The agreement announced March 7 includes the cancer drugs Taxol and Platinol, and the anti-anxiety agent BuSpar. Together, these drugs contributed about $2 billion in annual sales, the commission said.

"This case, and others we have brought and will bring, stands for an important proposition: competition must be on the merits, not through misusing the government to stifle your competition," Timothy Muris, FTC chairman, said in a statement.

Earlier this year, Bristol agreed to pay $670 million to settle a series of related suits brought by state attorneys-general (**The Cancer Letter**, Jan. 10). For more than two years, FTC acknowledged that it was investigating Bristol's conduct in the Taxol dispute. However, the agency's 27-page complaint against Bristol was not filed in court, and was first made public at the same time as the settlement agreement.

The documents are posted on the agency's Web site www.ftc.gov/opa/2003/03/bms.htm

"The company has agreed to these proposed terms in order to achieve a resolution of these matters which will allow it to continue its focus on discovering and developing quality medicines," the company said in a statement.

The state attorneys-general deferred to FTC to negotiate the injunctive relief provisions of the actions against Bristol. The states sued the pharmaceutical company over its efforts to protect Taxol and BuSpar, and did not involve Platinol. While the settlement of the BuSpar case has been completed, some issues related to the Taxol litigation are being worked out by the company and the states, sources said.

The settlement agreement with FTC prevents Bristol from making repeated use of 30-month stays that under FDA regulations allow companies to resolve patent disputes. Companies can obtain extension by listing disputed patents in the FDA Orange Book. Repeated use of this grace period allows pharmaceutical companies to continue blocking generics from entering the market.

Thus, a pharmaceutical company can claim one 30-month extension, and, just before the term runs out, it can claim another patent dispute and obtain another 30-month grace period to resolve it. Such consecutive claims constitute a loophole in the Hatch-Waxman legislation, which several legislative proposals are seeking to close.

According to an FTC study, disputed patents for Taxol, Platinol and BuSpar were among eight such patents listed in the Orange Book after generic competitors sought FDA approval for a competing generic version of the agent. Such patents are known in regulatory shorthand as "later-listed patents."

The FTC complaint states that the listings were "improper and unlawful, because the patent did not meet the statutory listing criteria, and Bristol could not reasonably believe that it did."

Under the agreement with FTC, Bristol will be prohibited from obtaining 30-month stays on later-listed patents. The agreement also bars Bristol from obtaining 30-month stays in cases where Bristol engaged in "misconduct in connection with obtaining and listing the patent," FTC said.

According to the agreement, misconduct would include "inequitable conduct before the Patent and Trademark Office in obtaining the patent; making false or misleading statements to the FDA in connection with listing the patent; or providing information about the patent to the FDA that is inconsistent with information provided to the PTO."

"Through Bristol's decade-long pattern of alleged anticompetitive acts, Bristol avoided competition by abusing federal regulations in order to block generic entry; deceived the PTO to obtain unwarranted patent protection; paid a would-be generic rival over $70 million not to bring any competing products to market; and filed baseless patent infringement lawsuits to deter entry by generics," said Joe Simons, Director of the FTC's Bureau of Competition. "The consent order will prohibit Bristol from engaging in unlawful behavior that keeps competitive generic products off the market and harms consumers."

By denying Bristol the benefit of the 30-month stay on later-listed patents, the order would reduce Bristol's "incentive to engage in improper behavior before the PTO and the FDA to obtain and list a patent for the purpose of obtaining an unwarranted automatic 30-month stay," the commission said.

The agreement does not limit Bristol's ability to sue generic companies for patent infringement under ordinary federal litigation procedures or to obtain a preliminary injunction to prevent sale of the generic product before conclusion of the suit if Bristol can demonstrate a likelihood of success on the merits, FTC said.

The agreement restricts Bristol's ability to act in concert with other firms to delay generic competition.

The FTC complaint states that Bristol had entered into two agreements with other companies to obstruct competitors.

"Before any ANDA for generic paclitaxel obtained FDA approval, BMS conspired with American BioScience Inc. to list improperly a … patent in the Orange Book… and thereby triggered again Hatch-Waxman's 30-month stay provision, and thus continued the BMS monopoly in the market for paclitaxel-based drugs," the complaint states.

The complaint also states that Bristol paid a potential BuSpar competitor Schein Pharmaceutical Inc. $72.5 million to refrain from competition until the Bristol patent expired.

Bristol's franchise extension strategy was part of an overall drive to increase sales and profits. Earlier this week, the company released its revised earnings for the years 1999 through 2001 and the first three quarters of 2002.

Overall, the restatement reduced net sales by $1,096 million, $475 million and $409 million for the years ended Dec. 31, 2001, 2000 and 1999. Net sales and pre-tax earnings for the six months ended June 30, 2002 were increased by $533 million and $401 million, respectively. In addition, net sales and pre-tax earnings were increased by approximately $860 million and $620 million, respectively, in the six months ended Dec. 31, 2002.

Waksal To Pay Back $800,000 In Profits From Stock Sales

Samuel Waksal earlier this week settled a civil suit in which the Securities and Exchange Commission contended that he had purchased put options on his former company, ImClone Systems Inc.

The purchase of the options, a new detail in the ImClone controversy, would represent an effort by Waksal to profit from the decline in stock price that followed the company's announcement that FDA would refuse to file the application for the cancer agent Erbitux.

In an amended complaint filed with a settlement agreement March 11, SEC said Waksal purchased 210 put options on ImClone through a Swiss brokerage house on Dec. 28, 2001. After the market closed on the same day, ImClone announced the FDA's action, precipitating a stock price decline on the next trading day, Dec. 31.

By placing this safe bet on the bad news he was about to announce, Waksal profited $130,000, SEC said.

Without admitting or denying the allegations, Waksal consented to the partial final judgment, agreeing to pay back $804,367 in profits from the put options transaction and the transactions involving the sale of his own and his daughter's ImClone stock ahead of announcing bad news.

The former ImClone executive also agreed never to serve as an officer or a director of a publicly traded company.

According to court documents, Waksal was first told about the upcoming RTF letter on the evening of Dec. 26, 2001.

"By selling before the announcement that ImClone had received an RTF letter from the FDA, Waksal illegally avoided trading losses and received illegal options trading profits," SEC said. According to SEC, Waksal failed to file the required documents disclosing his purchase of ImClone put options.

The SEC complaint against Waksal is posted at www.sec.gov/litigation/complaints/comp18026.htm

"We are glad that we have been able to reach this settlement with the SEC, and that Dr. Waksal will be able to put this part of his legal issues behind him," Waksal attorney Lewis Liman said in a statement.

Waksal's sentencing on related criminal charges is scheduled for May 29.

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