THE CANCER LETTER

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Senate Committee Passes Bill To Speed FDA Approval Of Follow-On Biologics

By Paul Goldberg

The Senate Health, Education, Labor and Pensions Committee earlier this week passed legislation that would speed approval of follow-on biologics.

The committee passed the bill in closed session June 27, and the legislation is expected to be inserted in the FDA Reform Act in the House-Senate conference.

It is likely that the House will have to pass some version of the bill, too, Capitol Hill insiders say. One was introduced by Rep. Henry Waxman (D-Calif.), and the other by Rep. Jay Inslee (D-Wash.)

The Congressional action is part of a worldwide effort to make it easier

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In the Cancer Centers:

Dana-Farber Cancer Institute Breaks Ground For First New Clinical Building In 30 Years

DANA-FARBER Cancer Institute broke ground June 18 on the Yawkey Center for Cancer Care, an outpatient care and clinical research facility. The 275,000-square-foot building—the center's first new clinical building in more than 30 years—will house adult clinical services, as well as translational research space and patient and family services. The facility is named in honor of the Yawkey Foundation for its $30 million gift. The building should be ready for occupancy in early 2011, the institute said. The groundbreaking drew several public officials, including **Sen. Edward Kennedy** (D-Mass.), Massachusetts Governor **Deval Patrick**, **Rep. Michael Capuano** (D-Mass.), Boston Mayor **Thomas Menino**, State **Rep. Jeffrey Sánchez**, Boston City Councilor **Michael Ross**, and three former Red Sox players: **Carl Yastrzemski**, **Johnny Pesky**, and **Rico Petrocelli**. . . . **MOORES UCSD** Cancer Center has received NCI renewal of its Cancer Center Support Grant, providing $21 million over the next five years. In a separate but related review process, the center also received NCI renewal of its status as a comprehensive cancer center. The grant covers administrative costs associated with research programs and operating 10 core facilities for the center's 330 clinicians and scientists. The award marks 28 years of continuous federal funding support, said **Dennis Carson**, the center director. . . . **FRED HUTCHINSON** Cancer Research Center of Seattle has established a Vaccine and Infectious Disease Institute to develop and implement prevention strategies for infectious

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Sponsors Would Have 12 Years Exclusivity Under Senate Bill

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for sponsors of "follow-on biologics" to compete with the agents' original sponsors. Last week, European authorities recommended approval of three versions of erythropoietin, which would compete with the erythropoiesis stimulating agents marketed by Johnson & Johnson, Roche, and Amgen Inc.

The version of the follow-on biologics bill passed by the Senate HELP committee gives the sponsors of biologics up to 12 years of "data exclusivity," counting from the time they receive FDA approval.

An earlier version of the Senate HELP bill called for five years of data exclusivity. This would have given biologics two years less data exclusivity than small-molecule drugs, which have five years of exclusivity. In Europe, the data exclusivity period for drugs and biologics is limited to 10 years, with an extra year that can be added for products when new indications are developed during the first eight years.

"This is an area of law where it is vital to be precise in legislative drafting," Sen. Edward Kennedy (D-Mass.), chairman of the HELP committee, said in a statement. "In the bill as filed, we used the phrase 'first licensed' to make clear that 12 years of exclusivity applied solely to the initial approval of a product, not to subsequent minor modifications. We added a new provision to provide greater clarity, specifying that this phrase 'first licensed' does not apply to any supplemental application or even a new license for a 'new indication,' route of administration, dosage form or strength."

In letters to the committee, the biotechnology industry and the Bush Administration are suggesting that the data exclusivity period should be extended beyond 12 years, that clinical trials of follow-on biologics be required, and that branded biologics should be exempt from substitution with generics. In the case of drugs, payers often mandate automatic substitution with generics, sometimes without notifying patients or doctors.

In a letter to the bill's sponsors, AARP wrote that the 12-year exclusivity period would be excessive. "Our members cannot afford to wait a minimum of twelve years for medication therapies that aid in the treatment of diseases like multiple sclerosis and cancer," wrote David Sloane, head of the association's government relations. "Every day, many forgo medicines they should be taking, but simply cannot afford. The price is even higher and options more limited for individuals who rely on biologic drugs. A person living with MS, for example, might spend from $16,500 to $29,000 each year on their biologic MS therapy."

The letter was sent to the bill's Senate sponsors: Kennedy, Michael Enzi (R-Wyo.), Hillary Clinton (D-NY), Charles Schumer (D-NY) and Orrin Hatch (R-Utah).

In separate written comments to the sponsors of the Senate bill, HHS Secretary Michael Leavitt and the biotechnology industry officials said the 12-year data exclusivity period would be insufficient.

"We continue to believe that a strong case has been made that 14 years of data exclusivity is the needed period required to strike the right balance between providing incentives for innovation and follow-on product entry," wrote Jim Greenwood, president and CEO of BIO.

The 14-year protection would be equivalent to the maximum term of exclusivity provided for small molecule pharmaceuticals under the Hatch-Waxman Act, Greenwood said. The patent term restoration provisions of the law that established the generic drug industry provides for up to 14 years of on-market patent life.

In a letter to Kennedy, HHS Secretary Leavitt wrote that additional exclusivity should be given to pioneer companies as an incentive to further develop their products. "The administration is pleased that the bill would provide for 12 years of data exclusivity, but is concerned that it does not include an additional period as an incentive to conduct trials supporting the approval of

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a new label indication, as is currently the case for other drugs," Leavitt wrote in a letter dated June 26.

The controversy over the duration of data exclusivity is evident in the two House bills: the Waxman measure offers no data exclusivity for pioneers, and the Inslee measure offers 14 years of protection.

The bill requires sponsors of follow-on products to conduct a clinical study that would assess immunogenicity, pharmacokinetics or pharmacodynamics of the new product. The studies would have to be "sufficient to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed."

Under the Senate bill, FDA would be given the authority to determine how much data would be needed to approve specific applications. Leavitt wrote that the administration believed that sponsors of the follow-on biologics should meet the same approval standards as innovator products.

Follow-on products shouldn't be interchanged with pioneer drugs without a physician's advice, Leavitt wrote, echoing the industry's concern.

"For many follow-on products, there is a known risk in repeatedly switching between products and a resulting negative impact on both patient safety and/or effectiveness," he wrote. "While there may be the possibility of determining interchangeability in the future, pharmacies or patients might substitute biological products determined to be biosimilar, but not determined to be interchangeable of one another, possibly resulting in serious injury or death. Therefore, in light of the current scientific limitations on the ability to make determinations of interchangeability, and because it is critical to protect patient safety, the administration believes that patients should not be switched from the innovator biological product to a follow-on biological product (or vice versa) without the express consent and advice of the patient's physician, and legislation should not allow for determinations of interchangeability at this time."

The bill establishes a process for rapid identification of patents that could be disputed and resolution of these disputes. "That process, like much of the rest of the bill, is a balance between competing concerns," Kennedy said. "The brand company must be able to assert its patent rights on all appropriate patents. But the process shouldn't be a roadblock for the approval follow-on products."

Under the bill, innovators are required to turn over any confidential information requested by prospective sponsors of follow-on products.

This confidential information could be used solely in order to allow the sponsor of the follow-on product to assess the risk of facing patent infringement claims. Information obtained in this manner cannot be disclosed or used for manufacturing or regulatory approval of follow-on products.

After review of a follow-on product begins, all parties would have to adhere to a rigid schedule. The sponsor of the pioneer product and the sponsor of a follow-on product would have 60 days to exchange patent information and asses the risk of infringement claims.

After that, the innovator would have another 60 days to state the basis for asserting patent infringement claims. The next stage, patent resolution, would be compressed into a 15-day period, and the filing of an infringement complaint would take no more than 30 days.

The industry's critique of these provisions of the bill hasn't been detailed, but insiders say lobbyists are trying to soften them.

"The patent litigation rules included in the bill must be revised to improve protections for the intellectual property rights of innovators, ensure timely resolution of all patent disputes and maintain incentives to develop future medical breakthroughs," BIO's Greenwood said in a statement.

"The bill does not permit the FDA or the FOB applicant to rely on innovator trade secrets or non-public data in evaluating follow-on biologics," said Jeffrey Joseph, a BIO spokesman. "However, the bill also does not fully protect patent rights in that it allows FDA approval and FOB entry prior to resolution of patent litigation, and even after a district court determination of patent validity and infringement."

If the bill is enacted, its impact in the U.S. will not be immediate. First, regulatory agencies would have to spend considerable time to develop approval standards and procedures. Regulatory requirements for evidence would likely change from one indication to another, which are expected to vary considerably from setting to setting.

Biotechnology industry insiders say the difference in price between follow-on biologics would be unlikely to be as great as the difference between prices of branded and generic small-molecule drugs. Also, the complexity of the manufacturing processes would likely make follow-on biologics inaccessible to small manufacturers.

Last week, the Committee for Medicinal Products for Human Use of the European Medicines Agency

recommended approval of three follow-on biologic versions of Proctit (epoetin alfa), which is marketed in Europe under the trade name Eprex.

If the agency follows advice, the three EPOs could be on the market by the end of the year. The three agents are: Binocrit, sponsored by Sandoz, Epoetin alfa Hexal, sponsored by Hexal Biotech, and Abseamed, sponsored by Medice Arzneimittel Pütter.

Sandoz and Hexal are units of Novartis, and Medice Arzneimittel Pütter is a Sandoz licensing partner.

The Eprex patent in Europe expired last year, but in the U.S., additional patents will likely protect the agent through 2013.

At Amgen, the last of the Aranesp the European patents is scheduled to expire in 2014. In the U.S., the Aranesp patent protection would end in 2024, Amgen officials said. The company's European patent for Neupogen expired last year, and the U.S. patent will expire in 2013. The Neulasta patents in the U.S. and Europe will expire in 2015.

According to a recent analysis by Citigroup, the U.S. patents for Herceptin expires in 2013, Rituxan in 2015, Avastin in 2019, and Tarceva in 2020. The Erbitux patents have already expired.

The Senate bill is posted at http://help.senate.gov/Hearings/2007_06_27_E/Biologics.pdf.

Leavitt's letter is posted at www.cancerletter.com. Kennedy's remarks are posted at http://kennedy.senate.gov/newsroom/press_release.cfm?id=6835fd68-5ec9-4a87-be43-a4880d669fec.

Senate, House Subcommittees Approve Small Raises For NIH

By Kirsten Boyd Goldberg

The Senate Labor, HHS, Education Appropriations Subcommittee approved a funding bill June 21 that would provide $29.9 billion to NIH, a 3.5 percent or $1 billion increase over FY07.

The bill includes $4.91 billion for NCI, a 2.3 percent or $113 million increase over the current fiscal year.

Earlier this month, the House Labor, HHS, Education Appropriations Subcommittee approved an appropriations bill that would provide $29.65 billion to NIH, a 2.6 percent or $750 million increase over FY07, including $4.87 billion to NCI, a 1.5 percent or $73 million increase.

In a statement, House Subcommittee Chairman David Obey (D-Wisc.) said the increase to NIH would raise the number of new and competing research grants by 545, lift a two-year freeze on the average cost of new research grants, provide funds for training the next generation of researchers, and provide $110.9 million for the National Children's Study and $300 million for the global AIDs fund.

Both the House and Senate funding proposals are lower than the 6.7 percent increase recommended by the Federation of American Societies for Experimental Biology, the American Society of Clinical Oncology, and many other biomedical and cancer organizations.

"The flat funding we have experienced over the past several years has had a devastating effect on the scientific enterprise," Leo Furcht, FASEB president, said in a statement. "Our best and brightest young scientists are being discouraged from pursuing research careers, the pace of discovery has slowed, and we have eroded our ability to take advantage of the wealth of scientific opportunities produced by our investment in NIH."

The scientific community ultimately would like a sustainable model for research funding, Furcht said. "To continue our astonishing progress in science and medicine, we need to recoup the losses caused by inflation during the period of flat funding," he said.

"A 6.7 percent increase each year for the next three years would get NIH back on track to restoring the erosion due to inflationary losses," said Furcht.

Even under the "best case" scenario of the Senate's 2.3 percent increase, NCI Director John Niederhuber said he would ask his division heads to begin planning for FY08 by identifying 3 percent of their budgets to cut. This would create a $70-million fund that NCI could use to restore some programs or start new ones, he said to the NCI Board of Scientific Advisors June 28.

Cancer Groups Urge Support For Cancer Care Legislation

Thirty national organizations representing cancer survivors, physicians and researchers have joined under the Cancer Leadership Council to urge Congress to enact legislation that would ensure that Medicare patients receive coordinated and high-quality cancer care.

The bill, H.R.1078, "The Comprehensive Cancer Care Improvement Act," was introduced by Reps. Lois Capps (D-Calif.) and Tom Davis (R-Va.), and co-sponsored by a bipartisan group of 45 other House members, would cover physician services for development of written care plans and follow-up survivorship plans. The bill would also enhance the design and implementation of systems for coordinated cancer care and the training of professionals in a

comprehensive approach to cancer therapy.

"Cancer survivors face difficult choices from the time of diagnosis and may confront special challenges coordinating their therapy with proper management of the symptoms of cancer and side effects of care, including nausea and vomiting, pain, fatigue, and depression," The CLC said in a June 27 letter to members of Congress. "Cancer care is complicated, requiring the involvement of a multi-disciplinary care team and including active treatment, symptom management, and monitoring of the late and long-term effects of treatment. Cancer survivors who enjoy a long life after diagnosis may require intensive treatment for the side effects of their initial therapy. We commend the sponsors of H.R. 1078 for recognizing these fundamental facts of cancer care and addressing them in a meaningful way."

The full text of the letter is available at www.cancerleadership.org/policy/medicare_payment/070627.html.

"As we continue to search for a cure for cancer, it is critical that we adopt a more comprehensive approach to providing care for our cancer patients and survivors," Capps said in a statement. "The Comprehensive Cancer Care Improvement Act would ensure that patients have access to proper management of their symptoms in order to provide the highest quality of care."

NCI Programs:

NCI Increases R01 Payline From 12th To 15th Percentile

By Kirsten Boyd Goldberg

NCI has eked out a bit more grant funding for individual investigators in the final quarter of fiscal 2007, despite an overall flat budget.

The end-of-year payline from R01 grants will increase from about the 12th percentile to the 15th percentile, NCI Director John Niederhuber said to the Board of Scientific Advisors at a meeting June 28. The payline for "Star" R01s for new investigators, will be increased from the 18th to the 21st percentile.

NCI's overall payline would be somewhat higher than the 15th percentile if it included about $20 million set aside for funding grant "exceptions," Niederhuber said. Those are grants that don't meet the payline, but are considered important for programmatic purposes.

Overall, the research project grant success rate is 19 percent. NCI received 6,591 grant applications in FY07, somewhat less than expected, Niederhuber said.

"I don't think that at the beginning of this year that anyone had the idea of being able to reach as high as this," Niederhuber said to the board.

Congress didn't approve NCI's FY07 budget until last February, six months into the fiscal year. Most NCI programs were directed to plan for cuts of five to 10 percent, but not all those cuts were made.

NCI will end the fiscal year funding about 5,175 total Research Project Grants, including 1,314 competing grants, and 205 grants for new investigators. However, non-competing grants took a 2.9 percent budget cut.

Some NCI grant programs were held flat, including training grants, the clinical trials cooperative groups, and the Specialized Centers of Research Excellence. The Cancer Centers Program received a 2 percent increase.

NCI advisors didn't greet the increase in the payline as much of an improvement. Several board members said they worried that members of Congress could think all's well in biomedical research.

"If I were one of the senators or representatives and heard this, I would think everything is fine," said BSA Chairman Robert Young, chancellor of Fox Chase Cancer Center. "The number of grants are up and the size of the grant awards are up. But I worry that we are playing a numbers game and playing into their hands.

"When do we talk about the opportunities lost and the number of grants not funded?" Young said. "If we don't share that, how will they learn the facts? The whole biomedical research industry is hurting bad."

In March, Niederhuber spoke to the board about NCI's missed opportunities, providing a list of program cuts (The Cancer Letter, March 9). In that presentation, he estimated that in FY06, the institute wasn't able to fund about 179 R01 grant applications that scored within the 20th percentile.

"It's a fine line to walk," Niederhuber said to the board at the June 28 meeting. In the past few years, following the doubling of the NIH budget which ended in FY03, NIH Director Elias Zerhouni has had to re-educate Congress about flat budgets, Niederhuber said. "We owe Dr. Zerhouni a debt of gratitude in getting over this," he said. "There is a new level of understanding present, that individual investigators have inflationary pressures. Laboratories are down a post-doc or two, or a couple of specific aims have been cut from a grant application. We have been communicating that. They are listening."

Young said he and several other NCI advisors were asked to sit on an NIH review committee to look at 2,215 grant applications from young investigators for an NIH-wide program. However, only 14 grants will be funded,

he said. "Most don't have a chance," he said.

"We are losing some investigators because of the frustration of getting grants," said board member Hoda Anton-Culver, chief of epidemiology at University of California, Irvine. "What would you tell investigators?"

"What I tell young people is that I think it's very important to be part of teams in the research environment where you live," Niederhuber said. "Also, I think things are beginning to get better. It will take a number of years."

The message to Congress should be that "all is not well," said board member Ellen Sigal, chairman of Friends of Cancer Research. "We are doing the best we can under the circumstances, but there is a crisis. It's kind of a mixed message."

"You would get no argument from either Dr. Zerhouni or Dr. Niederhuber on that," Niederhuber said. "Probably, Dr. Zerhouni and Dr. Niederhuber bend the rules as much as we can. We have been very vocal on the Hill."

"There is a belief by the public and Congress that academics are whining," said board member Kathleen Foley, a neurologist at Memorial Sloan-Kettering Cancer Center. Advocacy groups should issue "a clear report" on biomedical funding, she said.

"Part of the problem is that nobody knows what is the realistic number that the biomedical industry should be grown," Niederhuber said.

Conflict of Interest:

GAO Urges NIH To Tighten Policies On Voluntary Recusals

By Paul Goldberg

The Government Accountability Office recommended that NIH tighten its policies on voluntary recusals as a method of managing conflicts of interest by senior staff.

The report is a response to a Congressional inquiry that stemmed from an investigation of recusal by former NCI Director Richard Klausner, who was applying for jobs at Harvard at a time when his institute was deciding whether to fund a Harvard laboratory.

GAO recommended that NIH "expeditiously clarify its policies with regard to written recusals and supervisor notification related to senior employees' use of recusal to resolve conflicts of interest." According to GAO, HHS concurred with the recommendation and plans to revise portions of its policy manual within 6sixmonths.

While a letter from the House Committee on Commerce mentioned Klausner by name and cited the specifics of his recusal, the GAO report looks beyond any specific examples and approaches the issue in general terms (The Cancer Letter, Sept. 9, 2005).

According to the report, "NIH has not established clear recusal policies for senior employees, as the NIH policy manual is contradictory on whether senior employees must recuse in writing and notify their upervisors of their recusals," the report states.

"For example, the policy manual contains contradictory directions on how employees seeking nongovernment employment are to recuse. One section states that the employee 'must' put the recusal in writing and that his or her supervisor 'should' be notified, while another section states that the recusal 'may' be done in writing and that the supervisor 'must' be notified if the recusal is not written.

"Moreover, the two definitions of recusal in the policy manual imply that the employee must put a recusal into writing but do not explicitly require such action, and neither definition requires that the employee's supervisor be notified of the recusal. Senior employees who consult the policy manual may or may not put their recusals in writing and may or may not notify their supervisors, depending on what section of the policy manual they consult."

The document is posted at http://www.gao.gov/htext/d07319.html.

Professional Societies:

ASCO Award And Fellowship To Honor Gianni Bonadonna

The American Society of Clinical Oncology has established an annual award and fellowship to recognize outstanding research achievements in breast cancer in honor of Gianni Bonadonna, of the Instituto Nazionale Tumori in Milan, Italy.

The first recipient of the Gianni Bonadonna Breast Cancer Award and Fellowship will be announced in September. The special award established by the ASCO board, is supported by a grant from GlaxoSmithKline Oncology. The award will be presented at the 2007 Breast Cancer Symposium, to be held in San Francisco on Sept. 7-8.

The $10,000 annual award recognizes an active clinical or translational researcher with a distinguished record of accomplishments in advancing the field of breast cancer. The recipient will deliver a lecture during the symposium. The award will be accompanied by a

one-year, $50,000 fellowship grant, to be awarded by The ASCO Foundation to an early-career breast cancer researcher at the recipient's affiliated institution. The Fellowship Award will fund an investigator whose breast cancer research has a patient-oriented focus, including clinical trials or translational research involving human participants.

"Dr. Gianni Bonadonna is one of the world's most influential cancer researchers, and his work has improved the lives of countless people living with cancer," said Gabriel Hortobagyi, immediate past president of ASCO.

Bonadonna's work has led to the development of successful and widely used treatment regimens. He designed and conducted the first clinical trials exploring the use of doxorubicin and developed the doxorubicin, bleomycin, vinblastine and dacarbazine (ABVD) protocol, which remains the gold standard for treating Hodgkin's disease. Additionally, his patients were among the first to receive adjuvant therapy using the cyclophosphamide, methotrexate and, fluorouracil (CMF) combination.

"At a time when cancer research funding on a national scale is endangered, we need to do all we can to encourage the best and brightest to stay the course," said Allen Lichter, executive vice president and CEO of ASCO. "Through the Bonadonna Award—and all of our grants and special awards—we are pleased to honor individuals who are searching for more effective cancer treatments and advocating for high-quality care for patients. And we are particularly pleased that this award comprises an endowment as well so that an annual award will be possible long into the future."

Funding Opportunities:

Biomarkers Consortium Opens Web Site To Accept Proposals

The Biomarkers Consortium, a public-private biomedical research partnership managed by the Foundation for the NIH, has opened a Web site to encourage researchers to submit biomarker project concepts.

Financial support for concepts approved for development will be procured through fund-raising efforts by the foundation. The site is www.biomarkersconsortium.org.

The Web site provides access for submitting biomarker project concepts to therapeutic area steering committees within the consortium. The first three steering committees are composed of experts in neuroscience, metabolic disorders, and cancer. A fourth steering committee in inflammation and immunity is being assembled. When approved, concepts are developed into formal project proposals and, when approved by the consortium's executive committee, the foundation seeks the funds to implement them. To date, over $6 million has been raised to support the consortium's lung cancer and lymphoma biomarker projects.

In addition to the Foundation for NIH, founding members of the consortium include NIH, FDA, and the Pharmaceutical Research and Manufacturers of America. Also, 28 companies and non-profit trade associations and advocacy groups are participating in the consortium's contributing membership program.

The aim of the consortium is to accelerate delivery of technologies, medicines, and therapies for successful prevention, early detection, diagnosis, and treatment of disease.

In Brief:

NCI Imaging Director Sullivan To Retire, Advise RSNA, Duke

DANIEL SULLIVAN, associate director of NCI's Cancer Imaging Program in the Division of Cancer Treatment and Diagnosis for the past 10 years, plans to retire from NCI. He will serve as a senior science advisor for the Radiological Society of North America, where he will oversee efforts to develop imaging as a quantitative biomarker. He will also serve as a senior strategic advisor for imaging to the dean of Duke University School of Medicine, where he will help the university plan for a major reshaping of imaging facilities across the campus. . . . **NIH** is providing $4.8 million to establish and support a repository for its knockout mouse project. The award is the final component of a more than $50 million trans-NIH initiative to increase the availability of genetically altered mice and related materials. The University of California, Davis, and Children's Hospital Oakland Research Institute of Oakland will collaborate to preserve, protect, and make available 8,500 types of knockout mice and related products available to the research community, said **Barbara Alving**, director of the National Center for Research Resources. . . . **JOHN BUCHER** was named associate director of the National Toxicology Program. The NTP, of Research Triangle Park, N.C., is an interagency program that coordinates, conducts and communicates toxicological research across the U.S. government. "Our goal for the NTP is to closely coordinate its work with the NIEHS in-house research on environmental health so that we

can make the most of our resources and have an even greater impact on safeguarding public health," said **David Schwartz**, director of the NIEHS and the NTP. **Allen Dearry** was interim associate director of NTP from January 2006 through June 2007. . . . **MARY LASKER'S PAPERS** have been added to the National Library of Medicine's Profiles In Science Web site, at http://profiles.nlm.nih.gov. Lasker (1899-1994), the medical philanthropist and benefactor of NIH, was called "this country's First Lady of science and medicine" by former NCI Director **Vincent DeVita Jr.** Lasker was a well-connected fundraiser and astute advocate who through charm, energy, and skillful use of the media persuaded donors, congressmen, and presidents to provide greatly increased funds for biomedical research. "In the decades after World War II, Lasker acted as a catalyst for the growth of the world's largest and most successful biomedical research enterprise, with the National Institutes of Health (NIH) as its centerpiece," said **Donald Lindberg**, director of the National Library of Medicine. With her husband, the wealthy advertising pioneer **Albert Lasker** (1880-1952), she established the Lasker Foundation in 1942 to promote medical research. She led the reorganization of the American Cancer Society as a modern fundraising and lobbying organization powerful enough to persuade Congress to boost appropriations for cancer research. She was an early supporter of cancer chemotherapy, and urged scientists to apply their research findings to drug development more quickly.

In the Cancer Centers:

Three Researchers To Lead New Vaccine Institute At Hutch

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diseases, including HIV, malaria and cancer, said **Lee Hartwell**, president and director of the Hutchinson Center. The goal of the institute is to recruit and retain scientists in vaccine development and prevention of infectious diseases, he said. A second goal is to work with others in a regional vaccine alliance. Because of its interdisciplinary nature, the institute will have three co-directors. **Lawrence Corey**, principal investigator of the Hutchinson Center-based international HIV vaccine trials network and senior vice president, will oversee the clinical research component. Corey is head of the centers program in infectious disease and the virology division at the University of Washington. **M. Juliana McElrath**, director of the HVTN laboratory program, principal investigator of the Seattle HIV vaccine trials unit, and associate head of the program in infectious diseases at the Hutchinson Center, will oversee the laboratory. She also is professor of allergy and infectious disease at the UW School of Medicine. **Steven Self**, head of the program in biostatistics and biomathematics at the Hutchinson Center, will oversee the population sciences research. . . . **WINSHIP CANCER INSTITUTE** received a $500,000 donation from the Williams Family Foundation of Georgia to establish the Sabrina Williams Scholarship for Continuing Nursing Education. The scholarship will enable oncology nurses to continue their education, said WCI Director **Brian Leyland-Jones**. . . . **COLD SPRING HARBOR** Laboratory received a five-year grant for its pre-college science education programs from the Howard Hughes Medical Institute. "The program will be a model for how research institutions can interact with large school systems and transform science education for urban students," said **David Micklos**, executive director of Dolan DNA Learning Center at Cold Spring Harbor Laboratory. The program will add six genetics and biotechnology experiments to the curriculum of 820 New York public school teachers who will be trained at DNALC. . . . **UNIVERSITY OF ARKANSAS** for Medical Sciences Myeloma Institute for Research and Therapy in Little Rock received $4.5 million to establish the Nancy and Stephen Grand Laboratory for Myeloma Proteomic for research into the genetic profile of multiple myeloma. The laboratory, which will be located UAMS Arkansas Cancer Research Center, will be the first in the country with mass spectrometry equipment dedicated to analysis of the proteins produced by myeloma tumor cells and bone marrow cells. **Ricky Edmondson** will head the laboratory. **John Shaughnessy Jr**., professor of medicine, will lead the studies. Shaughnessy is director of basic research and director of the Lambert Laboratory of Myeloma Genetics at the Myeloma Institute. . . . **MICHAEL BRATTAIN** was named associate director for basic research at Eppley Cancer Center, University of Nebraska Medical Center June 1. Brattain will oversee basic science research initiatives, including collaborative and translational research opportunities. He also will continue to conduct translational research in colon and breast cancers. Brattain has four grants from NCI, three of which have been continuously funded for more than 20 years. He is in the top one percent of life scientists in terms of grant awards from NCI and NIH. Brattain was senior vice president for basic science at Roswell Park Cancer Institute and chairman of the Department of Pharmacology and Therapeutics of the Grace Drug Center at Roswell Park.

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