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News Analysis:

In Odd Aftermath of McClellan's Lecture, NCI Director Forwards Note to 3,000 Staff

Recently, FDA Commissioner Mark McClellan sent a brief, carefully phrased email to NCI Director Andrew von Eschenbach.

"I want to thank you again for the honor of being the inaugural speaker at the NCI Director's Seminar Series," McClellan wrote in a 14-line note that, under ordinary circumstances, would have been kept private.

Yet, in today's affirmation-hungry NCI, a routine sign of attention—even an innocent thank-you note—can be presented as an endorsement of

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In Brief:

NCI Treatment Division Head Ellen Feigal Accepts Job In Phoenix With TGen

ELLEN FEIGAL, acting director of the NCI Division of Cancer Treatment and Diagnosis since 2001, and the division's de facto head for several years prior to that, has accepted a position as vice president of clinical sciences and deputy scientific director for the Translational Genomics Research Institute in Phoenix, Ariz., effective April 18. Feigal, whose research interest has been HIV-associated lymphoma, joined the NCI Cancer Therapy Evaluation Program in 1992 as a senior investigator with responsibilities for lung cancer, head and neck cancer, and the Radiation Therapy Oncology Group. She was developed AIDS malignancy clinical trials programs in CTEP and oversaw the transfer of trials from the National Institute for Allergy and Infectious Diseases to NCI as part of a new AIDS malignancy group. She also developed new programs, including the annual National AIDS Malignancy Meeting, a multidisciplinary AIDS Malignancy Working Group, a multi-center specimen bank program for AIDS malignancy specimens, a training program for clinical investigators, and served as a liaison to NIH-wide AIDS activities. In 1997, she became deputy director of DCTD, leading the division while DCTD Director Robert Wittes served as NCI deputy director for extramural science. She continued to lead the AIDS malignancy programs. In 2000, she developed the Interagency Council on Biomedical Imaging in Oncology, which brings together FDA, the Center for Medicare and Medicaid Services, and NCI to serve as a sounding board for technology developers attempting to bring their products to market. The same year, she also convened a group of NCI, FDA, and CMS staff, four competing device manufacturers, and the NCI-sponsored American

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Email Blast of Thank-You Note Follows Return Of NCI Gift

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von Eschenbach's campaign "to eliminate suffering and death from cancer" by the year 2015.

More than a year after von Eschenbach first announced his "challenge goal," the NIH, FDA and the White House have not publicly acknowledged it, and multiple sources have said privately that the goal has not attracted many supporters in the Administration.

Thus, over the past few weeks, von Eschenbach attached great significance to the missive from McClellan, the Administration's point man on health, who was recently designated to take the top job at Centers for Medicare and Medicaid Services.

On Feb. 18, at a meeting of the National Cancer Advisory Board, von Eschenbach mentioned having received a letter "from my good friend Mark McClellan." Then, on Feb. 27, the director blasted the email to the Institute's 3,000 staff members.

"I am establishing a weekly email that will be sent every Friday from me to all NCI Staff to keep you abreast of topics of importance to us," von Eschenbach declared in the email blast.

At the very least, the broadcast of McClellan's note illustrates the awkwardness of NCI's interactions with people who haven't expressed support for the 2015 goal. Creation of the illusion of support appears to be the purpose of the lecture series that featured McClellan as the first speaker (**The Cancer Letter**, Feb. 6).

"This series is designed to bring the nation's leaders to the National Institutes of Health to discuss extraordinary advances in their fields as we work toward eliminating the suffering and death due to cancer by 2015," said an NCI press release announcing the McClellan lecture. This wording suggested that NIH and McClellan support the 2015 goal.

In his lecture, McClellan didn't join the drumbeat of imminent triumph over cancer, and spoke instead about substantial challenges in cancer research. For example, he noted that it takes about a decade to develop a cancer drug, implying that in order to have a shot of meeting the 2015 goal, scientists should now have the targets for every cancer.

After the FDA commissioner concluded his remarks, von Eschenbach handed him a large glass trophy, which he described as a token of "our enduring friendship relationship."

Experts in government ethics said to **The Cancer Letter** that the trophy, which McClellan clearly neither sought nor expected, far exceeded the token gift limit of $20, which made it inappropriate. FDA is a regulatory agency that oversees many NCI activities.

After a reporter pointed out a potential violation of federal regulations, FDA returned the gift to NCI, and the email from McClellan appears to be a politic effort to end this strange interaction on a high note.

Like his lecture, McClellan's email avoids mentioning the year 2015, but pays homage to the NCI director's stump speech, making a reference to the three "Ds" of cancer-fighting: "discovery, development and delivery."

The text of the email follows:

Dear Andy,

I want to thank you again for the honor of being the inaugural speaker at the NCI Director's Seminar Series. NCI's mission—to eliminate suffering and death due to cancer—and the means by which you are pursuing that mission are of vital importance to all Americans because so many of us have been, or will be, touched by cancer. To demonstrate my support for NCI's approach, I attempted to use my lecture to point to NCI's most pressing challenges, which are also your most important opportunities. More importantly, the new collaboration between NCI and FDA includes decisive steps that will accelerate the discovery, develop [sic.] and delivery of interventions to prevent, detect, and manage cancer so that people need not continue to suffer or die from the disease.

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I wish you all the best in your efforts, and look forward to continue working closely with you to achieve our shared goal of eliminating the burden of cancer.

Mark

The closest McClellan comes to endorsing the NCI goal is in the phrase "to demonstrate my support for NCI's approach," but even that is far from an unqualified expression of support for the 2015 goal. More likely, it is a reference to rigorous basic and clinical research that has been the mainstay of the Institute's approach to science.

The NCI director's "weekly e-mail" is the latest of his methods of communications, all of them weekly. It joins "The Director's Corner" on the NCI website and the NCI Cancer Bulletin, an electronic newsletter.

Von Eschenbach wrote that he decided to distribute McClellan's email because "Dr. McClellan was named by the White House this week to run the Centers for Medicare and Medicaid Services (CMS), so I thought it important to share his message as FDA Commissioner as we will continue these collaborations when he assumes his new post."

Last time the U.S. government declared an assault on cancer, three decades ago, this was done by the President, and echoed throughout the government.

Unlike Richard Nixon's War on Cancer, which received top billing, von Eschenbach's war was declared in low-key surroundings, in the middle of the director's winding speech at the National Cancer Advisory Board a year ago (**The Cancer Letter**, Feb. 14, 2003).

The von Eschenbach war didn't get a rollout at the White House, or even at the place known as "Downtown," the HHS headquarters. In speeches and actions that followed his anticlimactic declaration of war, von Eschenbach moved the 2015 goal to the front and center position at NCI.

Meanwhile, Institute officials are expected to evaluate existing programs in terms of their impact on the 2015 goal.

Von Eschenbach's supporters include the political organizations started by the financier and prostate cancer survivor Michael Milken, as well as a non-profit group called C-Change, formerly the National Dialogue on Cancer, where von Eschenbach serves as vice chairman of the board.

The goal also received an endorsement last year from the American Association for Cancer Research, soon after NCI agree to provide $2 million to help the association pay some of the costs of rescheduling its annual meeting, cancelled at the last moment due to the fear of the SARS virus in Toronto (**The Cancer Letter**, July 18, 2003).

In recent months, NCI, C-Change and the Milken groups started using nearly identical language as they call for "accelerating" cancer research.

Last week, C-Change held a press conference to introduce itself to the public after four years of working in obscurity and behind closed doors. According to the press release, the organization seeks to "accelerate the attack on cancer" (www.ndoc.org/about_ndc/newsroom/pressrelease/3-3-04.pdf).

Earlier this week, NCI announced that its new informatics program would similarly "accelerate" the attack (see story below).

The same buzzword figures in the name of a Washington think tank recently created by Milken, Center for Accelerating Medical Solutions, www.fastercures.org. The center is the culmination of Milken's 10 years in oncopolitics (**The Cancer Letter**, Feb. 20).

Von Eschenbach acknowledges Milken's role in shaping what has become the nation's cancer agenda.

"Michael Milken, with his vision of the future, recognized that cancer was not just a scientific problem, or a medical problem, but that it was an economic problem, a political problem, a cultural problem, and a societal problem" von Eschenbach said at the 2003 scientific retreat of Milken's group CaP CURE, which has since been renamed the Prostate Cancer Foundation.

"And that kind of vision and that kind of leadership, I personally think, is why God has gifted him with the ability to be with us over the past 10 years, to provide the kind of leadership to bring us together for a societal solution to the problem of cancer," von Eschenbach said.

The remarks are posted at www.mikemilken.com/events.taf.

NCI Programs:

Informatics Project Will Speed Research, NCI Director Says

Progress in cancer research will be "rapidly accelerated" by the NCI initiative known as the Cancer Biomedical Informatics Grid, or caBIG, Institute Director Andrew von Eschenbach said earlier this week.

Under the initiative, to which NCI has committed $20 million this year, the Institute will work initially with 50 NCI-designated cancer centers to create an

informatics infrastructure that will enable researchers to share standards, applications, and technologies.

The goal of caBIG, a three-year pilot project, is to "provide investigators with a unique opportunity to take data, convert it into information, and allow it to be disseminated as knowledge," von Eschenbach said to science reporters invited to an NCI seminar March 9 to discuss caBIG.

The project, which was actually launched last July, tests whether cancer centers can be joined in a common network of shared data, applications, and technologies. The project also explores whether centers can develop new tools that will support other centers and that centers can use caBIG for research, and seeks to create a versatile infrastructure that can continue to be expanded.

Ken Buetow, director of the NCI Center for Bioinformatics, said caBIG will be built on open-source software, with open access and development, in collaboration with cancer centers and other research institutions.

Buetow said the informatics system is needed because of the "explosion of information" in genomics. "The scientific communities have developed specialized vocabularies, publish in their own journals, collect data in their own databases," he said. "Each one has custom inputs and outputs. It's an informatics Tower of Babel."

The data produced by these communities need to be "integrated" in a common system so that researchers can extract information from published research that may be stored at individual centers and not readily accessible.

"caBIG will facilitate the sharing of information, all through this World Wide Web of cancer research," Buetow said.

The system will include an NCI "meta-thesaurus," which will serve as a translator of terminology, Buetow said.

In addition, in another initiative that will be included in caBIG, FDA will work with NCI to develop clinical trial management software to streamline Investigational New Drug applications. FDA and NCI will coordinate standards and develop tools to accelerate the regulatory review process for cancer drugs. This initiative was announced last spring (**The Cancer Letter**, June 6, 2003).

"This would reduce the barrier of regulatory filing," Buetow said.

Most of the $20 million per year cost will be given to participating centers as contracts. Centers are likely to have to provide additional resources, in the form of staff, space, data sets, study populations, or other in-kind commitments.

NCI Plans 18% Cut To Big R01s; Smaller Cuts For Other Grants

NCI plans to cut the budgets of large new R01 grants by a greater percentage than smaller grants and competing renewals, NCI Director Andrew von Eschenbach said last week.

Under the Institute's funding plan for fiscal 2004, the following "average reductions from requested budgets" will be made:

--New (Type 1) R01s recommended for seven modules or fewer will be cut by 10 percent.

--Competing renewal (Type 2) R01s recommended for seven modules or fewer will be cut by 5 percent.

--Type 1 R01s recommended for eight modules or more will be cut by 18 percent.

--Type 2 R01s recommended for eight modules or more will be cut by 10 percent.

The funding policy also will apply to P01 and R21 grants, and all other research project grant mechanisms except for R15 and R03 grants.

The policy will not apply to noncompeting continuation R01 (Type 5) grants. Non-modular Type 5 grants—in which direct costs exceed $250,000—will receive cost-of-living adjustments of 3 percent.

The reductions, which are larger than the grant budget cuts NCI has made over the past two years, are necessary to maintain the R01 payline at the 20th percentile, von Eschenbach said in a statement.

"This budget adjustment will enable us to support 75 more R01 grants than would have been possible if we maintained budget reductions at recent levels," von Eschenbach said.

"Even after the reduction is taken, renewal grants will receive, on average, an approximately 10 percent budget increase over the current grant level," von Eschenbach said. "Furthermore, no competing renewal grant will be reduced below its current level of support unless the principal investigator has requested a smaller budget."

NCI has sought the advice of its external advisory boards on funding policies every year, von Eschenbach said. "Our advisors consistently express the view that, while we need to be cautious about imposing budget reductions in excess of 15 percent on competing grants, funding more R01s is a greater good—and should be a higher priority—than funding fewer grants with budgets

as requested," he said.

"Given the unprecedented increases in the NIH and NCI budgets in recent years and the intense competing demands on the overall federal budget, we at NCI must plan for a period of nearly flat growth in the foreseeable future," he said.

Von Eschenbach's statement on the RPG funding policy is posted at www.cancer.gov/directorscorner/.

In the Cancer Centers:

New Director, Funding In Place For San Antonio Institute

The University of Texas Health Science Center at San Antonio and the Cancer Therapy and Research Center have increased funding to and changed the leadership of the San Antonio Cancer Institute, an NCI-designated cancer center.

David Boldt, professor of medicine and chief of the hematology division in the department of medicine at the Health Science Center since 1985, was named SACI interim director.

Charles Coltman Jr., director of SACI since its inception, will remain as a senior adviser to Boldt. Coltman has been president and CEO of the CTRC since 1976 and is chairman of the Southwest Oncology Group.

"It was Dr. Coltman's vision, along with the vision of the late Dr. William McGuire, to establish the San Antonio Cancer Institute," Boldt said. "Dr. Coltman has been a terrific and effective leader and is a nationally recognized cancer expert. We have benefited from his wisdom."

SACI has 158 members including full-time faculty, clinical faculty and community physicians, with more than $65 million in extramural peer-reviewed cancer research funding, of which about two-thirds is from NCI. The center combines the academic and basic research components of the Health Science Center with the clinical treatment, research and prevention programs of the CTRC. Both parent institutions have made substantial new commitments to the joint enterprise.

"We are continuing, and even increasing, the strong cancer research and compassionate clinical care that have put San Antonio in the forefront nationally," said Francisco Cigarroa, president of the Health Science Center. "This is a positive endorsement by both institutions, and I am extremely proud of the faculty, physicians and administrators of both."

The CTRC will contribute space and funding including $3.5 million of developmental funds over the next five years. The Health Science Center will provide $3.5 million initially and another $2.5 million in support over the next five years. These funds are in addition to the $2.8 million annual NCI Cancer Center Support Grant, which was transferred last fall to the Health Science Center. The Health Science Center also is allocating 10,000 square feet of laboratory and office space for SACI activities.

"Although the NCI grant that partially supports SACI has been transferred to the Health Science Center, it is important to point out that the strong partnership between the HSC and the CTRC will continue with renewed emphasis," said Steven Wartman, executive vice president for academic and health affairs and dean of the Health Science Center School of Medicine. "We made the change because the majority of the research was at the university, and it seemed that was the right place for the grant to be located. NCI was very supportive of the move."

SACI funds 14 core laboratories providing expertise in mouse modeling, cytogenetics, microarrays, flow cytometry, biostatistics and bioinformatics, and other areas. The research programs target cancer spread, geriatric oncology, experimental therapeutics, cancer prevention and health promotion, and the cell biology of cancer, including tumor suppressor genes, DNA repair and cell signaling.

"Our partnership in SACI with the Health Science Center is a confirmation of our commitment to work together in serving the needs of cancer patients in the South Texas region," said Bob Shaw, executive vice president and chief operating officer of the CTRC. "Being designated as one of the 61 National Cancer Institute-designated centers brings resources and cutting-edge cancer services not available in most communities."

* * *

The UT Health Science Center at San Antonio dedicated the new **Children's Cancer Research Institute** on Feb. 24 in a ceremony attended by state and local officials as well as NCI Director Andrew von Eschenbach.

Sharon Murphy, the institute director, former chairman of the Pediatric Oncology Group, and former director of Children's Memorial Institute for Education and Research in Chicago, said that although progress has been made in the treatment of childhood cancer over the past 30 years, the time has come for even more dramatic improvements.

"I came here with a determination to make a difference here and to build a world-class research

facility," Murphy said in her remarks at the dedication. "I have devoted the past 30 years of my professional career to treating children with cancer and to conducting clinical research. Over those years, I have personally cared for literally hundreds of children and their families... and I've been privileged over those years to see tremendous improvements in survival rates, and I've helped to bring about some of those improvements. But I've also seen lots of suffering and many children for whom treatments failed who lost their struggle with cancer—and I'm here to tell you I don't want to see that anymore."

The CCRI is supported by a $200 million endowment from the state's tobacco settlement. It is the nation's largest single endowment for cancer.

"Cancer still remains the leading cause of death from disease among children," Murphy said. "By assembling a top-notch team of researchers here who will be engaged in research relevant to childhood cancer, I can also tell you that we hope to impact the problem of cancer occurring at all ages among adults, because childhood cancer is really a model for cancer in general."

State Sen. Judith Zaffirini spoke about the evolution of the state's settlement with the tobacco companies. As chairwoman of the state Senate Committee on Health and Human Services, Zaffirini played a key role in the distribution of the tobacco settlement.

The 100,000-square-foot CCRI includes laboratory and office space for 18-20 scientific teams. It was designed by architects Garza Bomberger and Associates and the building contractor was Bartlett Cocke General Contractors.

Funding Opportunities:

RFP Available

RFP N02-PC-45002-61: Surveillance Support Services for NCI

Response Due Date: May 17, 2004

NCI Division of Cancer Control and Population Sciences supports an integrated extramural program of cancer epidemiologic, genetic, behavioral, social, health services and economics, outcomes, and surveillance research. The objective of the surveillance research is to monitor and explain patterns in the national cancer burden, including trends in cancer incidence, mortality, survival, risk factors, and the delivery of preventive and therapeutic health services. The primary approach for obtaining information about cancer trends is through surveys and evaluation studies, and the development and validation of methods for surveillance activities. The contractor should perform surveillance projects that fall under three categories: 1) rapid response to emerging issues; 2) evaluation, and; 3) methods development. The task areas include: 1) Planning and Liaison, 2) Survey/Study Operations and Data Coordination Center, 3) Survey/Study Implementation, 4) Biological Specimen Collection and Management, 5) Computer Processing and Analysis, and 6) Submission of Deliverables. The RFP is available at www.fedbizopps.gov.

Inquiries: Charles Jackson Jr., contracting officer, phone 301-435-3829; fax 301-402-8579, e-mail cj14k@nih.gov.

Program Announcement

PA-04-071: Pathogenesis and Treatment of Lymphedema and Lymphatic Diseases

National Heart, Lung, and Blood Institute, National Institute of Child Health and Human Development, National Institute of Arthritis and Musculoskeletal and Skin Diseases, NCI, National Institute of Nursing Research, National Center for Complementary and Alternative Medicine, and National Institute on Biomedical Imaging and Bioengineering invite applications for research projects on the biology of the lymphatic system, to characterize at the molecular, cellular, tissue, organ, and intact organism levels, the pathophysiologic mechanisms that cause the disease, to develop methods for quantitating and imaging lymph flow, to discover therapeutic interventions, and to determine the safety, efficacy and mechanisms of action of complementary and alternative therapies.

NCI, NINR, NIBIB, and NCCAM are interested in approaches that will identify the developmental, molecular, and cellular defects that contribute to lymphedema as well as the development of effective therapeutic interventions to treat both primary and secondary lymphedemas. These include: insufficiency of lymphatic circulatory function; lymphatic vascular valvular insufficiencies; complex congenital vascular proliferative diseases of the lymphatic vasculature, including but not limited to, so-called lymphangioma, cystic hygroma, lymphangiosarcoma, lymphangio-leiomyomatosis; and developmental disorders of the lymphatic system, e.g. lymphangiectasia, chylous reflux and complex vascular malformations, such as Klippel-Trenauny Syndrome. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-04-071.html.

Inquiries: Suresh Mohla, chief, Tumor Biology & Metastasis Branch, Division of Cancer Biology, phone 301 435 1878; fax 301 480-0864; e-mail mohlas@mail.nih.gov.

In Brief:

Hinestrosa Joins NBCC As Executive Vice President

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College of Radiology Imaging Network investigators to develop a controlled clinical trial evaluating digital and screen film mammography for detection of breast cancer in asymptomatic women. She was appointed acting division director when Wittes moved to Memorial Sloan-Kettering Cancer Center in 2001. One of her accomplishments in that position was to lead the development of the National Lung Screening Trial of spiral CT *vs*. chest x-ray in individuals at risk for lung cancer. She continued to see patients in the intramural AIDS clinic and served as co-investigator on several clinical trials. Feigal received a BS in biology and MS in molecular biology and biochemistry at University of California, Irvine, and an MD from University of California, Davis. She completed residency in internal medicine at UC Davis and Stanford University. She was a fellow in a joint hematology and oncology program at the University of California, San Francisco. In 1989, she was recruited to the University of California, San Diego, and was the principal investigator of an R01 grant assessing novel therapeutic approaches to HIV-associated lymphoma until her move to NCI. . . . **MARIA CAROLINA HINESTROSA** has joined the National Breast Cancer Coalition as executive vice president for programs and planning. She was a founder of Nueva Vida, a support network for Latinas with breast and cervical cancer in Washington, D.C. "Carolina knows NBCC inside and out, because she has been involved in our work since the very early days of the coalition," said **Fran Visco**, NBCC president. Hinestrosa, an NBCC board member since 1998, is chairwoman of the Integration Panel of the Department of Defense Breast Cancer Research Program. She served on the Institute of Medicine Committee on Technologies for the Early Detection of Breast Cancer and the National Action Plan on Breast Cancer Consumer Involvement Working Group. . . . **VINCENT DEVITA JR.** was appointed the Amy and Joseph Perella Professor of Medicine by the Yale Cancer Center in recognition of his contributions to cancer research and treatment. Following his tenure, the chair will be renamed the Vincent T. DeVita Professor of Medicine and will support a physician at Yale Cancer Center. The chair was endowed with a gift of $2.5 million last December. DeVita is chairman of the Yale Cancer Center Advisory Board and is a Yale University School of Medicine professor of internal medicine, epidemiology, and public health. He was director of NCI from 1980-88. . . . **MADELEINE KANE**, professor of medicine, has been selected as medical director for the Clinical Investigations Core at the University of Colorado Cancer Center, beginning in April. She will take over for **Anthony Elias**, associate professor of medical oncology, who served as interim director. . . . **SUSAN G. KOMEN Breast Cancer Foundation** honored politicians and activists March 9 at its annual public policy luncheon. Secretary of Health and Human Services **Tommy Thompson** received the Komen Women's Health Advocate Award for his work to increase funding for breast and cervical cancer screening. The Connie Mack Lifetime Achievement Award was presented to **Rep. John Dingell** (D-MI) and **Deborah Dingell**. John Dingell was recognized for sponsoring legislation including the Mammography Quality Standards Act. Deborah Dingell is vice chairwoman of the General Motors Foundation. **Rep. Deborah Pryce** (R-OH) received the Komen Champion of Change Award for her legislative initiatives such as a bill that gives seniors Medicare coverage of oral cancer medications and a bill that requires health care coverage for routine care costs during clinical trials. . . . **SATDARSHAN SINGH MONGA**, assistant professor of pathology at the University of Pittsburgh School of Medicine, has been awarded $2 million by the National Institute of Diabetes and Digestive and Kidney Diseases and the American Cancer Society for liver cancer research. Projects funded by the grants, $1.2 million over five years from NIDDKD and $720,000 over four years from ACS, will focus on the biological mechanisms of tumor formation, specifically those related to the proteins Wnt/beta-catenin and Hepatocyte Growth Factor-Met-Autocrine. . . . **ESTHER MUSCARI** was named presenter of the 2004 Oncology Oncology Nursing Society/Schering Plough Oncology Clinical Lectureship during the ONS 29th Annual Congress on April 30 in Anaheim. Muscari is an oncology clinical nurse specialist/acute care nurse practitioner and owner of Lymphedema Therapies of Charlottesville, Va., and is affiliated with the Martha Jefferson Hospital Cancer and Rehabilitative Programs in Charlottesville. The award recognizes and supports her work in clinical nursing practice. . . . **NATIONAL ADVISORY Board for Biosecurity** will be created in a government-wide effort to improve biosecurity for legitimate biological research that could be misused to threaten public health or national security-so-called dual use research, HHS Secretary **Tommy Thompson** said. The 25-member board will be managed by NIH.

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