THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE: A new program at the National Institute of Allergy and Infectious Diseases (NIAID), one of the National Institutes of Health (NIH), aims to better understand the complex biochemical networks that regulate the interactions between infectious organisms and the human or animal cells they infect. The Program in Systems Immunology and Infectious Disease Modeling (PSIIM) will employ a powerful new approach called computational systems biology to develop a deeper understanding of how pathogens cause disease and how the immune system responds to them. -- additional information is included in this Washington Report.

The *CSTE Washington Report* is provided as an information resource for members of the Council of State and Territorial Epidemiologists on federal legislation and regulation affecting public health and epidemiology in the U.S. Legislation cited in the report can be accessed via http://www.thomas.loc.gov Regulations cited can be accessed via http://www.gpo.gov

SENATE COMMITTEE FINISHES WORK ON FY2007 APPROPRIATIONS – The Senate Appropriations Committee finished work on the FY 2007 Labor-HHS-Education Appropriations bill on July 20th. The House Appropriations Committee finished its corresponding bill last month. Funding levels for specific health programs from the Senate bill are provided below. The report (109-287) can be read at: http://thomas.loc.gov/

The House leadership has stalled bringing its bill to the House floor because Democrats successfully attached an amendment to raise the minimum wage during full Committee consideration. However, health advocates are now hearing that the minimum wage amendment will be stripped from the bill and it will be brought to the House floor in September. It is unclear whether the Senate bill will also see floor action in September, but final conference to reconcile differences between the bills is not expected to occur until after the November elections. The Senate bill contains nearly $1 billion more funding than the House bill. Promises made earlier this year by the House leadership to Moderate Republicans to add another $3 billion to the Labor-HHS-Education Appropriations bill is still possible. There is pressure in the Senate, as well, to add another $2 billion to the Senate bill to honor the 73-27 vote on the Senate Budget Resolution in favor of increasing the bill by $7 billion over the President's budget request. The bill was increased by $5 billion, not the full $7 billion.

Meanwhile, public health advocates are gearing up to help defeat two budget process measures that could seriously impact the survival of health programs in the future: the Presidential line item veto and the creation of Sunset Commissions. Both provisions, if enacted, would empower the Executive Branch at the expense of the Congress which is generally more sensitive to advocacy pressure. The House has already passed a line item veto bill and may take up and pass a Sunset Commission bill later this week which would create a partisan majority appointed panel with fast-track ability to circumvent the regular Congressional Committee process and pass legislation to reorganize, consolidate, abolish, expand, or transfer any federal program reviewed. Advocates will focus on stopping the measures in the Senate.

CENTERS FOR DISEASE CONTROL AND PREVENTION

FY 2006	$ 6,380,183,000
FY 2007 Pres.Rqst.	$ 6,099,052,000
FY 2007 House	$ 6,173,368,000
FY 2007 Senate	$ 6,195,765,000

Infectious Diseases

FY 2006	$ 226,768,000
FY 2007 Pres.Rqst.	$ 245,346,000
FY 2007 House	$ 225,938,000
FY 2007 Senate	$ 266,366,000

Emerging Infections

FY 2006	$ 101,623,000
FY 2007 Pres.Rqst.	$ 96,770,000
FY 2007 House	$ 101,623,000

FY 2007 Senate	$	130,000,000

HIV/AIDS

FY 2006	$	651,118,000
FY 2007 Pres.Rqst.	$	739,579,000
FY 2007 House	$	706,316,000
FY 2007 Senate	$	670,294,000

Immuunization

FY 2006	$	519,872,000
FY 2007 Pres.Rqst.	$	507,369,000
FY 2007 House	$	614,577,000
FY 2007 Senate	$	479,303,000

Chronic Disease

FY 2006	$	838,664,000
FY 2007 Pres.Rqst.	$	818,727,000
FY 2007 House	$	846,744,000
FY 2007 Senate	$	835,752,000

Heart/Stroke

FY 2006	$	44,469,000
FY 2007 Pres.Rqst.	$	43,888,000
FY 2007 House	$	53,000,000
FY 2007 Senate	$	50,231,000

Diabetes

FY 2006	$	63,119,000
FY 2007 Pres.Rqst.	$	62,420,000
FY 2007 House	$	69,000,000
FY 2007 Senate	$	65,356,000

Cancer Prevention and Control

FY 2006	$	307,913,000
FY 2007 Pres.Rqst.	$	304,690,000
FY 2007 House	$	307,536,000
FY 2007 Senate	$	313,179,000

Tobacco

FY 2006	$	104,799,000
FY 2007 Pres.Rqst.	$	102,685,000
FY 2007 House	$	102,253,000
FY 2007 Senate	$	105,629,000

Nutrition/Physical Activity/Obesity

FY 2006	$	41,520,000

FY 2007 Pres.Rqst.	$	41,477,000
FY 2007 House	$	41,477,000
FY 2007 Senate	$	44,450,000

PHHS Block Grant

FY 2006	$	99,000,000
FY 2007 Pres.Rqst.	$	0
FY 2007 House	$	100,000,000
FY 2007 Senate	$	100,000,000

Environmental Health

FY 2006	$	149,985,000
FY 2007 Pres.Rqst.	$	141,095,000
FY 2007 House	$	139,439,000
FY 2007 Senate	$	137,002,000

Health Tracking

FY 2006	$	24,200,000
FY 2007 Pres.Rqst.	$	24,000,000
FY 2007 House	$	24,000,000
FY 2007 Senate	$	20,000,000

State/local Bioterrorism Grants

FY 2006	$	823,674,000
FY 2007 Pres.Rqst.	$	823,674,000
FY 2007 House	$	823,674,000
FY 2007 Senate	$	823,674,000

Injury

FY 2006	$	139,036,000
FY 2007 Pres.Rqst.	$	138,214,000
FY 2007 House	$	138,561,000
FY 2007 Senate	$	139,656,000

NIOSH

FY 2006	$	255,272,000
FY 2007 Pres.Rqst.	$	250,194,000
FY 2007 House	$	251,000,000
FY 2007 Senate	$	257,881,000

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Maternal and Child Health Block Grant

FY 2006	$	692,521,000
FY 2007 Pres.Rqst.	$	693,000,000
FY 2007 House	$	700,000,000

FY 2007 Senate $ 693,000,000

ANNOUNCEMENT TO HELP SPEED ADOPTION OF ELECTRONIC HEALTH RECORDS -- The first round of ambulatory electronic health record products (EHRs) have been certified by the Certification Commission for Healthcare Information Technology (CCHIT), HHS Secretary Mike Leavitt announced July 18. HHS awarded CCHIT a contract in fall 2005 to develop certification criteria and a certification process.

"This seal of certification removes a significant barrier to wide-spread adoption of electronic health records. It gives health care providers peace of mind to know they are purchasing a product that is functional, and interoperable and will bring higher quality, safer care to patients," Secretary Leavitt said.

CCHIT certification indicates that EHR products meet base-line levels of functionality, interoperability and security in compliance with CCHIT's published criteria. This impartial seal of approval paves the way for adoption of health IT products by limiting the risk associated with investing in health IT. CCHIT is continuing to evaluate products, and additional results will be announced at the end of the month and quarterly thereafter.

"Volunteers from across the health care spectrum developed CCHIT's criteria and inspection process, ensuring fairness and balance between the interests of diverse stakeholders," said Dr. Mark Leavitt, CCHIT Chair.

In September 2005, HHS awarded a $2.7 million contract to CCHIT, a private, non-profit organization, to develop an efficient, credible, and sustainable mechanism for certifying health care information technology products. The CCHIT will certify health IT products in three initial phases:

* First, outpatient or ambulatory EHRs;
* Second, inpatient, or hospital EHRs; and
* Third, architectures, or systems that enable the exchange of information between and among health care providers and institutions.

The announcement of the first round of vendors to earn certification for electronic health record products from the CCHIT came at the George Washington University's Medical Faculty Associates, who adopted an EHR system last year. That system achieved certified status today.

"George Washington Medical Faculty Associates was an early adopter of the electronic health record system which has transformed our practice, enabling us to be proactive instead of reactive," said Stephen Badger, CEO of the George Washington University Medical Faculty Associates. "It has enhanced the overall patient care, significantly reduced our administrative costs and led to happier physicians and patients, because of this transformation."

Additionally, Secretary Leavitt noted that HHS will soon publish rules creating Anti-Kickback statute safe harbors and Physician Self-Referral law exceptions. These changes will allow certain donations of health information technology that may not have been permitted before, allowing hospitals and other health care providers and suppliers to take a more active role in contributing to health IT adoption. The regulations will finalize proposals made by the Office of Inspector General and the Centers for Medicare & Medicaid Services on Oct. 11, 2005.

To learn more about the CCHIT, and for a list of certified products, visit www.cchit.org.

NEW NIAID PROGRAM AIMS TO MODEL IMMUNE RESPONSES AND KEY INFECTIOUS DISEASES -- A new program at the National Institute of Allergy and Infectious Diseases (NIAID), one of the National Institutes of Health (NIH), aims to better understand the complex biochemical networks that regulate the interactions between infectious organisms and the human or animal cells they infect. The Program in Systems Immunology and Infectious Disease Modeling (PSIIM) will employ a powerful new approach called computational systems biology to develop a deeper understanding of how pathogens cause disease and how the immune system responds to them.

“Understanding the daunting complexity of biological systems is the greatest challenge and at the cutting-edge of science in the 21st century,” says NIH Director Elias A. Zerhouni, M.D. “The creation of this program will strengthen the intramural research program here on the NIH campus.”

The wealth of information gleaned about the human genome in recent years has identified many of the genes, proteins and other molecules involved in various biological systems. But understanding how these pieces work together to produce the complex physiological and pathological behavior of cells and organisms is not well understood. The goal of the PSIIM, which is a component of NIAID’s Division of Intramural Research (DIR) under the leadership of immunologist Ronald N. Germain, M.D., Ph.D., is to create a way to ask how whole systems of molecules, cells and tissues interact during an immune response or when confronted with an infectious agent.

“The idea of the PSIIM,” says NIAID Director Anthony S. Fauci, M.D., “is to use systems biology to allow scientists to ask very big questions they may not have been able to fully address even a few years ago — such as how infectious organisms invade human cells, how the toxins they produce cause cell and tissue destruction and how these pathogens evade or manipulate the immune response.”

“Once we understand these interactions, we can make strategic decisions about how to interfere with infectious disease pathology or how to direct immune responses to better fight infections,” says DIR Director Kathryn C. Zoon, Ph.D., adding that these new insights can serve as the starting point for the design of new drugs to treat diseases or the development of new vaccines.

By creating computer models of complex molecular interaction networks, PSIIM investigators will be able to simulate the biology of cells, tissues and, eventually, organisms. The program will also use state-of-the-art experimental approaches to determine how closely these simulations predict real behavior. As the models improve, scientists should gain the ability to predict how drugs and other interventions will affect a cell or organism and whether such treatments will be tolerated by the host while they fight the infectious agent. Although most of the studies will be conducted with less dangerous pathogens, special facilities in the new C. W. Bill Young Center for Biodefense and Emerging Infectious Diseases at NIH will enable PSIIM scientists to examine such questions with microbes that cause diseases such as anthrax, virulent forms of influenza, tularemia and plague. The program will encourage collaboration between NIAID researchers and other scientists from both inside and outside NIH in efforts to better understand infectious diseases and the immune system.

The cornerstone of the PSIIM research project is a software package called Simmune, which enables biologists to model many types of biological systems. Created by NIAID scientist Martin Meier-Schellersheim, Ph.D., and his colleagues, the software allows a scientist to use a simple graphical interface to easily define the interactions between individual molecules in a large network, or the behaviors of cells in response to external signals. Once a scientist inputs quantitative information obtained by laboratory measurements, Simmune can then simulate the behavior of the whole signaling network or of an entire cell. The software does this by automatically creating a mathematical model involving special equations and then solving these equations for the specific conditions the user entered into the program.

Before Simmune, making such mathematical models by hand often took months and required extensive expertise in applied mathematics. In addition, making changes to an existing model was very time-consuming, which limited the complexity of what could be modeled. “With Simmune, we are trying to empower a broad range of biological experts, allowing them to easily make and modify detailed quantitative models of the biological systems they have studied in the lab for years. The hope is that these models will provide a deeper understanding of *how* complex behaviors arise, leading to new insights into disease,” says Dr. Germain. “One of the great advantages of Simmune is that it gives biologists a way to do the difficult mathematics needed for such modeling without having to actually be involved with the mathematics.”

In the first stringent test of the new software, Drs. Meier-Schellersheim, Germain and their colleagues demonstrated that Simmune can accurately predict cell function in both time and space. In an article to be published July 21 by the journal *PLoS Computational Biology*, they describe how they used the software to model a complicated cell-biological behavior known as chemosensing — a fundamental biological process whereby cells sense and respond to external signals, such as inflammatory chemicals involved in an immune response. Using Simmune, the NIAID team modeled what happens in a stimulated cell to the distribution of a membrane-associated molecule known as a phospholipid. The concentration of the phospholipid changes during chemosensing mainly due to the action of two enzymes that synthesize or break down this molecule.

Scientists had thought that the destructive biochemical reaction that helps produce high and low concentrations of the phospholipid in different parts of the cell was regulated through some unknown mechanism acting throughout the cell. But a new model developed with Simmune predicted that the enhanced concentration of phospholipid at the “front” end of the cell (facing the source of chemical signals) resulted from a combination of two known mechanisms — a very rapid local inhibitory activity and the slower movement of another molecule to a distant part of the cell. The NIAID researchers, who tested their predictions in the laboratory, found that the experimental data matched very closely what they had predicted with Simmune.

The real power of the software, Dr. Meier-Schellersheim adds, is that it can do this same sort of modeling in nearly any cell-based biological system. “This is a tool that can simulate signaling and cellular processes in general,” he says, “whatever system or process you are interested in.” Because of the general utility of the approach, PSIIM is planning to collaborate extensively with scientists in other NIH institutes and centers, such as the National Cancer Institute’s Center for Cancer Research, to help support research in areas such as cancer biology that are outside of the field of immunity and infectious diseases.

MORE PHYSICIANS USING ELECTRICAL MEDICAL RECORDS -- CDC's National Center for Health Statistics is issuing a new Health E-Stat today entitled "Electronic Medical Record use by Office-based Physicians: United States, 2005."

The E-Stat is the latest look at the growing trend towards electronic record-keeping in the medical community. Some of the key findings in the report include:

Nearly one in four (23.9 percent) of physicians reported using full or partial electronic medical records (EMRs) in their office-based practice in 2005 - a 31 percent increase from the 18.2 percent reported in 2001.

Physicians in the Midwest (26.9 percent) and West (33.4 percent) were more likely to use EMRs than those in the Northeast (14.4 percent).

Physicians in metropolitan statistical areas (nearly 24.8 percent) were more likely to use EMRs than were those in non-metropolitan areas (16.9).

Only one in ten (9.3 percent) physicians, however, used EMRs with all four of the basic functions (computerized orders for prescriptions, computerized orders for tests, reporting of test results, and physician notes) considered necessary for a complete EMR system.

The entire E-Stat can be accessed at the CDC/NCHS web site at www.cdc.gov/nchs.

FDA NAMES FIRST MEDICAL DIRECTOR FOR EMERGING AND PANDEMIC THREAT PREPAREDNESS IN THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH -- The Food and Drug Administration (FDA) July 20 announced the appointment of Mark Goldberger, MD, MPH, as Medical Director for

Emerging and Pandemic Threat Preparedness in FDA's Center for Biologics Evaluation and Research (CBER). Dr. Goldberger was selected after a national search of eligible candidates. In this newly created position, Dr. Goldberger will serve as a Senior Advisor for CBER's pandemic flu program to plan, coordinate and implement activities related to the development and evaluation of products for emerging and pandemic threats.

"Emerging infectious diseases present a constant challenge for public health agencies, and FDA is committing resources and leadership to combat this growing threat. The creation of this position and Dr Goldberger's appointment together represent an important step forward in that effort." said Acting FDA Commissioner Andrew von Eschenbach, MD. "Dr. Goldberger has been at the forefront of combating other emerging infectious diseases, and we are grateful he has agreed once more to help tackle another monumental challenge, preparing for pandemic influenza and other future threats."

Dr. Goldberger began his career with the agency in 1989 as a medical reviewer, and currently serves as the Director of the Office of Antimicrobial Products in FDA's Center for Drug Evaluation and Research (CDER). He received his medical degree from Columbia University where he also did his Medical Residency and Infectious Diseases Fellowship, and practiced and taught clinical Infectious Diseases for nearly 10 years. He also served as an Epidemic Intelligence Service Officer at the Centers for Disease Control and Prevention (CDC), performing outbreak investigations and work on Swine Flu vaccine-associated Guillian-Barre syndrome.

"Dr. Goldberger's expertise and dedication to our public health mission will help enhance our preparedness activities," said Jesse L. Goodman, MD, MPH, Director of CBER. "His regulatory and public health experience with a wide range of infectious diseases and emerging threats, including influenza, SARS, pandemic influenza and West Nile Virus, will be a major asset in our strategic response."

Dr. Goldberger will be part of CBER's Senior Leadership Team, and will chair CBER's Pandemic Influenza Steering Committee (PISC). He will begin meeting with staff over the next few weeks and will be joining the Center full time at the end of August.