THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE:. "Infectious diseases cross national borders and require a global response, but the United States should help lead efforts to reverse the complacency in industrialized countries regarding this problem," said Margaret Hamburg, vice president for biological programs, Nuclear Threat Initiative, Washington, D.C., and co-chair of the Institute of Medicine committee that has just released an important new report on the threats infectious diseases pose to the American public. "On the whole, aggressively responding to microbial threats is in America's economic, humanitarian, and security interests, and should be a national priority." Details of the full report are provided 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 ACTS ON BUDGET – The Senate passed its FY 2004 (covers a 10 year period, but only the coming fiscal year is statutorily enforceable) Budget Resolution on 3/26. The House passed its version earlier this month. The Senate version contains fully $4.3 billion more for health discretionary programs – the agencies and programs of the U.S. Public Health Service, including CDC, NIH, etc. – than the House version. The House version actually cuts public health spending $1.4 billion, nearly 3 percent, below FY 2003 funding levels. Function 550 in the Senate was boosted via an amendment offered by Senators Arlen Specter (R-PA), and Tom Harkin (D-IA), respectively the Chairman and Ranking Minority Member of the Labor-HHS-Education Subcommittee on Appropriations. The amendment allots $1.8 billion more than the President's FY 2004 request for NIH, $600 million more for CDC and $400 million more for HRSA. However, since the Budget Resolution does not actually provide specific program funding, which is the function of the appropriations process, the effect of the amendment is an overall boost for all federal public health spending. The two differing versions of the budget resolution, which differ very significantly with regard to tax cuts as well – the Senate providing only one-half the total amount of tax cuts, or $350 billion as the House's $726 billion – will need to be worked out over the next week or so. Meanwhile, public health groups are urging conferees to support the higher Senate Budget Resolution funding level for public health agencies and programs.

SMALLPOX UPDATE – Legislation to address the problem of compensation for smallpox vaccinees who suffer adverse reactions, or those who are accidentally adversely affected by the vaccine, has been postponed in both the House and the Senate. The bill was scheduled for a vote in the Senate HELP Committee on Wednesday (3/26) and on the House floor this week, but negotiations between Republicans and Democrats over how generous the program's benefits should be broke down. Democrats had argued that funding for the bill should be mandatory rather than discretionary and therefore subject to annual appropriations, and that the $50,000 total cap on lost wages was too low. Republicans are likely to move ahead in the House with the Administration's version of the bill and pass it on a party line vote. The Senate is still negotiating; any controversial legislation in the Senate can be filibustered and the filibuster can only be broken by 60 votes – difficult to achieve in a closely divided chamber. Meanwhile, the next installment of the continuing IOM advisory reports on the smallpox vaccination process notes that the lack of a compensation program has impacted the low numbers of volunteers that have come forward to be vaccinated. Two recent heart attack deaths closely following smallpox vaccination is now being evaluated on an emergency basis by CDC officials and IOM experts.

BIOSHIELD PASSES SENATE HELP COMMITTEE – The Senate Health, Education, Labor and Pensions Committee unanimously approved the Administration's proposed BioShield program, a plan to expand and speed up the availability of vaccines and treatments to combat bioterrorism agents. The federal government would provide 6

billion over 10 years both to create these products and then purchase them – guaranteeing a buyer for the pharmaceutical industry. FDA would, additionally, have authority to expedite the approval process for vaccines and treatments and approve their use in the event of a bioterrorist attack. The House has held a hearing on BioShield, but has not yet held a vote.

APPROPRIATIONS UPDATE – The President presented his $74.7 billion FY 2003 supplemental request for funds to conduct the war in Iraq and tighten homeland security. Included in the supplemental is $250 million, "… a portion of which…" will be devoted to the smallpox compensation plan. The smallpox funding is located within the Executive Office of the President and may not include a specific amount as the negotiations about how generous the benefit package needs to be are still on-going, at least in the Senate. Appropriators have vowed to take up the supplemental appropriations request on Tuesday next week, but concerns about too much flexibility in the defense accounts may slow it down.

AMERICA SHOULD FOSTER SYSTEMATIC EFFORT TO COMBAT INFECTIOUS DISEASES HERE, ABROAD, IOM SAYS -- The nation should take decisive steps to fortify its public health system to tackle microbes that trigger infectious diseases such as West Nile encephalitis, AIDS, and tuberculosis, says a new report from the Institute of Medicine of the National Academies. In addition, the U.S. government should play a significant role in building the capacity of poor countries to monitor, prevent, and respond to disease outbreaks. In the developing world, infectious diseases kill one in every two people.

Microbial threats endanger public health across the globe. Moreover, the potential use of biological agents in terrorist attacks or warfare underscores the urgent need for better strategies and tools to grapple with infectious diseases, the report notes.

"Infectious diseases cross national borders and require a global response, but the United States should help lead efforts to reverse the complacency in industrialized countries regarding this problem," said Margaret Hamburg, vice president for biological programs, Nuclear Threat Initiative, Washington, D.C., and co-chair of the committee that wrote the report. "On the whole, aggressively responding to microbial threats is in America's economic, humanitarian, and security interests, and should be a national priority."

At the outset, America has a lot of work to do domestically. Its ability to track and respond quickly to infectious diseases rests on a public health infrastructure that has suffered from years of neglect, the report says. Efforts to prevent and control microbial threats must be enhanced and expanded at all levels of government. Upgrades in everything from laboratory facilities to training programs will require much larger, and sustained, investments. The National Institutes of Health, working with other federal research institutions, also should develop a comprehensive research agenda for infectious-disease prevention and control.

The committee pointed out several major areas of concern. Reporting of infectious diseases by health care providers and clinical laboratories to both state and local health officials remains inadequate, for instance. Open lines of communication and solid working relationships among providers, laboratories, and public health authorities are critical to maintaining effective infectious-disease surveillance systems – and successfully carrying out response activities. The Centers for Disease Control and Prevention should craft innovative strategies to improve communication among these groups.

Likewise, a skilled health care work force is essential. Knowledge of how to confront microbial threats should be fully integrated into training programs for all health care professionals, the committee said. Specifically, CDC, NIH, and the U.S. Department of Defense should expand existing programs and develop new ones that educate health care workers about field-based and laboratory approaches to preventing infectious disease in this country and abroad.

Also, health care professionals also should heed the importance of etiologic diagnosis, which identifies the microbial causes of infectious diseases, the report says. Along with surveillance, such diagnoses are the cornerstone of control and prevention measures. For various reasons, etiologic diagnoses have decreased significantly over the past decade. The result has been a dangerous overuse of broad-spectrum antibiotics to treat illness, fueling microbial resistance to therapeutic drugs. Public health agencies and professional societies should disseminate and publicize guidelines calling for widespread use of etiologic diagnostic tools. Also, CDC and other federal agencies should work together with private industry to develop and assess new diagnostic tests.

At the same time, efforts to educate practitioners and the public about inappropriate uses of therapeutic drugs should be strengthened. A steady, global increase in the number of microbial agents that are resistant to available therapies has made it difficult to treat infections, the committee said. This problem is compounded by the pharmaceutical industry's decreased development and production of new anti-microbials, compared with previous years.

The report also urges the Food and Drug Administration to ban the use of certain anti-microbials for growth promotion in animals if those same drugs may be used to treat illness in humans. The goal should be to reduce the chances of developing drug-resistant organisms in animals that could eventually spread to people.

Concerns about vaccines have mounted, too. Research and development initiatives have been inadequate. Periodic shortages of existing vaccines have occurred. And there is a lack of vaccines against infectious diseases that disproportionately affect people in developing countries, such as malaria. Looking at the big picture, the report calls for high-level federal leadership to accelerate the development of new anti-microbials, maintain adequate vaccine supplies, and implement a U.S. national vaccine strategy to resolve the concerns. The secretaries of Health and Human Services and Defense and the director of Homeland Security should join together with other top officials from the

public and private sectors to take immediate action in all of these areas. Their work should include partnerships with global organizations to promote the creation and distribution of vaccines against the diseases that are devastating the developing world. An aggressive campaign to produce new pesticides and repellents to combat mosquitoes and other carriers of infectious diseases also is needed.

As for U.S. disease-surveillance systems, they are fragmented and have not kept up with technological advances that could improve the timeliness and integration of data, the report notes. The CDC should set up a national electronic reporting system that feeds data from major clinical laboratories to state health departments, including information about patterns of microbial resistance. And the federal government should support research on innovative surveillance approaches that take advantage of cutting-edge information technology. Any new processes should be carefully evaluated before they are put in place, however.

Similarly, global surveillance is key to responding to and containing microbial threats before isolated outbreaks mushroom into regional or worldwide pandemics. The United States should work with key international agencies, such as the World Health Organization, to build up existing surveillance initiatives around the world – focusing on microbial threats in developing nations. Assistance should include financial and technical support. In the long run, America should take a leadership role in promoting a comprehensive system of surveillance for global infectious diseases. "Still, this effort should be multinational because it will require regional and global coordination, advice, and resources from participating nations," said committee co-chair Joshua Lederberg, professor emeritus and Sackler Foundation Scholar, Rockefeller University, New York City. "In the context of infectious diseases, we all share the same landscape."

The human element plays a critical role in interactions that result in disease emergence, the report says. Increases in the size and density of populations can promote the spread of disease, for example. Land development may situate people close to wild animals that carry pathogens. And individual behavior, such as unprotected sexual activity or use of intravenous drugs, can lead to the transmission of a number of diseases.

Several other factors contribute to the emergence of disease. In shipping goods from one place to another, people may unknowingly transport a disease carrier, and they can carry diseases during travel to and from international destinations. Breakdowns in public health measures – especially a lack of potable water or basic sanitation – have dramatically raised the persistence of infectious diseases throughout the world. The risk of intentional biological attacks also remains high.

The study was sponsored by the U.S. Centers for Disease Control and Prevention, National Institutes of Health, Ellison Medical Foundation, U.S. Department of Agriculture, U.S. Agency for International Development, U.S. Department of Defense, U.S. Food and Drug Administration, and the Joint Institute for Food Safety Research. The Institute of Medicine is a private, nonprofit institution that provides health policy advice

under a congressional charter granted to the National Academy of Sciences. A committee roster follows.

Read the full report of **Microbial Threats to Health: Emergence, Detection, and Response** for free on the Web, as well as 2,500 other publications from the National Academies Press; tel. (202) 334-3313 or 1-800-624-6242 or on the Internet at **http://www.nap.edu**

FEDERAL GOVERNMENT ANNOUNCES FIRST FEDERAL eGOV HEALTH INFORMATION EXCHANGE STANDARDS --The Departments of Health and Human Services (HHS), Defense (DoD) and Veterans Affairs (VA) March 21 announced the first set of uniform standards for the electronic exchange of clinical health information to be adopted across the federal government.

These standards are part of the foundation of the National Health Information Infrastructure that will serve consumers, patients, health care providers and public health professionals. Standardized information exchange, with privacy and security protections, makes it easier for health care providers to share relevant patient information and for public health professionals to identify emerging public health threats. Standardized information exchange also makes portable electronic medical records more likely and easily achievable.

The three federal departments that deliver health care services are coordinating with numerous other federal agencies to standardize across federal clinical health information as part of the Consolidated Health Informatics initiative (CHI). CHI is the health care component of President Bush's eGov Initiatives, created under the President's Management Agenda, to make it easier for citizens and businesses to interact with the government, save taxpayer dollars and streamline citizen-to-government transactions.

The new standards will help improve the quality of care by ensuring federal entities use a common coding system that will make it easier to coordinate care and exchange needed information. Currently, federal entities use different coding systems that make it difficult to maintain up-to-date information needed for quality care.

The members of the CHI are also participating in a number of projects -- individually and as part of the Consolidated Health Informatics group -- looking to establish widespread use of electronic health data systems and programs including electronic health records. Under today's announcement, as part of new systems development efforts, all federal agencies will:

* Adopt Health Level 7 (HL7) messaging standards to ensure that each federal agency can share information that will improve coordinated care for patients such as entries of orders, scheduling appointments and tests and better coordination of the admittance, discharge and transfer of patients.

* Adopt certain National Council on Prescription Drug Programs (NCDCP) standards for ordering drugs from retail pharmacies to standardize information between health care providers and the pharmacies. These standards already have been adopted under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, and today's announcement will make sure that parts of the three federal departments that aren't covered by HIPAA will also use the same standards. .

* Adopt the Institute of Electrical and Electronics Engineers 1073 (IEEE1073) series of standards that allow for health care providers to plug medical devices into information and computer systems that allow health care providers to monitor information from an ICU or through telehealth services on Indian reservations, and in other circumstances.

* Adopt Digital Imaging Communications in Medicine (DICOM) standards that enable images and associated diagnostic information to be retrieved and transferred from various manufacturers' devices as well as medical staff workstations.

* Adopt laboratory Logical Observation Identifier Name Codes (LOINC) to standardize the electronic exchange of clinical laboratory results.

For more information http://www.egov.gov.

HHS ANNOUNCES BIOTERRORISM AID FOR STATES, INCLUDING SPECIAL OPPORTUNITY FOR ADVANCE FUNDING -- HHS Secretary Tommy G. Thompson March 20 announced $1.4 billion to be provided to states this year to help them enhance preparations against terrorism or other public health emergencies. At the same time, he announced special provisions that would allow states to obtain up to 20 percent of their 2003 funding immediately in order to support current activities, including smallpox vaccination for selected health workers and emergency responders.
"Once again, we are rapidly getting federal funding for public health preparedness into the hands of our states and hospitals," Secretary Thompson said. "Together, we've made strong progress in the past year to strengthen our public health systems, but this remains an ongoing endeavor. We will continue to work with our state and local partners to enhance our readiness and our ability to respond to public health emergencies. Our combined efforts will result in a stronger public health system to care for Americans in emergencies, whether it be an outbreak of the flu or a biological incident."

Secretary Thompson said that some states will need a share of their 2003 funds right away, while others will want to receive them later following the planning process -- that decision is left to each state. But HHS is prepared to rapidly release up to 20 percent of this year's funds to any states that request it for ongoing public health and hospital preparations.

Part of the funding ($870 million) supports enhancement of states' public health agencies, and the rest ($498 million) is provided to states to support hospital preparedness for possible bioterror or other mass casualty events.

The funding is part of a total of about $3.5 billion in HHS funding this year for bioterrorism preparedness, including research into potential bioterror disease agents and potential treatments and vaccines. The fiscal year 2003 funding is up from about $1.8 billion for these activities in 2002.

Secretary Thompson emphasized that HHS "will continue to ensure that funds provided to the states are spent effectively, to build the strongest possible protection and response capability for Americans." As in 2002, states will be required to submit work plans to HHS outlining their public health and hospital preparedness activities, including regional planning for areas that cross state lines.

While most funding for states will be released following approval of their plans, Secretary Thompson told governors their states could receive up to 20 percent of their fiscal year 2003 allocation immediately in order to:

* Support their smallpox vaccination activities for health workers and emergency responders.
* Support activities already approved in 2002 state plans which need additional resources now.
* Enhance or intensify critical activities already approved under last year's state plans.
* Accelerate timelines for these critical activities.

Secretary Thompson said that the states would be notified of the expedited application procedure for obtaining the advance portion in the coming week. The offer is similar to last year's action, in which states obtained 20 percent of their 2002 funding in order to jump-start state actions.

HHS' BUDGET PLAN INCLUDES $100 MILLION TO PREPARE FOR A POTENTIAL WORLDWIDE FLU OUTBREAK --President Bush has proposed a new $100 million initiative to prepare for a possible influenza pandemic involving a worldwide outbreak of a dangerous new flu variant, HHS Secretary Tommy G. Thompson told lawmakers March 20
.
In testimony to the Senate Appropriations Subcommittee on Labor, HHS and Education, Secretary Thompson said the initiative would better prepare America for an outbreak such as the one that occurred in 1918 and killed 25 million people worldwide.
"Our budget proposes this $100 million increase to build the nation's vaccine production capabilities in the event that the world experiences a pandemic on the devastating scale experienced three times in the last century," Secretary Thompson said. "The recent cases of what has been called Severe Acute Respiratory Syndrome remind us all of the potential

danger posed by emerging infectious diseases, especially a possible new influenza strain. This is why HHS and its agencies are continually preparing for potential new disease outbreaks."

Under President Bush's fiscal year 2004 budget plan, HHS would receive an additional $100 million to spur development of capacity to produce influenza vaccine year-round, and the development of and implementation of production techniques that could be scaled up rapidly in the event of a pandemic. HHS would work closely with industry to ensure this capacity exists -- so that new vaccine can be produced quickly if and when needed. The constant changes in circulating influenza strains makes it impossible to stockpile vaccine as is done with other vaccines. A flu pandemic can occur when there is a major change in the virus' genetic structure, creating a new strain that causes widespread illness and death. For example, the 1918 influenza pandemic claimed more than 500,000 lives in the United States alone.