THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE: -- The U.S. Department of Health and Human Services October 13 announced $139 million in grants and contracts to promote the use of health information technology (HIT). Awarded through HHS' Agency for Healthcare Research and Quality (AHRQ), this multi-year program builds on President Bush's initiative to use HIT to improve the nation's health care system."Increased adoption of information technology will speed the transformation of health care services in this nation," HHS Secretary Tommy G. Thompson said. "We're heeding the President's call to improve patient safety and quality of care. Technology can help to efficiently and effectively deliver the information caregivers need to take better care of their patients. These grants will help us ensure that the right patients are getting the right care at the right time.". -- additional details 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

CONGRESS ADDRESSES FLU VACCINE SHORTAGE – The House Committee on Government Reform held a hearing on October 8th entitled, ``The Nation's Flu Shot Shortage: How it Happened and Where We Go from Here." Testimony was heard from the following officials of the Department of Health and Human Services: Julie L. Gerberding, M.D., Director, Centers for Disease Control and Prevention; Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, NIH; and Lester M. Crawford, M.D., Acting Commissioner, FDA; Robert Stroube, M.D., Commissioner, Department of Health, State of Virginia; and public witnesses.

Senator Evan Bayh (D-IN) held a press conference this morning (October 20th) to urge passage this year, during the post-election lame-duck session, of legislation he introduced last January addressing the flu vaccine shortage. The bill (S. 2038/H.R. 3758) would offer tax credits for expansion of flu vaccine production facilities and a government "buy back" guarantee for suppliers that end up with surplus vaccine at the end of the flu season. The bill currently has 8 co-sponsors with one Republican, Sen. Larry Craig (R-ID) who serves on the Senate Aging Committee with Sen. Bayh. In his press statement, Sen. Bayh criticizes CDC for presenting ideas in the past few days that he had incorporated in his bill, Flu Protection Act, and had asked Secretary Thompson and CDC to adopt last year to prevent a vaccine shortage crisis. He said Congress needs to act this year because flu vaccine suppliers make decisions about production for next year's season as early as February. Below is a detailed summary of the legislation:

Flu Protection Act of 2004:
Ensures Sufficient Flu Vaccine Supply. The main goal of the bill is to guarantee that the nation does not suffer another year of vaccine shortages. The legislation requires the CDC to purchase an amount of unused doses at the end of the flu season through a government fallback guarantee purchase program to remove the current economic disincentives facing vaccine manufacturers.

Supports Flu Vaccine Awareness Campaign. Calls for a public awareness campaign and outreach efforts to educate the public on the importance of receiving the flu vaccine, ways to avoid catching the flu, and what populations are most at risk from the flu. The legislation will also emphasize the safety and benefit of the vaccine for the public good.

Encourages an Increase in Vaccine Production Capacity. Offers tax incentives for vaccine manufacturers to expand their production capabilities. The tax credit would be 20% for vaccine and biotechnology companies to encourage investment in the construction of new or renovation of existing facilities in the United States for the production of new and improved vaccines. The tax credit would exist for five years.

Prepares for a Pandemic or Epidemic. Encourages states to develop contingency plans for maximizing influenza immunization for high-risk populations in the event of a delay or shortage of influenza vaccine. Also authorizes $100 million in annual funding in FY 2004—FY 2008 for CDC to implement a protocol if the flu reaches epidemic or pandemic levels. The CDC would

be required to use funds provided to address issues including:
* Exploring methods to coordinate dissemination of the vaccine to key populations in a pandemic and epidemic.
* Examining current methods to produce and manufacture vaccines approved by the FDA faster and in larger quantities.
* Conducting research to develop improved influenza vaccines.
* Formulating recommendations on what strains to include in the vaccine annually.
* Increasing public awareness on the need to be vaccinated.
* Implementing alternative checks to prevent the spread of the flu and prevent complications from the flu, such as through antiviral medications.
* Using a tracking method for publicly and privately sold and circulating vaccines, to determine how much vaccine supply is in circulation in case of an emergency.
* Conducting international and national surveillance, building state surveillance capacity, conducting vaccine safety and efficacy data collection and engaging in epidemiological studies and research on novel viruses.
* Assisting states with preparedness for rapid state and local response to influenza panic.
* Developing systems to routinely measure the impact of influenza on pediatric and high-risk populations.

BY 2020, ONE IN TWO AMERICANS OVER AGE 50 WILL BE AT RISK FOR FRACTURES FROM OSTEOPOROSIS OR LOW BONE MASS -- U.S. Surgeon General Richard H. Carmona, M.D., M.P.H., F.A.C.S., warned October 14 in a new report that by 2020, half of all American citizens older than 50 will be at risk for fractures from osteoporosis and low bone mass if no immediate action is taken by individuals at risk, doctors, health systems, and policymakers. This new report, "Bone Health and Osteoporosis: A Report of the Surgeon General" says that 10 million Americans over the age of 50 have osteoporosis, the most common bone disease, while another 34 million are at risk for developing osteoporosis. And each year, roughly 1.5 million people suffer a bone fracture related to osteoporosis.

This report is the first-ever Surgeon General's report on the topic of bone health. Osteoporosis and other bone diseases, such as Paget's disease and osteogenesis imperfecta can lead to a downward spiral in physical health and quality of life, including losing the ability to walk, stand up, or dress, and can lead to premature death.

"This report will shape the way we approach, talk, and act about bone diseases," HHS Secretary Tommy G. Thompson said. "The more we learn, the more we realize that so many diseases are preventable, from obesity, to many types of cancer, and now bone disease. I want to thank Dr. Carmona and all the scientists and researchers who worked on this report. I look forward to the impact this new information will make in the health of communities."

Other findings in the report include:

* About 20 percent of senior citizens who suffer a hip fracture die within a year of fracture.
* About 20 percent of individuals with a hip fracture end up in a nursing home within a year.
* Hip fractures account for 300,000 hospitalizations each year.
* The direct care costs for osteoporotic fractures alone are already up to $18 billion each year. That number is expected to increase if action to prevent osteoporosis is not taken now.

"Osteoporosis isn't just your grandmother's disease. We all need to take better care of our bones," Dr. Carmona said. "The good news is that you are never too old or too young to improve your bone health. With healthy nutrition, physical activity every day, and regular medical check-ups and screenings, Americans of all ages can have strong bones and live longer, healthier lives. Likewise, if it's diagnosed in time, osteoporosis can be treated with new drugs that help prevent bone loss and rebuild bone before life-threatening fractures occur."

According to the new report, osteoporosis is a "silent" condition because many Americans are unaware that their bone health is in jeopardy. In fact, four times as many men and nearly three times as many women have osteoporosis than report having the condition. One of the most dangerous myths about osteoporosis is that only women need to worry about bone health. Osteoporosis affects men and women of all races, and while bone weakness manifests in older Americans, strong bones begin in childhood.

The Surgeon General's report is a call for Americans to take action to improve and maintain healthy bones. The report includes recommendations on what Americans can do to decrease the likelihood of developing osteoporosis.

These recommendations include:

* Getting the recommended amounts of calcium and vitamin D. High levels of calcium can be found in milk, leafy green vegetables, soybeans, yogurt and cheese. Vitamin D is produced in the skin by exposure to the sun and is found in fortified milk and other foods. For individuals who are not getting enough calcium and vitamin D in the diet, supplements may be helpful. The average adult under 50 needs about 1000mg of calcium per day and 200 International Units (IU) of Vitamin D (one cup of vitamin D fortified milk provides 302 mg of calcium and 50 IU of Vitamin D).
* Maintaining a healthy weight and being physically active at least 30 minutes a day for adults and 60 minutes a day for children, including weight-bearing activities to improve strength and balance.
* Taking steps to minimize the risk of falls by removing items that might cause tripping, improving lighting, and encouraging regular exercise and vision tests to improve balance and coordination.

"I always worried about heart disease and cancer, but was never concerned about the health of my bones," said Abby Perelman, who is being treated for osteoporosis. "I wish I

knew then what I know now -- that a healthy diet and physical activity can make bones stronger and healthier."

The report also calls on health care professionals to help Americans maintain healthy bones by evaluating risks for patients of all ages, recommending bone density tests for women over the age of 65 and for any man or woman who suffers even a minor fracture after the age of 50. In addition, the report calls on health care professionals to look for "red flags" that may indicate that someone is at risk, including people who are under 50 who have had multiple fractures, or patients who take medications or have a disease that can lead to bone loss.

"All health care professionals need to be aware of the early indicators of bone disease," said Dr. Lawrence Raisz of the University of Connecticut Health Center, one of the scientific editors of the report. "Many of my patients had no idea their minor fracture was an indication of a larger problem. The health care system can do a better job of helping patients protect themselves from bone disease."

In addition to the release of the report, the Surgeon General has published a companion "People's Piece" specifically written for the American people. The magazine-style, full-color booklet offers ready-to-use information on how people can improve their bone health. This is the second People's Piece that Dr. Carmona has produced as part of his commitments to improving the health literacy of Americans and providing the best scientific information available in a way that everyone can understand and use to live longer, healthier lives. The first People's Piece discussed the health consequences of smoking and was released in May 2004.

The free People's Piece, *The 2004 Surgeon General's Report on Bone Health and Osteoporosis: What It Means To You*, is available by calling toll free 1-866-718-BONE or visiting www.surgeongeneral.gov.

"Thirty years ago, doctors thought weak bones and osteoporosis were a natural part of aging, but today we know they are not. We can do a lot to prevent bone disease," said Dr. Carmona. "Everyone has a role to play in improving bone health, and this report is a starting point for national action on bone health. Let's get started by taking action today in homes, health care settings, and communities across our nation."

HHS AWARDS $139 MILLION TO DRIVE ADOPTION OF HEALTH INFORMATION TECHNOLOGY -- The U.S. Department of Health and Human Services October 13 announced $139 million in grants and contracts to promote the use of health information technology (HIT). Awarded through HHS' Agency for Healthcare Research and Quality (AHRQ), this multi-year program builds on President Bush's initiative to use HIT to improve the nation's health care system.

"Increased adoption of information technology will speed the transformation of health care services in this nation," HHS Secretary Tommy G. Thompson said. "We're heeding the President's call to improve patient safety and quality of care. Technology can help to

efficiently and effectively deliver the information caregivers need to take better care of their patients. These grants will help us ensure that the right patients are getting the right care at the right time."

These awards will provide insight into how best to use health information technologies to improve patient safety by reducing medication errors; increasing the use of shared health information between providers, laboratories, pharmacies and patients; helping to insure safer patient transitions between health care settings, including hospitals, doctors' offices, and nursing homes; and reducing duplicative and unnecessary testing.

In addition to improving care for patients and giving health care providers additional support, health information technology has the potential to produce savings of up to10 percent of the country's total annual spending on health care.

"These grants will provide the momentum needed to move forward with the creation of a safer U.S. health care system based on proven health information technologies, especially in the rural and small communities throughout America where the need is so great," said AHRQ Director Carolyn M. Clancy, M.D. "Health care systems across the country can learn from our grantees' experiences and follow their lead."

The $139 million will be used in the following ways:

* *Promoting access to HIT* -- Over 100 grants to communities, hospitals, providers, and health care systems to help in all phases of the development and use of health information technology. The grants are spread across 38 states, with a special focus on small and rural hospitals and communities. First year funding is $41 million and will total nearly $96 million over three years.
* *Developing statewide and regional networks* -- Five-year contracts to five states or their designees to help them develop statewide networks that are secure, ensure privacy of health information, and make an individuals' health information more available to health care providers. The five states are Colorado, Indiana, Rhode Island, Tennessee and Utah. Participants include major purchasers of health care, public and private payers, hospitals, ambulatory care facilities, home health care providers and long-term care providers. First-year funding is $1 million for each state and will total $25 million over the course of the contracts.
* *Encouraging adoption of HIT by sharing knowledge* -- The creation of the National Health Information Technology Resource Center to aid grantees and other federal partners by providing technical assistance, provide a focus for collaboration, serve as a repository for best practices, and disseminate needed tools to help providers explore the adoption and use of health information technology to improve patient safety and quality of care. The two-year contract, renewable for up to three years, was awarded to NORC, a national organization for research at the University of Chicago. First year funding is $4 million, with an estimated value of $18.5 million over the course of the contract.

"I view these awards as a building block to advance the adoption of electronic health records," said David J. Brailer, M.D., Ph.D., National Coordinator for Health Information Technology. "These projects will encourage real world laboratories for innovation and provide models for other organizations as we move forward in developing an electronic health record."

The awards address directly the four goals of Secretary Thompson's recently announced Framework for Strategic Action, "The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care," which are: informing clinical practice and the use of electronic health records, electronically connecting clinicians to other clinicians so they can exchange health information using information tools to personalize care delivery, and advancing surveillance and reporting for population health improvement. The Framework for Strategic Action was released in July, 2004 by Secretary Thompson at a Secretarial Summit on Health Information Technology that brought together many of the nation's technology and health leaders.

President Bush in April called for electronic health records for most Americans within 10 years. An executive order provided for the establishment of the office of the "National Coordinator for Health Information Technology" and in May, Secretary Thompson appointed Dr. Brailer to the new position.

For specific information on each grant, go to http://www.ahrq.gov/research/hitfact.htm

HHS AWARDS $232 MILLION IN BIODEFENSE CONTRACTS FOR VACCINE DEVELOPMENT -- HHS Secretary Tommy G. Thompson October 7 announced four new contracts totaling more than $232 million to fund development of new vaccines against three potential agents of bioterrorism: smallpox, plague and tularemia. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), will administer the contracts.

"We are moving as quickly as possible to develop new vaccines to ensure that our nation is protected against an array of potential bioterror agents," Secretary Thompson said. "These new contracts are the next steps in our plans to build a robust stockpile of critical medical countermeasures and supplies, so we are even more prepared to respond to a biological attack or outbreak."

These awards respond to a key objective of the NIAID biodefense research agenda, which emphasizes the development of new and improved medical products against "Category A" agents-those considered by the Centers for Disease Control and Prevention to pose the greatest threat to national security.

The smallpox awards continue advanced development work that began in February 2003 on two modified vaccinia Ankara (MVA) vaccine candidates. These contracts will support larger scale manufacturing of the vaccines as well as further safety and effectiveness studies in animals and humans. The tularemia and plague awards will fund early-stage product development of the respective vaccines, which will include dosage

formulation, pilot batch production and initial clinical assessment. All four contracts are for purchases of vaccine lots intended for research use. Any future purchases of additional vaccines for stockpiling in the event of an emergency will depend on the results of the research currently underway.

"In a short period of time, we have greatly expanded our partnerships with industry to spur the development of vaccines against the most deadly agents of bioterrorism," said Anthony S. Fauci, M.D., director of NIAID. "These important new contracts reflect our commitment to develop medical tools to protect citizens against pathogens that could be deliberately introduced into society."

NIAID awarded two contracts totaling up to $177 million for advanced development of MVA vaccines against smallpox. The three-year contracts were awarded to Bavarian Nordic A/S of Copenhagen, Denmark, and Acambis, Inc., of Cambridge, Mass., and Cambridge, England. MVA is a highly weakened form of the vaccinia virus that cannot replicate in human cells.

Previous NIAID research has demonstrated that MVA is nearly as effective as the standard smallpox vaccine, making it a promising candidate for use in children and pregnant women as well as people with weakened immune systems or skin conditions such as eczema. The new contracts will allow the companies to continue the work they began under contracts awarded in February 2003.

For the plague vaccine, NIAID awarded a contract to Avecia Biotechnology, Ltd., of Manchester, England. The three-year, $50.7 million contract covers the manufacture of a new plague vaccine as well as animal testing and initial human trials. There is currently no licensed plague vaccine, and the pneumonic form of the disease, which infects the lungs and can spread from person to person through the air, is nearly always fatal unless antibiotic treatment is started within 24 hours of infection.

NIAID also modified an existing contract with DynPort Vaccine Company LLC of Frederick, Md., to include the manufacture of a pilot batch of live, attenuated tularemia vaccine. The three-year, $4.5 million contract modification also covers stability testing of the vaccine. Tularemia is a highly infectious bacterial disease most often transmitted by ticks and insects. In humans, illness is characterized by intermittent fever, headache and swelling of the lymph nodes. This live, attenuated vaccine contains a weakened form of the tularemia bacterium, enabling the immune system to recognize and produce neutralizing antibodies against the bacterium if it is encountered again.

NIAID is a component of NIH, an agency of the U.S. Department of Health and Human Services. NIAID supports basic and applied research to prevent, diagnose and treat infectious diseases such as HIV/AIDS and other sexually transmitted infections, influenza, tuberculosis, malaria and illness from potential agents of bioterrorism. NIAID also supports research on transplantation and immune-related illnesses, including autoimmune disorders, asthma and allergies.

PANEL FINDS THAT SCARE TACTICS FOR VIOLENCE PREVENTION ARE HARMFUL -- Programs that rely on “scare tactics” to prevent children and adolescents from engaging in violent behavior are not only ineffective, but may actually make the problem worse, according to an independent state-of-the-science panel convened by the National Institutes of Health (NIH). The panel, charged with assessing the available evidence on preventing violence and other health-risking behaviors in adolescents, announced today its assessment of the current research.

The panel found that group detention centers, boot camps, and other “get tough” programs often exacerbate problems by grouping young people with delinquent tendencies, where the more sophisticated instruct the more naïve. Similarly, the practice of transferring juveniles to the adult judicial system can be counterproductive, resulting in greater violence among incarcerated youth.

“The good news is that a number of intervention programs have been demonstrated to be effective through randomized controlled trials,” explained Dr. Robert L. Johnson, Chair of the Department of Pediatrics at the University of Medicine and Dentistry of New Jersey, who chaired the state-of-the-science panel. “We were pleased to find several programs that work, and we hope that communities will adopt them and continue to develop other interventions that incorporate the features common to successful programs.”

The panel highlighted two programs that are clearly effective in reducing arrests and out-of-home placements: Functional Family Therapy, and Multisystemic Therapy. Among the important characteristics that these programs have in common are a focus on developing social competency skills, a long-term approach, and family involvement.

The panel also identified strengths and weaknesses in the field of violence prevention research, and made a number of recommendations to shape future efforts. Among these, the panel advocated a national population-based adolescent violence registry, and greater emphasis on economic research into the cost-effectiveness of intervention to prevent violence.

The panel released its findings in a public session this morning, following two days of expert presentations and panel deliberations. The full text of the panel's draft statement will be available late today at http://consensus.nih.gov. The final version will be available at the same Web address in three to four weeks. Statements from past conferences and additional information about the NIH Consensus Development Program are also available at the Web site, or by calling 1-888-644-2667.

The panel is independent and its report is not a policy statement of the NIH or the Federal Government. The NIH Consensus Development Program, of which this conference is a part, was established in 1977 as a mechanism to judge controversial topics in medicine and public health in an unbiased, impartial manner. NIH has conducted 119 consensus development conferences, and 23 state-of-the-science (formerly "technology assessment") conferences, addressing a wide range of issues.

The conference was sponsored by the Office of Medical Applications of Research and the National Institute of Mental Health, of the NIH. Cosponsors included the Office of Behavioral and Social Sciences Research, the National Institute of Alcohol Abuse and Alcoholism, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, National Institute of Nursing Research, the National Library of Medicine, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, the U.S. Department of Education, and the U.S. Department of Justice.

The 13-member panel included practitioners and researchers in community and family medicine, pediatrics, nursing, psychiatry, behavioral health, economics, juvenile justice, outcomes research, and a public representative. The panel reviewed an extensive collection of scientific literature related to youth violence prevention, including a systematic literature review prepared by the Southern California Evidence-Based Practice Center, under contract with the Agency for Healthcare Research and Quality. A summary of the Evidence Report on Preventing Violence and Related Health-Risking Social Behaviors in Adolescents is available at http://www.ahrq.gov/clinic/epcsums/adolvisum.htm.