THE CSTE WASHINGTON REPORT

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INSIDE THIS ISSUE

EDITOR'S NOTE: HHS Secretary Tommy G. Thompson November 13 announced that the number of Americans with diabetes rose to an all-time high with an estimated 18.2 million people in 2003. "These new estimates show we are diagnosing more people who live with diabetes, and the overall prevalence of this disease continues to increase," Secretary Thompson said. "Clearly, diabetes remains a serious and growing health threat. We are fighting this terrible disease by promoting better lifestyle choices and increasing awareness among all Americans." Details about HHS's efforts to reach people with diabetes who are undiagnosed are 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

CONGRESS WRAPPING UP FY 2004 APPROPRIATIONS – House and Senate senior Appropriators are in the process of wrapping five unfinished FY 2004 appropriations bills, including the Labor-HHS-Ed bill which funds all CDC programs, into an omnibus bill. It is their intent to strip out of the Senate bill the provision prohibiting the Labor Department from implementing new overtime rules. However, Senator Specter (R-PA), Chairman of the Senate Labor-HHS-Education Appropriations Committee, is threatening to oppose the omnibus package if that occurs. The White House is also adamant that the bill will be vetoed if the provision is not stripped out. This continuing stand-off could delay finalizing FY 2004 appropriations by the current November 21st deadline. Other items that will be included in the omnibus bill, such as $1.3 billion in increased funding for veterans health added in the Senate version of the VA-HUD bill, may be dealt with by implementing an across-the-board cut in all other programs. The final Senate version of the VA-HUD bill includes $73.5 million for the Agency for Toxic Substances and Disease Registry (ATSDR). This is the same amount as provided in the House bill, so the omnibus will reflect this level of funding – a $8.5 million cut over the FY 2003 level of $82 million. CSTE had advocated $91.5 million for ATSDR, including $9.5 million for enhanced state environmental health capacity to respond to chemical terrorism.

TOBACCO UPDATE – On November 12th the Senate Committee on Commerce, Science and Transportation held a hearing on the historic 1998 tobacco settlement and a report released by a coalition of public health groups of states' progress in implementing tobacco prevention programs with settlement monies. The coalition (American Cancer Society, American Heart Association, Campaign for Tobacco Free Kids, American Lung Association) found that only four states – Maine, Delaware, Mississippi and Arkansas – currently fund tobacco prevention and cessation programs at minimum levels recommended by the CDC. Thirty-eight states and the District of Columbia fund tobacco prevention programs at less than half the CDC's minimum level, or provide no state funding at all. In a press release, the groups state, "Over the past two years, the states collectively have cut funding for tobacco prevention programs by 28 percent or $209 million. In contrast, the tobacco industry has increased its marketing expenditures to record levels. In the first three years after the settlement, tobacco marketing increased by 66 percent to a record $11.5 billion in 2001, or $31.4 million a day, according to the most recent report on tobacco marketing by the Federal Trade Commission (FTC)."

NEW BILLS INTRODUCED – Sen. Daschle (D-SD) and Rep. Cummings (D-MD) each introduced legislation on November 6th that has several co-sponsors each to improve the health of minorities (S. 1833/H.R. 3459). The bills are comprehensive in nature calling for expanded coverage, culturally and linguistically appropriate health services, promoting health workforce diversity, enhancing racial, ethnic, and primary language health data collection at the local, State, and Federal level, among other purposes. Rep.

Pallone (D-NJ) introduced a bill on November 17th (HR. 3513) that would expand and intensify programs with respect to research and related activities concerning elder falls.

HIV CASE REPORTING NOT RELIABLE ENOUGH TO USE IN ALLOCATING RYAN WHITE CARE ACT FUNDS -- The reporting of HIV cases is not complete and accurate enough nationwide to allow these numbers to be used in determining how funds from the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act (RWCA) should be allocated among states and metropolitan areas, says a new report from the Institute of Medicine of the National Academies. The estimated number of AIDS cases should continue to be the main criterion used in RWCA allocation formulas, at least until HIV case reporting or other estimation techniques provide better data about regional numbers of HIV cases, said the committee that wrote the report.

The RWCA distributes funding to states, metropolitan areas, and public and private organizations to enable uninsured and underinsured individuals with HIV disease or AIDS to obtain care and support services. The estimated number of AIDS cases in each area has been the main factor for determining distribution of funds because such reporting is well-established across the nation and because people who have developed AIDS tend to need more care and visit health care facilities more frequently, where their illness is identified and recorded. Although it is harder to reliably detect and count cases of diagnosed HIV infection -- infected individuals may not get sick and need care -- many believe that the number of HIV cases might be a better indicator of resource needs than AIDS cases alone. Concerns about the equity of how the funds are distributed prompted Congress, during its reauthorization of the act in 2000, to specify that data on reported cases of HIV disease be incorporated into the allocation formulas, provided that reliable data are available from each state. Congress asked IOM to assess the quality of these data and determine if they are accurate enough for inclusion in RWCA allocation formulas, and to recommend improvements in HIV reporting systems.

While all but one state and one city currently have HIV case reporting systems in place, some of the systems have been implemented only recently. Moreover, states differ in how they gather and report data, including whether they record individuals' names or use codes instead, and procedures have not been developed to eliminate duplicate reports. Until HIV case reporting or other estimation techniques provide better data about regional variability in the number of HIV cases, information on HIV cases cannot be used to determine distribution of funds, the committee concluded. An effort should be made to improve the consistency, quality, and comparability of reporting systems so that data on HIV cases eventually can be incorporated into the allocation formulas.

"Data on HIV cases should be comparable across jurisdictions so that incorporating the data increases -- rather than decreases -- the fairness of the CARE Act fund allocations," said committee chair Paul Cleary, professor of health care policy, Harvard Medical School, Boston.

Among specific steps recommended in the report, the Centers for Disease Control and Prevention should partner with states to develop methods to collect and use HIV case information from all states, regardless of whether the states use name-based or code-based reporting systems. CDC currently does not accept data from 15 states that use code-based systems because it is difficult to ensure that each case is counted only once in code-based systems, especially across states. The agency should be given enough funding to develop a way to eliminate duplication of cases. The U.S. Department of Health and Human Services should appoint an independent body to evaluate methods to estimate the total number of people infected with HIV, such as modeling and survey-based approaches, as alternatives or supplements to case reporting.

A portion of RWCA funds is intended to be directed to states and metropolitan areas with the greatest resource needs, but the process of determining severity of need is hampered by the lack of comparable data across jurisdictions. The committee outlined a new approach that entails developing measures of resource needs -- such as interviews of patients to determine the kinds of services they need or disease-surveillance studies -- and identifying predictors of the areas with the greatest needs. The Health Resources and Services Administration's HIV/AIDS Bureau should further develop and use such approaches to predict regional variations in resource needs.

RWCA grantees and administrators have implemented a variety of quality improvement initiatives, but more can be done to measure and improve the quality of care, the report says. While many clinics assess their own organizations' attempts to improve care, the committee found that more effort should be made to assess the patients' experiences with the care they receive and to measure quality at a broader population level. The report proposes a framework for developing such comprehensive quality measures and recommends an initial set of standard measures to assess the quality of care given by all RWCA-funded providers.

The study was sponsored by the U.S. Department of Health and Human Services' Health Resources and Services Administration and the Centers for Disease Control and Prevention. 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.
The report **Measuring What Matters: Allocation, Planning, and Quality Assessment for the Ryan White CARE Act** is available on the Internet at **http://www.nap.edu**. Copies of the final book will be available for purchase later this year from the National Academies Press; tel. 202-334-3313 or 1-800-624-6242.

POTENTIAL ENVIRONMENTAL PROBLEMS WITH ANIMAL BIOTECH RAISE SOME CONCERNS; NO EVIDENCE CLONED ANIMALS ARE UNSAFE TO EAT, BUT DATA STILL LACKING -- The possibility of certain genetically engineered fish and other animals escaping and potentially introducing engineered genes into wild populations tops the list of concerns associated with advances in animal biotechnology, says a new report from the National Academies' National Research Council. On the other hand, no evidence yet exists that products from cloned livestock

are unsafe for human consumption, although the committee that wrote the report found it difficult to identify concerns without additional information about food composition, which could be collected using available analytical tests.

The report was requested by the Food and Drug Administration as it prepares to rule on the safety of certain animal-biotechnology products, particularly cloned cattle. The committee was asked only to identify science-based concerns; it was not asked to identify potential benefits from animal biotechnology or to make policy recommendations.

"As is the case with any new technology, it is almost impossible to state that there is no concern, and in certain areas of animal biotechnology we did identify some legitimate ones," said committee chair John G. Vandenbergh, professor of zoology, North Carolina State University, Raleigh. "By identifying these concerns, we hope we can help this technology be applied as safely as possible without denying the public its potential benefits."

The committee said the greatest concern is the ability of certain genetically engineered organisms to escape and reproduce in the natural environment. Genetically engineered insects, shellfish, fish, and other animals that can easily escape, that are highly mobile, and that become feral easily are of particular concern, especially if they are more successful at reproduction than their natural counterparts. For example, it is possible that if transgenic salmon with genes engineered to accelerate growth were released into the natural environment, they could compete more successfully for food and mates than wild salmon.

By creating transgenic animals with genes from another species, or by removing or "turning off" genes, animals can be produced to grow bigger and more rapidly, or possess traits beneficial to humans, such as meat with more protein and less fat, eggs with less cholesterol, milk containing pharmaceutical products, or even tissues and organs suitable for human transplantation. And through somatic cell nuclear transfer -- the technique used to clone Dolly the sheep -- scientists can create an almost identical copy of an adult animal with desirable traits. The owners of a few hundred cows cloned this way in the United States have been asked by FDA to hold off selling the cows' milk and meat, or breeding them, pending regulatory approval.

In transgenic animals developed for human consumption, there is a low probability that a few new proteins expressed when genes are inserted from another species may trigger allergic or hypersensitive reactions in a small, but unknown, percentage of people. The potential for allergenicity is difficult to gauge, however, since it can only be detected once a person is exposed and experiences a reaction. While a reaction will be recognizable, as it is with well-known allergens like peanuts and shellfish, the uncertainty surrounding new proteins and potential impact on consumers who may be allergic is serious enough to elicit a moderate level of concern, according to the committee.

Animals genetically engineered to produce non-food products, such as cows that produce drugs in their milk, are not intended to enter the food supply. But the committee said there are grounds for concern that adequate controls be in place to ensure restrictions on the use of carcasses from such animals. In at least one instance, meat from the carcasses of such animals was used to make a food product.

The applications of biotechnology may someday reduce the number of animals needed for food and fiber production, but they also can have adverse effects on the welfare of animals, the committee noted. For example, calves and lambs produced through **in vitro** fertilization or cloning tend to have higher birth weights and longer gestation periods, which leads to difficult births often requiring caesarian sections. In addition, some of the biotechnology techniques in use today are extremely inefficient at producing fetuses that survive. Of the transgenic animals that do survive, many do not express the inserted gene properly, often resulting in anatomical, physiological, or behavioral abnormalities. There is also a concern that proteins designed to produce a pharmaceutical product in the animal's milk may find their way to other parts of the animal's body, possibly causing adverse effects.

Although the committee was not asked to make any policy recommendations, it suggested that the current regulatory framework may not be adequate given that the responsibilities of federal agencies for regulating animal biotechnology are unclear in some respects.

The study was sponsored by the Food and Drug Administration. The National Research Council is the principal operating arm of the National Academy of Sciences and the National Academy of Engineering. It is a private, nonprofit institution that provides science and technology advice under a congressional charter. A committee roster follows. Read the full text of **Animal Biotechnology: Science-Based Concerns** for free on the Web, as well as more than 1,800 other publications from the National Academies. Printed copies are available for purchase from the **National Academy Press** Web site or by calling (202) 334-3313 or 1-800-624-6242.

HHS RELEASES 2003 NATIONAL DIABETES ESTIMATES -- HHS Secretary Tommy G. Thompson November 13 announced that the number of Americans with diabetes rose to an all-time high with an estimated 18.2 million people in 2003. "These new estimates show we are diagnosing more people who live with diabetes, and the overall prevalence of this disease continues to increase," Secretary Thompson said. "Clearly, diabetes remains a serious and growing health threat. We are fighting this terrible disease by promoting better lifestyle choices and increasing awareness among all Americans."

The new diabetes numbers, which were released in advance of World Diabetes Day, reflect an annual update of national estimates based on data from HHS' Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH) and the Indian Health Service (IHS). Highlights of the updated data include:

* Diabetes continues to be the sixth leading cause of death in the United States.

* An estimated 13 million Americans have been diagnosed with this disease, and about 5.2 million additional Americans have the disease but have not been diagnosed.

* Diabetes is the leading cause of blindness among adults between 20 and 74 years old.

* 14.9 percent of American Indians and Alaska Natives who are at least 20 years old and receive care from IHS have diabetes. On average, American Indians and Alaska Natives are 2.3 times as likely to have diabetes than non-Hispanic whites of similar age.

* 11.4 percent of non-Hispanic blacks aged 20 years or older have diabetes. On average, non-Hispanic blacks are 1.6 times as likely to have diabetes than non-Hispanic whites of a similar age.

* 8.4 percent of non-Hispanic whites aged 20 years or older have diabetes.

* 8.2 percent of Hispanics aged 20 years or older have diabetes. On average, Hispanic Americans are 1.5 times more likely to have diabetes than non-Hispanic whites of similar age.

* Native Hawaiians and Japanese and Filipino residents of Hawaii aged 20 years or older are twice as likely to have diabetes as white residents of Hawaii.

The data, which is included in HHS' new 2003 National Diabetes Fact Sheet, will help national, state and local health officials understand the health and economic burden of diabetes and better direct efforts to reach populations hardest hit by the disease. "Prevention is the key to stemming this unfolding epidemic," CDC Director Dr. Julie Gerberding said. "By eating a healthy diet and engaging in regular physical activity, individuals can greatly reduce their risk of developing type 2 diabetes."
Many Americans are unaware that they may be at risk -- or already have -- diabetes. Early diagnosis and proper treatment of diabetes can delay, and even prevent, the progression of serious health problems such as heart disease and stroke, blindness, lower limb amputations and kidney failure.

In an effort to identify persons with undiagnosed type 2 diabetes or at risk, HHS this month began a new community-based effort. The Diabetes Detection Initiative: Finding the Undiagnosed (DDI) is focused on helping Americans better understand their diabetes risk so that they can take appropriate actions based on those risks.
A broad-based community effort, the DDI encourages individuals to determine their risk for undiagnosed diabetes using a customized self risk assessment tool adapted from the

American Diabetes Association. A person found to be at high risk will be given clear messages regarding referral to a health care site for appropriate blood testing. The DDI is currently being piloted in 10 communities in a variety of urban and rural settings.
The 2003 National Diabetes Fact Sheet is available at http://www.cdc.gov/diabetes/pubs/factsheet.htm.

HHS LAUNCHES NEW EFFORT TO REACH PEOPLE WITH DIABETES WHO ARE UNDIAGNOSED -- HHS Secretary Tommy G. Thompson November 3 announced a new community-based effort to identify persons with undiagnosed type 2 diabetes and refer them for follow-up blood testing and treatment if appropriate. The focus of this initiative is to help Americans better understand their diabetes risk and take appropriate actions based on those risks.

The Secretary's Diabetes Detection Initiative: Finding the Undiagnosed (DDI) supports HHS' Steps to a HealthierUS and the President's HealthierUS programs to create a healthier, prevention-oriented society. The goals of the DDI are to increase blood testing for individuals who are at high-risk for diabetes and to increase diagnosis for those with unrecognized diabetes.

"The strength of this program is that all levels of society -- state and local health departments, community-based organizations, business sector, tribal communities and many others -- have been brought together under HHS leadership to focus on a common goal: the detection of unrecognized type 2 diabetes," Secretary Thompson said.
As a broad-based community effort, the DDI encourages individuals to determine their risk for undiagnosed diabetes using a customized paper risk assessment tool adapted from the American Diabetes Association. The results of this self-administered risk assessment tool will give the individual a clear message regarding appropriate blood testing to confirm the risk. A finger stick/capillary blood test will be part of the medical assessment that takes place in a health care site and this result, combined with other information, will inform the health care provider of the need for further testing to diagnose diabetes. Risk tests will be distributed through a variety of community channels including social-service, faith-based, grass- roots and fraternal organizations and retail outlets.

The DDI is being piloted in 10 communities throughout the country: Oakland, Calif.; Wichita and Sedgwick County, Kan.; Springfield/Holyoke, Mass.; Flint, Mich.; East Harlem, N.Y., Choctaw Nation, Okla.; Orangeburg County, S.C.; Seattle, Wash.; Fayette and Greenbrier Counties, W.Va.; and Wind River Indian Reservation, Wyo. These sites were selected to reach high-risk populations in a variety of urban and rural settings. In the future, it is expected that the DDI will be expanded to other locations across the country.
"November is National Diabetes Awareness Month, so it is an appropriate time to recommit ourselves to the fight against diabetes," Secretary Thompson said. "Diabetes is now the sixth leading cause of death in the U.S. and cost the nation $132 billion in 2002. Through programs like the Diabetes Detection Initiative, we're working at the community level to find Americans who have type 2 diabetes but do not know it. Early diagnosis and proper treatment of diabetes can delay, and even prevent, the progression of serious

health problems such as heart disease and stroke, blindness, lower limb amputations, and kidney failure. It is vitally important that we reach the undiagnosed sooner rather than later."

More information about the DDI initiative, as well as other up-to-date diabetes information, is available at http://www.ndep.nih.gov