THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE: The U.S. Food and Drug Administration (FDA) December 6 issued final regulations on the establishment and maintenance of records to protect the U.S. human food and animal feed supply in the event of credible threats of serious adverse health consequences or death to humans or animals. FDA also issued draft guidance to FDA staff and industry, which details the internal procedures the agency will follow before requesting access to records. "Publication of this recordkeeping rule represents a milestone in U.S. food safety and security," said Secretary of Health and Human Services, Tommy G. Thompson. "There is more work to do yet, but our nation is now more prepared than ever before to protect the public against threats to the food supply." Details of these new rules 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

UNITED STATES PLEDGES 20 MILLION DOSES OF SMALLPOX VACCINE TO GLOBAL STOCKPILE--U.S. Secretary of Health and Human Services Tommy G. Thompson announced December 10 that the United States is pledging 20 million doses of smallpox vaccine to the global stockpile managed by the World Health Organization (WHO). The United States donation is by far the largest contribution to date to the global stockpile.

"The United States is proud to make a significant contribution to a global stockpile that will serve as a critical line of defense in the event of a smallpox attack anywhere in the world," Secretary Thompson said. "This is an important step toward ensuring the health and safety of the American people."

Secretary Thompson also thanked and congratulated the governments of Canada, France, Germany, and the United Kingdom for their pledges to the stockpile.

At a 2003 Ministerial Meeting of the Global Health Security Initiative (GHSI), the United States encouraged its international partners to develop the WHO Smallpox Vaccine Bank, which would consist of a physical stockpile in Geneva and a virtual global stockpile of pledged vaccine stocks from around the world. This vaccine stockpile could quickly dispatch vaccine to any country that might be experiencing an outbreak of smallpox.

Under the framework established by the WHO, governments or organizations can commit vaccine in their national stocks for the virtual global stockpile or provide vaccine or funds to the WHO Secretariat to purchase vaccine for the physical stockpile in Geneva.

The 20 million doses of vaccine pledged by the United States will physically remain in the U.S. Strategic National Stockpile, but will be available for the WHO to use in the event of an emergency. The global stockpile will be used only if at least one case of smallpox is confirmed in the human population.

The reemergence of smallpox in any country would constitute an international emergency and would pose a serious threat to the national security of the United States. Yet most countries, especially those in the developing world, have no smallpox vaccine and are not prepared to respond to an outbreak of smallpox. The WHO global stockpile addresses this vulnerability and ensures that the world is better prepared to deal with this threat.

Experts from U.S. agencies have worked with experts from the WHO and other countries on developing an operational framework for the WHO Smallpox Vaccine Bank, including establishing standards on vaccine potency, stability, and purity and addressing legal liability concerns. Further work remains in developing plans for vaccine delivery and distribution.

These efforts around the world complement the United States' ongoing efforts to prepare our homeland for a possible smallpox attack. Since 2001, the United States has dramatically improved its capacity to respond to this threat. In 2001, the U.S. had only 15

million doses of smallpox vaccine available in the U.S. Strategic National Stockpile. Today, there are more than enough doses to vaccinate every person in America, if necessary. If there is a release of smallpox in the U.S., HHS will immediately make vaccine in the stockpile available to the general public.

Secretary Thompson reassured Americans that the U.S. pledge to the WHO does not compromise in any way America's ability to provide vaccines for its own citizens in the event of a smallpox outbreak.

"We have stockpiled more than enough smallpox vaccine for every man, woman, and child in America," Secretary Thompson said. "But in this age of global interconnectedness, we need to take extra steps to be prepared for threats around the world."

The last case of smallpox occurred in the United States in 1949, and the WHO declared the disease eradicated worldwide in 1980. Vaccinations to prevent smallpox have not been routinely administered in the United States since 1972.

Secretary Thompson made the smallpox announcement while meeting with foreign health ministers at the GHSI's Fifth Ministerial Meeting in Paris. This week's meetings also include discussions on improving preparedness for a possible global influenza pandemic.

Founded after September 11, 2001, at the urging of Secretary Thompson, the GHSI brings together the health ministers of Canada, France, Germany, Italy, Japan, Mexico, the United Kingdom, and the United States, plus the Health Commissioner of the European Union and the Director-General of the WHO. It was formed to promote collaboration in preparedness and response planning for public health emergences and potential bioterrorist attacks.

MARRIED ADULTS ARE THE HEALTHIEST, NEW CDC REPORT SHOWS -- A new report from the Centers for Disease Control and Prevention suggests that married adults are healthier than divorced, widowed or never married adults.

The report, “Marital Status and Health: United States, 1999-2002,” was based on interviews with 127,545 adults aged 18 and over as part of the National Health Interview Survey, conducted by CDC’s National Center for Health Statistics. The study looked at health status and limitations, health conditions, and health-related behaviors according to marital status and also by age, race/ethnicity and socioeconomic factors such as education and poverty status.

Among the findings in the report:

* Nearly 60 percent of adults are married, 10.4 percent are separated or divorced, 6.6 percent are widowed, 19 percent are never married and 5.7 percent are living with a partner. Marital status varies greatly among race/ethnic groups: approximately 61 percent

of white adults, 58 percent of Hispanic adults, and 38 percent of black adults are married, according to the survey.

* Married adults are less likely than other adults to be in fair or poor health, and are less likely to suffer from health conditions such as headaches and serious psychological distress.

* Married adults are less likely to be limited in various activities, including work and other activities of daily living.

* Married adults are less likely to smoke, drink heavily or be physically inactive. However, married men are more likely to be overweight or obese than other men.

* Adults who live in cohabiting relationships are more likely to have health problems than married adults and more closely resemble divorced and separated adults.

* The association between marital status and health is most striking in the youngest age group although it persists throughout the age groups studied.

While the results show that married adults are generally in better health than unmarried adults, the reasons for better health status among married adults cannot be determined with the cross-sectional data collected in the National Health Interview Survey.

The report, “Marital Status and Health: United States, 1999-2002,” is available at the CDC/NCHS web site at www.cdc.gov/nchs/.

DATA ON FIREARMS AND VIOLENCE TOO WEAK TO SETTLE POLICY DEBATES; COMPREHENSIVE RESEARCH EFFORT NEEDED -- The role of guns in U.S. society is a subject of intense policy debate and disagreement. However, current research and data on firearms and violent crime are too weak to support strong conclusions about the effects of various measures to prevent and control gun violence, says a new report from the National Academies' National Research Council. A comprehensive research program on firearms is needed if criminal-justice and crime-prevention policy is to have a sound basis.

Some of today's most pressing policy issues in this area cannot be tackled with existing data and research methods, which are weak, the report says. For example:

-- There is no credible evidence that "right-to-carry" laws, which allow qualified adults to carry concealed handguns, either decrease or increase violent crime. To date, 34 states have enacted these laws.

-- There is almost no evidence that violence-prevention programs intended to steer children away from guns have had any effects on their behavior, knowledge, or attitudes regarding firearms. More than 80 such programs exist.

-- Research has found associations between gun availability and suicide with guns, but it does not show whether such associations reveal genuine patterns of cause and effect.

"Policy questions related to gun ownership and proposals for gun control touch on some of the most contentious issues in American politics: Should regulations restrict who may possess firearms? Should there be restrictions on the number or types of guns that can be purchased? Should safety locks be required? These and many related policy questions cannot be answered definitively because of large gaps in the existing science base," said Charles F. Wellford, professor, department of criminology and criminal justice, University of Maryland, College Park, and chair of the committee that wrote the report. "However, we do know what kind of data and research are needed to fill those gaps and, in turn, inform policy debates in a more meaningful way."

The study committee was not asked to address any issues of policy and did not do so. Rather, the committee evaluated the research base on firearms violence and on prevention, intervention, and control strategies. It also explored how new methods of merging scientific findings and data could inform strategies for reducing gun-related crime, suicide, and accidental fatalities. The federal government should support a robust research program in this area, concluded the committee.

Firearms, Criminal Violence, and Privacy Issues

Research linking firearms to criminal violence and suicide is seriously limited by a lack of credible information on who owns firearms and on individuals' encounters with violence, the report says. Moreover, many studies have methodological flaws or provide contradictory evidence; others do not determine whether gun ownership itself causes certain outcomes.

Assessing the potential of several ongoing national surveys to provide useful data on firearms should be a starting point, the report says. For instance, questions about gun use and access could be added to or fine-tuned in the Monitoring the Future project or the Youth Risk Behavior Survey. For research purposes, scientists also need appropriate access to federal and state data on gun use, manufacturing, and sales.

One of the largest barriers to better understanding gun violence is the lack of high-quality and extensive data on gun ownership and use. Some people have expressed concerns about expanding the government's data on gun ownership. Others have noted that some individuals -- especially those who use guns illegally -- will always be reluctant to disclose ownership information. Yet scientists in other fields, such as health care, have found effective ways to collect individual data on sensitive topics while protecting privacy. Research is needed -- and can indeed be done -- to determine whether ownership data can be accurately collected with minimal risk to legitimate privacy concerns, the report says.

Do Firearms Deter Crime?

Many Americans keep firearms to defend themselves against criminals, but research devoted to understanding the defensive and deterrent effects of guns has resulted in mixed and sometimes widely divergent findings, the report says. In addition, the accuracy of responses in gun-use surveys is a topic that has not been thoroughly investigated. The committee called for systematic research to define what is being measured in studies of defensive and deterrent effects of guns, to reduce reporting errors in national gun-use surveys, and to explore ways that different data sets may be linked to answer complex questions.

Likewise, new research tools are needed to evaluate right-to-carry laws. Existing studies that use similar methods and data yield very dissimilar findings. Some studies indicate that the laws reduce violent crime. Other studies show negligible effects, while still others suggest that they increase violent crime. It is impossible to draw any strong conclusions about their effects from these studies, the report says.

A Look at Interventions

Firearms are bought and sold in both formal markets, such as gun shops, and informal ones, such as the underground economy. Market-based interventions aimed at reducing criminals' access to guns include taxes on weapons and ammunition, limits on the number of firearms that can be purchased in a given time period, and gun "buy back" initiatives. Arguments for and against these approaches are largely based on speculation rather than scientific evidence. Data on gun markets -- on how many guns are sold through various channels, or how systematically background checks are performed, for instance -- are virtually nonexistent. Greater attention should be paid to research design and data needs regarding gun markets, the report says. More studies also should be conducted on potential links between firearms policies and suicide rates.

Programs created to prevent gun violence are common in the nation's public schools. However, the actual effects of particular programs on violence and injury rates are difficult to predict, the report says. Some studies suggest that children's curiosity and teenagers' attraction to risk make them resistant to the programs or that the projects actually increase the appeal of guns. But few programs have been adequately evaluated. Gun-safety technologies, such as trigger locks, also have been proposed as a way to prevent injuries. Yet how these technologies affect injury rates remains unknown. Government programs for prevention of firearm violence should include evaluation.

Available scientific evidence on how policing interventions and tougher sentencing policies affect firearms violence is both limited and mixed, the report adds. Several cities, including Boston and Richmond, Va., have implemented highly publicized programs designed to suppress crime and gun offenses. It is difficult to gauge the value of the measures because social and economic factors behind criminal acts are often complex and interwoven, and the efforts are narrow in scope. Without much better research, the benefits and costs of policing and sentencing interventions remain largely unknown.

Data limitations are immense in the study of firearms and violence, the committee emphasized. The report calls for the development of a National Violent Death Reporting System and a National Incident-Based Reporting System. No single data system can answer all questions about violent events, but it is important to start collecting accurate and reliable information that describes basic facts about violent injuries and deaths.

The report includes a dissenting opinion written by one committee member regarding the effects of right-to-carry laws on homicide rates, and a response by the committee.

The study was sponsored by the National Institute of Justice, Centers for Disease Control and Prevention, Joyce Foundation, Annie E. Casey Foundation, and the David and Lucile Packard Foundation. 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.

FDA ISSUES FINAL RULE ON THE ESTABLISHMENT AND MAINTENANCE OF RECORDS TO ENHANCE THE SECURITY OF THE U.S. FOOD SUPPLY UNDER THE BIOTERRORISM ACT -- The U.S. Food and Drug Administration (FDA) December 6 issued final regulations on the establishment and maintenance of records to protect the U.S. human food and animal feed supply in the event of credible threats of serious adverse health consequences or death to humans or animals. FDA also issued draft guidance to FDA staff and industry, which details the internal procedures the agency will follow before requesting access to records.

"Publication of this recordkeeping rule represents a milestone in U.S. food safety and security," said Secretary of Health and Human Services, Tommy G. Thompson. "There is more work to do yet, but our nation is now more prepared than ever before to protect the public against threats to the food supply."

This final regulation implements section 306 of the Bioterrorism Act, which directs the HHS Secretary to issue regulations requiring persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records. These records identify the immediate previous source of all food received, as well as, the immediate subsequent recipient of all food released.

"These records will be crucial for FDA to deal effectively with food-related emergencies, such as deliberate contamination of food by terrorists," said Dr. Lester M. Crawford, Acting FDA Commissioner. "The ability to trace back will enable us to get to the source of contamination. The records also enable FDA to trace forward to remove adulterated food that poses a significant health threat in the food supply."

The final regulation is the fourth regulation designed to increase the safety and security of the U.S. human and animal food supply under the authority of the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (the Bioterrorism Act).

The record retention period for human foods ranges from six months to two years depending on the shelf life of the food. Records for animal food, including pet food, must be retained for one year. The maximum record retention requirement for transporters of all types of food is one year.

Records must be retained at the establishment where the activities covered in the records occurred or at a reasonable accessible location. To minimize the burden on food companies affected by the final rule, companies may keep the required information in any format, paper or electronic. All businesses covered by this rule must comply within 12 months from the date the rule is published in the Federal Register, except small and very small businesses. Small businesses (11-499 full-time equivalent employees (FTEs)) must comply within 18 months from this date, and very small businesses (10 or fewer FTEs) have to comply within 24 months from this date.

When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records or other information to which FDA has access must be available for inspection and copying as soon as possible, not to exceed 24 hours from time of receipt of the official request. The records access authority applies both to records required to be established and maintained by the final rule, or any other records a covered entity may keep to comply with federal, state, or local law or as a matter of business practice.

The Bioterrorism Act allows FDA to bring a civil action in federal court to enjoin the persons who fail to comply with this rule. FDA also can seek criminal actions in federal court to prosecute persons who fail to establish and maintain records, as required by the final rule.

FDA has already issued three other final regulations under the Bioterrorism Act, which are in effect. They cover:

* Registration foreign and domestic food facilities;
* Prior notice of food shipments imported or offered for import into the U.S.; and
* Administrative detention, so that food products that might pose a threat of serious adverse health consequences or death may be detained.

FDA will be holding seven public meetings in January and February 2005 to explain the requirements of the final rule to interested parties and answer questions.

Registration is on a first-come, first served basis. Additional information on how to register for one of the public meetings or information about all four rules designed to protect the U.S. food supply is available at http://www.fda.gov/oc/bioterrorism/bioact.html.