THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE: In East Baltimore's inner city, a group of hypertensive young African-American men gained control of their high blood pressure, thanks to a comprehensive intervention conducted at the community level by a multidisciplinary health care team. Forty-four percent of the men receiving the intensive form of the intervention attained control after three years, whereas at the study's start, only 17 percent had control. Conducted by The Johns Hopkins University School of Nursing, the research

is described in an article entitled "Hypertension Care and Control in Underserved Urban African American Men: Behavioral and Physiologic Outcomes at 36 Months, " which appears in the November issue of *The American Journal of Hypertension*. The study was funded by the National Institute of Nursing Research (NINR), part of the National Institutes of Health (NIH), Department of Health and Human Services. The public health implications of the study are obvious for the broader community and may lead to additional successful interventions. 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

CONTINUING RESOLUTIONS EXTEND FUNDING UNTIL NOVEMBER 21 – On November 5th, the U.S. House of Representatives passed a new Continuing Resolution funding the federal government at FY 2003 levels until November 21st. The Senate will follow suit shortly. The current CR expires on November 7th. There are a number of appropriations bills which have not cleared the Senate and several are still hung up in conference, including the Labor-HHS-Education bill which funds all of CDC, necessitating the extension of the CR. The major stumbling block in the Labor-HHS-Ed conference is a Senate provision prohibiting implementation of new Labor Department overtime rules. Senate Subcommittee Chairman, Arlen Specter (R-PA) offered a compromise which the White House just rejected making it more likely that the Labor-HHS-Ed bill will get included in a giant omnibus appropriations bill that will wrap together all unfinished bills. Another bill that is likely to be included in the omnibus is the VA-HUD Appropriations bill. The Senate bill includes a significant increase for Veterans health care which puts the bill over its allocation. The House and Senate leaderships are expected to impose an across-the-board cut for all programs in the omnibus bill to pay for the additional Veterans funding.

IMPACT BILL MAKES PROGRESS -- The IMPACT bill, Improved Nutrition and Physical Activity Act, S. 1172, was marked up and reported out of the Senate Health, Education, Labor and Pensions Committee on October 29th. CSTE endorsed this bill which addresses obesity. The following is a Congressional Research Service summary of the bill's provisions:

"Expands an existing grant program for training for health profession students to include the treatment of overweight, obesity, and eating disorders. Creates a grant program for training for health professionals in such areas.

Creates grant programs at the local level to promote increased physical activity and improved nutrition (in place of current law, which provides for grants to promote childhood nutrition and physical activity). Targets partnerships with businesses, schools, senior centers, day care facilities and other institutions. Allows the Secretary of Health and Human Services (the Secretary) to give priority in awarding grants to recipients who provide matching contributions.

Permits the Director of the Center for Disease Control and Prevention to provide technical assistance to grantees.

Allows the Secretary, acting through the National Center for Health Statistics, to provide for the collection and analysis of certain data, including data collected as part of the National Health and Nutrition Examination Survey. Permits the Secretary to: (1) make grants to States, public entities, and nonprofits to further the collection and analysis of such data; and (2) provide technical assistance to such grantees.

Directs the Secretary of Agriculture to request that the Institute of Medicine conduct a study or contract for a study on the food and nutrition programs run by the Department of Agriculture.

Permits the use of preventive health and health services block grants for community education programs which promote healthy eating and exercise habits.

Establishes reporting requirements with regard to: (1) obesity research; and (2) the national campaign to change children's health behaviors and reduce obesity."

A similar House bill, H.R. 716, has seen no action to date, although it has attracted 61 bipartisan co-sponsors.

OTHER HEALTH LEGISLATION UPDATE -- Tobacco/FDA bill boggs down – After public health groups rejected Senate HELP Committee Chairman Gregg's (R-NH) draft bill to provide FDA with the authority to regulate tobacco as too full of loopholes, Gregg dropped further consideration of the bill for the session. However, Substance Abuse and Mental Health Subcommittee Chairman, Sen. Mike DeWine (R-OH) re-started negotiations with all interested parties. To date, no breakthroughs. Harmful Algal Bloom and Hypoxia Research and Control Amendments Act – This reauthorizing legislation passed the Senate on 10/28. H.R. 3431 – New bill introduced to require NIOSH to monitor the long-term health of firefighters involved in fighting fires within Federal disaster areas. It has 110 bipartisan co-sponsors. To the Committee on Education and the Workforce. No specific funding amount, just such sums as necessary, is authorized for NIOSH to conduct the monitoring. S. 1817 – New bill introduced to include influenza vaccines in the Vaccine Injury Compensation Program; to the Committee on Finance.

HRSA REPORT COMPARES HEALTH OF TEENS IN THE U.S., EUROPE -- HHS' Health Resources and Services Administration (HRSA) October 31 released *Teens in Our World: Understanding the Health of U.S. Youth in Comparison to Youth in Other Countries*, the first HRSA-supported overview of health and well-being among U.S. adolescents compared with European teens.

Highlighted data for U.S. teens were taken from the international "Health Behavior in School-aged Children" study, which coordinated school-based surveys of teens ages 11, 13 and 15 in U.S. schools and in 29 locations throughout Europe in 1997/98. Findings are organized under the topics of general health and well-being, fitness, family and peer relationships, school relationships, smoking, alcohol use and violence.

“This new research is valuable for those interested in creating more effective teen programs nationwide," says HRSA Administrator Elizabeth M. Duke.

According to the report, U.S. students were:

* more likely to have stomachaches, backaches, headaches and difficulty sleeping "at least once a week" and were more likely to feel tired or "low" in the morning -- a new finding.

* less likely to smoke than students in almost all other countries, but ranked in about the middle range for drinking alcohol "at least once a week."

* among the highest ranked in enthusiasm toward school, but approximately four out of five reported liking school "only a little," "not very much" or "not at all."

* ranked relatively high for "never" or "rarely" feeling safe at school, and ranked in about the middle range among students bullied at school "at least sometimes." They also were in the higher ranking of students who reported that they bully others frequently.

Authors suggested that American students' feelings of fatigue may be associated with their fitness levels related to diet and exercise, since they often ate high-fat or high-sugar foods while exercising in the middle to lower range. The authors also recommended carrying out assessments of family stability, transient neighborhoods and limited community support among U.S. families to help develop teen programs that deter unwanted behaviors such as bullying.

The report was supported by HRSA's Maternal and Child Health Bureau and developed in collaboration with NIH's National Institute of Child Health and Human Development.

FDA ISSUES GUIDANCE ON EVALUATING THE SAFETY OF ANTIMICROBIAL NEW ANIMAL DRUGS TO HELP PREVENT CREATING NEW RESISTANT BACTERIA -- The Food and Drug Administration (FDA) October 23 released a new guidance document that for the first time outlines a comprehensive evidence-based approach to preventing antimicrobial resistance that may result from the use of antimicrobial drugs in animals.

Antimicrobial drugs, such as antibiotics, are medicines often used to treat bacterial infections in both humans and animals. Their use has been one of the great advances in modern medicine – helping to prevent many of the leading causes of death for most of human history.

Regardless of why bacteria develop resistance to antimicrobials, when bacteria do develop such resistance, human and animal health is at risk because the medicines that we depend on to treat infections become ineffective. There are several important sources of this problem, including inappropriate use of antibiotics in people, that have been the subject of many public health initiatives by the Department of Health and Human

Services and other organizations. The guidance released today by FDA is, however, the first that addresses, in a comprehensive manner, the issue of the use of antimicrobials in food producing animals as a contributing factor to the development of antimicrobial resistance.
The guidance provides a scientific process for assessing the likelihood that an antimicrobial drug used to treat an animal may cause an antimicrobial resistance problem in humans consuming meat or other byproducts from that animal. This process can help prevent antimicrobial drugs with a high risk of causing such problems from being improperly used in food producing animals, and thereby potentially leading to antimicrobial resistance in humans.

The new guidance encourages drug sponsors to use a risk assessment process to demonstrate that an antimicrobial drug used to treat food-producing animals will not create a risk of antimicrobial resistant bacteria likely to lead to human health problems. The document, Guidance for Industry (GFI) #152 ("Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern"), is not a regulation. Instead it explains a science-based process drug sponsors may use when they seek approval of an antimicrobial for use in food-producing animals.

Sponsors may still use other methods to establish drug safety for these uses, as long as these methods comply with statutory and regulatory requirements. In general, written guidance helps sponsors understand FDA's process of evaluating whether a proposed product for approval can be used safely and effectively, in this case with respect to risks of creating antimicrobial resistance.

"Resistance to the antimicrobial drugs needed to treat human illnesses is a serious public health threat, and we intend to use the best science-based methods to prevent it," said FDA Commissioner Mark B. McClellan, M.D., Ph.D. "There are many factors contributing to the development of resistant bacteria. Attacking the problem on all fronts, including the appropriate use of antimicrobial drugs in veterinary medicine, is the best way to protect the health of the public. It's also the best way to promote the safe use of antimicrobials to protect the health of animals, including food-producing animals."
Stephen Sundlof, D.V.M., Ph.D., Director of FDA's Center for Veterinary Medicine, added, "This guidance uses science to develop a risk-based approach to the issue of antimicrobial resistance. It permits us to help protect human health while giving veterinarians and livestock producers the tools they need to treat animals."
The pathway suggested in the guidance document establishes a three-part system for determining an antimicrobial drug's potential risk to humans if used to treat food-producing animals. The system's three parts are these:

* **Part One** is the "release assessment" which determines the probability that resistant bacteria will be present in animals as a result of the use of the antimicrobial new drug.
* **Part Two** is the "exposure estimate" which gauges the likelihood that humans would ingest the resistant bacteria.

* **Part Three** is the “consequence assessment“ which assesses the chances that human exposure to the resistant bacteria would result in adverse human health consequences. In this context, these are situations in which a physician has difficulty treating a person with an antimicrobial drug because the bacteria infecting the person had acquired resistance to the drug and that resistance came from use of the drug in animals.

Under this system, all of these assessment processes are considered and integrated to determine the overall level of human health risk from resistant bacteria associated with an antimicrobial drug’s use in animals.

If the assessments showed that the risks were significant, FDA could deny the application for marketing authorization, thus preventing the use of the drug in food animals, or FDA could approve the drug, but place conditions on its use designed to ensure it would not pose a human health risk.

More information is available online at www.fda.gov/oc/antimicrobial/questions.html.

INTERVENTION IMPROVES CONTROL OF HIGH BLOOD PRESSURE IN YOUNG INNER-CITY AFRICAN-AMERICAN MEN -- In East Baltimore's inner city, a group of hypertensive young African-American men gained control of their high blood pressure, thanks to a comprehensive intervention conducted at the community level by a multidisciplinary health care team. Forty-four percent of the men receiving the intensive form of the intervention attained control after three years, whereas at the study's start, only 17 percent had control.

Conducted by The Johns Hopkins University School of Nursing, the research is described in an article entitled "Hypertension Care and Control in Underserved Urban African American Men: Behavioral and Physiologic Outcomes at 36 Months, " which appears in the November issue of *The American Journal of Hypertension*. The study was funded by the National Institute of Nursing Research (NINR), part of the National Institutes of Health (NIH), Department of Health and Human Services.

Over one in four Americans has high blood pressure. The number of cases is nearly 40 percent higher for African Americans than Caucasians, and the effects of hypertension are more frequent and severe. African Americans may also experience greater organ damage resulting from the condition. Young African -American men in particular have the lowest rates of awareness, treatment and control of hypertension of any population group in the United States. These men's low socioeconomic status and higher risk factors such as obesity, smoking, and alcohol and drug use contribute to the high incidence of hypertension and the lack of its control.

According to principal investigator Martha N. Hill, PhD, RN, Dean of the School of Nursing, "To my knowledge, until now no hypertension studies have targeted high-risk, young urban African American men, who are underserved by the health care system. We found that in many cases, participation in our study was the first time some of the men

had contact with formal health care. They were pleased to be part of the research and to improve their health."

Dr. Hill further indicated, " Of note is that we used a comprehensive health care team approach with these men, who are considered hard to reach. The team approach was key to achieving control of hypertension and to retaining more than 90% of these men in the study protocol over three years' time."

The study population involved 309 hypertensive young men between 21 and 54 years of age, who were randomly divided into two groups. The group with more intensive care received individual attention from a health care team consisting of a nurse practitioner, who focused on blood pressure management; a community health worker, who made home visits and provided social services that included referrals, job training, and housing assistance; and a physician, who was available for consultation. The young men in the less intensive group received referral to sources of hypertension care within the community, a phone call twice a year to provide counseling, and along with the more intensive group, a visit once a year to the Outpatient General Clinical Research Center. Dr. Patricia A. Grady, Director of the NINR, stated, "This study is an important example of research that addresses health care disparities in our country. Ethnically and culturally sensitive research is vital when dealing with vulnerable populations at the community level, such as young urban African-American men, and this research shows how it can work well."

Among other positive findings — a decrease for both intervention groups in smoking, eating salty foods all or most of the time, unemployment, low income, and lack of health insurance. Taking medications to reduce blood pressure increased for both groups. "It is not enough to see these patients in a clinic and achieve beneficial results," concluded Dr. Hill. "The evidence suggests modifications of care are necessary. Culturally appropriate outreach that includes one-on-one visits in the home to supplement clinic visits are effective strategies, as is care that addresses lifestyle risk factors, such as poor nutrition and alcohol abuse," she said.

Future research is planned to evaluate cost effectiveness of the intervention and to devise methods that focus on reducing obesity and substance abuse as part of comprehensive care.

More information about nursing research is available at the NINR website at http://www.nih.gov/ninr.

THE NATIONAL INSTITUTES OF HEALTH (NIH) SEEKS PUBLIC COMMENT ON THE NIH STRATEGIC RESEARCH PLAN AND BUDGET TO REDUCE AND ULTIMATELY ELIMINATE HEALTH DISPARITIES,FISCAL YEARS 2002-2006 --

The National Institutes of Health is posting the *NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities, Fiscal Years 2002-2006*, on the NCMHD website at www.ncmhd.nih.gov to invite public comment on the NIH health

disparities research agenda. The NIH is seeking comments on its research plans for Fiscal Years 2004-2006.

"Despite tremendous medical advances and improved public health in America in recent decades, African Americans, Hispanics, American Indians, Alaska Natives, Asian and Pacific Islanders, and other medically underserved communities continue to suffer an unequal burden of illness, premature death and disability. In developing and updating the Strategic Plan to eradicate these health disparities, the NIH affirms its ongoing commitment to biomedical research discovery that will ensure improved health for all Americans," said NIH Director, Elias A. Zerhouni, M.D.

The Plan was developed by the NIH National Center on Minority Health and Health Disparities (NCMHD) in collaboration with the NIH Office of the Director, the other NIH Institutes and Centers, and the National Advisory Council on Minority Health and Health Disparities. The NCMHD leads, coordinates, supports and assesses the NIH effort to eliminate health disparities. The NCMHD supports and conducts basic, clinical, social sciences, and behavioral research; promotes research infrastructure and training; fosters emerging programs and the dissemination of health information; and reaches out to minority and other health disparities communities.

According to Dr. John Ruffin, Director, NCMHD, "The Strategic Plan defines a broad framework for future efforts of research partners throughout the country to advance scientific knowledge that will improve diagnostic, treatment, and prevention strategies for reducing and eliminating the health disparities afflicting racial and ethnic minority populations and other health disparities populations across the Nation."
He further noted that "the genesis of heath disparities is multi factorial and requires a coordinated interdisciplinary effort. The Strategic Plan reflects the ongoing commitment of a strong research alliance that is necessary to eliminate health disparities. At the heart of this coalition of NIH Institutes and Centers are our constituencies. Their input is essential to our success in identifying innovative and diverse approaches to eliminate health disparities."

The Strategic Plan has three main goals:

* **Research** — to investigate the development and progression of diseases and disabilities that cause disparities in health in minority and other populations.

* **Research Infrastructure** — to increase minority health and health disparities research training, career development and institutional capacity.

* **Public Information and Community Outreach** — to ensure the public, healthcare professionals, and research communities are informed about the latest advances in health disparities research.

The *NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities, Fiscal Years 2002-2006* is currently posted on the NCMHD website at

www.ncmhd.nih.gov. Written comments should be sent to the Strategic Plan Review Group, NCMHD, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892-5465 or may be transmitted electronically, via e-mail, to NIHHealthDisparitiesPlan@mail.nih.gov and should include contact information, such as, name, organization, address, and telephone and fax numbers.

INSTITUTE OF MEDICINE INITIATIVE SEEKS TO COMMUNICATE EXPERT HEALTH FINDINGS AND RECOMMENDATIONS TO LOCAL COMMUNITIES

-- The Institute of Medicine of the National Academies today initiated the Kellogg Health of the Public Fund, an effort to improve the health of American communities -- particularly underserved and disadvantaged communities -- by significantly increasing the Institute's capacity to reach out to individuals and local health authorities and communicate about health.

The Kellogg Health of the Public Fund is supported by an initial grant of $2.5 million from the W.K. Kellogg Foundation of Battle Creek, Mich., and a commitment to match up to $2.5 million in additional funds raised by IOM. The Institute will use the challenge grant from the Kellogg Foundation to raise $2.5 million from other sources to create a $7.5 million endowed fund.

"The Institute of Medicine is recognized nationally as a source of authoritative, reliable, and scientifically sound advice on issues pertaining to health care, medical research, and health policy, but much of this advice is not fully reaching the communities and citizens it could ultimately benefit," said IOM President Harvey V. Fineberg. Every year, the Institute produces dozens of major scholarly reports. Many of these documents are distributed to only a few hundred experts and policy-makers, however, because funds are limited or unavailable for broader dissemination or for translating the reports' key messages into more widely accessible formats. "The **Kellogg Health of the Public Fund** will support Institute communication and dissemination activities that will have the greatest impact in creating healthy communities, particularly in areas that traditionally have been underserved and have had little access to high-quality health services and information about public health," Fineberg said.

Through the fund, the Institute will leverage the expert findings and recommendations gained through its studies by developing new materials, such as pamphlets, CD-ROMs, videos, online publications, and other information tools to help inform health care and public health workers or individuals in need of particular health information. The Institute also will organize regional and local forums, training programs, community meetings, and other events in partnership with entities such as philanthropic organizations, professional groups, state and local governments, and community organizations.

"A public that is fully informed and empowered to make decisions about health and health care is essential for the nation's wellbeing, and the Institute of Medicine is the ideal organization to take a leading role in getting scientifically validated health

information out to public health professionals and communities," said Kellogg Foundation President and CEO William Richardson.

The Institute of Medicine was chartered in 1970 by the National Academy of Sciences. Working outside the framework of government to ensure scientifically informed analysis and independent guidance, the Institute serves as adviser to the nation on matters of health care, medical sciences, and public health. For more information, visit **http://www.iom.edu**.

The W.K. Kellogg Foundation was established in 1930 to help people help themselves through the practical application of knowledge and resources to improve their quality of life and that of future generations. Its programming activities center around the common vision of a world in which each person has a sense of worth; accepts responsibility for self, family, community, and societal wellbeing; and has the capacity to be productive and to help create nurturing families, responsive institutions, and healthy communities. For more information, visit **http://www.wkkf.org**.