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ONE HUNDRED ELEVENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

MEMORANDUM

September 14, 2010

To: Members of the Subcommittee on Health

Fr: Committee on Energy and Commerce Democratic Staff

Re: Subcommittee on Health Markup

On Thursday, September 16, 2010, at 10:00 a.m. in room 2123 Rayburn House Office Building, the Subcommittee on Health will meet in open markup session to consider the following bills:

- **H.R. 758**, Pediatric Research Consortia Establishment Act
- **H.R. 1032**, Heart Disease Education, Analysis Research, and Treatment for Women Act
- **H.R. 1210**, Arthritis Prevention, Control, and Cure Act of 2009
- **H.R. 1230**, Bone Marrow Failure Disease Research and Treatment Act of 2009
- **H.R. 1347**, Concussion Treatment and Care Tools Act of 2009
- **H.R. 1362**, National MS and Parkinson's Disease Registries Act
- **H.R. 1995**, Eliminating Disparities in Diabetes Prevention Access and Care Act of 2009
- **H.R. 2408**, Scleroderma Research and Awareness Act
- **H.R. 2818**, Methamphetamine Education, Treatment, and Hope Act of 2009
- **H.R. 2941**, Johanna's Law Reauthorization
- **H.R. 2999**, Veterinary Public Health Workforce and Education Act
- **H.R. 5354**, Gestational Diabetes Act of 2009 or GEDI Act
- **H.R. 5462**, Birth Defects Prevention, Risk Reduction, and Awareness Act of 2010
- **H.R. 5986**, Neglected Infections of Impoverished Americans Act of 2010
- **H.R. 6012**, To direct the Secretary of Health and Human Services to review uptake and utilization of diabetes screening benefits and establish an outreach program with respect to such benefits, and for other purpose
- **H.R. 6081**, Stem Cell Therapeutic and Research Reauthorization Act of 2010
- **H.R. 6109**, Health Data Collection Improvement Act

The Subcommittee may also consider **H.R. 211**, Calling for 2-1-1 Act of 2009, and **H.R. 6110**, Telehealth Improvement and Expansion Act of 2010.

I. H.R. 758, PEDIATRIC RESEARCH CONSORTIA ACT

H.R. 758, sponsored by Rep. Diana DeGette, addresses the need for increased coordination on research on pediatric illnesses. This bill requires the National Institutes of Health (NIH) to establish up to 20 pediatric research consortia throughout the nation. Each consortium will be a collaborative effort involving a leading "hub" pediatric medical center and numerous supporting "spoke" institutions. The consortia will focus on both basic and translational research, as well as training for new researchers. Funding will be based on the likelihood of bringing together investigators from multiple disciplines to comprehensively address child health and lifelong genetically-based chronic illness.

A manager's amendment in the nature of a substitute is anticipated that would do the following:

- Eliminate the requirement that the NIH Director make awards to establish pediatric research consortia. Instead, the bill would provide authority to make such awards at the discretion of the Director.
- Clarify that NIH can extend payments to grantees beyond the five year maximum based upon a scientific review.

II. H.R. 1032, HEART DISEASE EDUCATION, ANALYSIS RESEARCH, AND TREATMENT FOR WOMEN ACT

H.R. 1032, sponsored by Rep. Lois Capps, is designed to provide necessary resources to address the problem of heart disease among women. The bill codifies Food and Drug Administration (FDA) regulations that require the inclusion of women in clinical trials submitted to FDA to support an application for a drug, device, or biologics approval. It requires that patient safety data reported to and among the network of patient safety databases be stratified by gender. In addition, the bill requires that the Department of Health and Human Services (HHS) carry out an education campaign about heart disease and women and reauthorizes the WISEWOMAN program at the Centers for Disease Control and Prevention (CDC). The bill authorizes the WISEWOMAN program at: $70 million for fiscal year 2010; $73.5 million for fiscal year 2011; $77 million for fiscal year 2012; $81 million for fiscal year 2013; and $85 million for fiscal year 2014.

A manager's amendment in the nature of a substitute is anticipated that would do the following:

- Eliminate codification of the referenced FDA regulations. Instead, the bill would require a U.S. Government Accountability Office (GAO) report to Congress on the extent to which companies comply with such regulations.

- Require an FDA report to Congress on its plans to correct any deficiencies identified by GAO.
- Transfer to the Secretary of HHS the requirement that the Agency for Healthcare Research and Quality (AHRQ) report on quality of and access to care for women with heart disease.
- Eliminate the requirement that the work product of the network of patient safety databases be stratified by sex.
- Eliminate the requirement that HHS conduct an education campaign.
- Reduce the authorization level for each fiscal year.

III. H.R. 1210, ARTHRITIS PREVENTION, CONTROL, AND CURE ACT FOR 2009

H.R. 1210, sponsored by Rep. Eshoo, provides resources to improve health care for the hundreds of thousands of Americans who suffer from arthritis. The bill requires the Secretary of the Department of Health and Human Services (HHS) to develop and implement a National Arthritis Action Program, at a level of $32 million in fiscal year 2010, rising to $40 million in fiscal year 2014. The program would support control, prevention, surveillance, research, education, and outreach activities, through grants and direct support to public or private nonprofit entities and states. The bill further authorizes the Secretary to expand and intensify programs of the National Institutes of Health with respect to research and related activities concerning various forms of juvenile arthritis and related conditions.

In addition, the bill provides for the CDC to award grants or enter into cooperative agreements for the collection, analysis, and reporting of data on juvenile arthritis, and supports the development of a national juvenile arthritis population-based database. It authorizes $25 million for each of the fiscal years 2010-2014 for these CDC surveillance activities. In addition, the bill requires the Secretary to provide grants to support pediatric rheumatology training at a level of $3.75 million for each of fiscal years 2010- 2014. It also directs the Secretary to establish and carry out a pediatric rheumatology loan repayment program, as needed. For the purposes of this subsection, the Secretary may reserve funding from amounts already appropriated to the Health Resources and Services Administration for the fiscal year involved.

A manager's amendment in the nature of a substitute is anticipated that would do the following:

- Eliminate authorization levels for the National Institutes of Health.
- Eliminate the bill's requirement regarding interagency councils.

IV. H.R. 1230, BONE MARROW FAILURE DISEASE RESEARCH AND TREATMENT ACT OF 2009

H.R. 1230, sponsored by Rep. Doris Matsui, addresses the need to improve research and treatment for individuals diagnosed with bone marrow disease. This bill requires the Secretary of HHS, acting through the Director of CDC, to develop a system

to collect data on acquired bone marrow failure diseases and to establish the National Acquired Bone Marrow Failure Disease Registry and allows the Secretary to award grants to, and enter to contracts and cooperative agreements with public or private nonprofit entities for the management of the Registry. It also requires the Secretary to conduct pilot studies to determine which environmental factors may cause acquired bone marrow failure diseases. The bill authorizes $3 million for each of fiscal years 2010-2014 to carry out these activities.

The bill further requires the HHS Secretary to establish outreach and information programs targeted to minority populations affected by such diseases and to award grants to, or enter into cooperative agreements with, entities to perform research on such diseases. It authorizes $2 million for each of fiscal years 2010-2014 to carry out these activities. Finally, the bill requires the Secretary, acting through the Director of the Agency on Healthcare Research and Quality (AHRQ), to award grants to entities to improve diagnostic practices and quality of care with respect to patients with acquired bone marrow failure diseases.

A manager's amendment in the nature of a substitute is anticipated that would do the following:

- Require HHS to conduct research on acquired bone marrow failure, and allow AHRQ to award grants to researchers to study best practices on diagnosing acquired bone marrow failure.
- Eliminate the requirement to establish a Bone Marrow Failure Registry at the CDC.
- Eliminate the requirement to establish an Advisory Committee on Acquired Bone Marrow Failure Disease.
- Eliminate the pilot studies at the Agency for Toxic Substances and Disease Registry (ATSDR).

V. H.R. 1347, CONCUSSION TREATMENT AND CARE TOOLS ACT OF 2009

H.R. 1347, sponsored by Rep. Bill Pascrell, addresses the growing concern about concussions and other serious head injuries among school-aged children. The bill directs the Secretary of the Department of Health and Human Services to establish concussion management guidelines that address the prevention and management of concussions in school-aged children, including standards for student athletes to return to play after a concussion. The bill also authorizes the Secretary to convene a conference of medical, athletic, and educational stakeholders to establish such guidelines.

In addition, the bill authorizes the Secretary to make grants to states for: (1) adopting, disseminating, and ensuring the implementation by schools of the guidelines; and (2) funding implementation by schools of preseason baseline and post-injury neuropsychological testing for student athletes. To carry out theses grants, the bill authorizes $5 million for fiscal year 2010 and such sums as necessary for each of fiscal years 2011 through 2014.

A manager's amendment in the nature of a substitute is anticipated that would do the following:

- Authorize youth sport associations to be eligible for grants.
- Allow (but not require) computerized testing as an eligible use of grants.
- Require the Secretary of HHS to make recommendations on how best to disseminate guidelines to the public that are to be developed on sports-related concussions.
- Specify funding levels for each fiscal year the program is authorized.

VI. H.R. 1362, NATIONAL MS AND PARKINSON'S DISEASE REGISTRIES ACT

H.R. 1362, sponsored by Rep. Chris Van Hollen, is designed to bring greater attention to two neurological diseases whose impact on patients may be devastating. This bill requires the Secretary of the Department of Health and Human Services to develop surveillance systems, in the form of registries, for both Multiple Sclerosis and Parkinson's disease. It also requires the HHS Secretary to establish an advisory committee on Neurological Disease Registries to review and make recommendations to the Secretary on the surveillance activities authorized in this bill, including the development and maintenance of the systems. The bill authorizes $5 million for each of fiscal years 2010-2014 to carry out the bill's activities.

A manager's amendment in the nature of a substitute is anticipated that would do the following:

- Eliminate the requirement that the Secretary of HHS establish two separate surveillance systems in the form of registries (one for multiple sclerosis; one for Parkinson's disease). Instead, it provides the Secretary with flexibility in collecting and storing data on neurological conditions, including these two diseases.
- Eliminate the requirement to establish a new advisory committee. Instead, it directs the HHS Secretary to consult with individuals with specified expertise.
- Clarify that relevant privacy standards applicable to data collected, stored, and shared (as appropriate) are privacy and security protections at least as stringent as HIPAA.
- Update the authorization period to FY2012 through FY2016.

VII. H.R. 1995, ELIMINATING DISPARITIES IN DIABETES PREVENTION ACCESS AND CARE ACT OF 2009

H.R. 1995, sponsored by Rep. Diana DeGette, addresses the growing concern about diabetes and its impact on minority populations. This bill requires the National Institutes of Health to expand, intensify, and support ongoing research and other activities with respect to pre-diabetes and diabetes in minority populations and carry out health care professional mentorship and education activities specific to diabetes. It also requires

the CDC to conduct and support research and other activities with respect to diabetes in minority populations, conduct and support public education efforts, and carry out culturally-appropriate diabetes health promotion programs. In addition, the bill requires the Health Resources and Services Administration (HRSA) to conduct and support programs to educate health professionals on diabetes in minority populations. It authorizes such sums as may be necessary for fiscal year 2010 and each subsequent fiscal year to carry out the bill's activities.

A manager's amendment in the nature of a substitute is anticipated that would do the following:

- Eliminate the requirement that various HHS agencies support research and other public health activities related to diabetes within minority populations. Instead, it requires the HHS Secretary to report to Congress on current HHS research and other public health activities regarding diabetes and this population. Such report must include an evaluation of diabetes research, surveillance and data collection, community-based interventions, and education and training of health professionals (including community health workers).

VIII. H.R. 2408, SCLERODERMA RESEARCH AND AWARENESS ACT

H.R. 2408, sponsored by Rep. Lois Capps, addresses the need for research on scleroderma, a chronic systemic autoimmune disease that involves changes in the skin, blood vessels, muscles, and internal organs. This bill directs the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMSD) of the National Institutes of Health (NIH) to expand, intensify, and coordinate activities relating to scleroderma. It requires NIAMSD to research the causes and treatment of scleroderma and to establish a scleroderma patient registry at authorization levels of $25 million for fiscal year 2010, $30 million for fiscal year 2011 and $35 million for fiscal year 2012. It also requires the Director of the Centers for Disease Control and Prevention (CDC) to carry out an education campaign to increase awareness of scleroderma and authorizes $2.5 million for fiscal years 2010-2012 for this activity.

A manager's amendment in the nature of a substitute is anticipated that would do the following:

- Eliminate the requirement that the NIAMSD Director carry out research. Instead, it provides authority to the NIH Director to support such research at his discretion.
- Eliminate the requirement that NIAMSD establish a patient registry.
- Eliminate the requirement that NIH include information on the status of scleroderma research at NIH in its biennial report.
- Transfer to the HHS Secretary the requirement that CDC establish an education campaign.
- Eliminate the requirement that CDC report to Congress on the status of its activities.
- Eliminate the authorization of appropriations for both NIH research and the CDC education campaign.

IX. H.R. 2818, METHAMPHETAMINE EDUCATION, EDUCATION, TREATMENT, AND HOPE ACT OF 2009

H.R. 2818, sponsored by Rep. Jerry McNerney, addresses the ongoing concern about methamphetamine use among pregnant women. This bill expands and strengthens the Substance Abuse and Mental Health Services Administration's (SAMHSA) activities to address the prevention and treatment of addiction to methamphetamine and other drugs. It refines an existing family-centered residential drug treatment program for pregnant and postpartum women and authorizes $20 million for fiscal year 2010, $21 million for fiscal year 2011, $22 million for fiscal year 2012, $23 million for fiscal year 2013, and $24million for fiscal year 2014. The bill also requires support for a workplace-based drug information clearinghouse, and student involvement in prevention programs for methamphetamine and other drugs.

A manager's amendment in the nature of a substitute is anticipated that would do the following:

- Require that the Drug-Free Workplace Information Clearinghouse provide materials on comprehensive drug-free workplace programs and substance abuse prevention and treatment resources.
- Replace a specific student-driven methamphetamine awareness project with a requirement that the Director of SAMSHA's Office of Substance Abuse Prevention involve youth in the development and implementation of prevention strategies, with regard to methamphetamine and other drugs.
- Update the authorization years to begin in FY 2012.

X. H.R. 2941, JOHANNA'S LAW REAUTHORIZATION

H.R. 2941, sponsored by Rep. Rosa DeLauro, reauthorizes and expands Centers for Disease Control and Prevention (CDC) programs to educate women and healthcare providers about gynecologic cancers. It authorizes $16.5 million for the period of fiscal years 2010-2012 and such sums as are necessary for each subsequent fiscal year for these efforts. It further creates demonstration projects to evaluate research and outreach strategies for educating women and healthcare providers about gynecological cancers. For fiscal years 2010-2012, $15 million is authorized for these activities; such sums as are necessary are authorized for each subsequent fiscal year.

A manager's amendment in the nature of a substitute is anticipated that would do the following:

- Update the authorization years to FY2012 through FY2014.

XI. H.R. 2999, VETERINARY PUBLIC HEALTH WORKFORCE AND EDUCATION ACT

H.R. 2999, sponsored by Rep. Tammy Baldwin, is designed to provide resources to increase the nation's supply of public health veterinarians. Such individuals are critically important in addressing major public health programs such as swine flu and HIV/AIDS. This bill authorizes a competitive grant program for schools of veterinary medicine. Schools can use these grants for faculty recruitment, physical capacity expansion, or the development of curricula to retrain midcareer professionals. It authorizes $100 million for fiscal year 2010, $100 million for fiscal year 2011 and $50 million for each of fiscal years 2012-2014 for these activities. The bill also establishes a loan repayment program whereby the federal government repays loans for veterinarians that make a four-year teaching commitment at a school of veterinary medicine. It authorizes $20 million for each of fiscal years 2010-2014 for this program. In addition, the bill creates two fellowship programs for public health veterinarians that would be administered by the Department of Health and Human Services but would be available to all federal agencies that utilize public health veterinarians. The bill also authorizes $2.5 million for each of fiscal years 2010-2014 to support these fellowships. Finally, the bill establishes a Division of Veterinary Medicine and Public Health at the Health Resources and Services Administration (HRSA).

A manager's amendment in the nature of a substitute is anticipated that would do the following:

- Eliminate the requirement that the HHS Secretary award veterinary education capacity building grants.
- Clarify that veterinary public health professionals are considered public health professionals for public health loan repayment programs and for grants for public health training institutions.

XII. H.R. 5354, GESTATIONAL DIABETES ACT OF 2009

H.R. 5354, sponsored by Rep. Eliot Engel, targets resources specifically at gestational diabetes, a form of that disease that traditionally receives far less attention and fewer resources than other types of diabetes. This bill requires the Centers for Disease Control and Prevention to conduct a multi-site gestational diabetes research project to expand and enhance surveillance data and public health research on gestational diabetes. It would award competitive grants to eligible entities for demonstration projects to build capacity with key stakeholders, establish new surveillance systems, and implement and evaluate evidence-based interventions to reduce the incidence of gestational diabetes and its recurrence and to prevent type 2 diabetes after pregnancy. The bill authorizes $5 million for each of fiscal years 2010-2014 for these activities.

In addition, the bill requires the CDC Director to conduct research on the epidemiology of gestational diabetes, and on screening methods at an authorization level of $5 million for each of fiscal years 2010- 2014. Finally, the bill requires the CDC

Director to encourage postpartum screenings after a diagnosis of gestational diabetes within CDC-funded state-based diabetes prevention and control programs.

A manager's amendment in the nature of a substitute is anticipated that would do the following:

- Eliminate the requirement to establish a Research Advisory Committee on gestational diabetes.
- Update the authorization years to FY2012 through FY2016.

XIII. H.R. 5462, BIRTH DEFECTS PREVENTION, RISK REDUCTION, AND AWARENESS ACT OF 2010

H.R. 5462, sponsored by Rep. Rosa DeLauro, addresses the ongoing need to provide pregnant women with the information they need to experience a healthy pregnancy and to avoid adverse pregnancy outcomes. This bill requires the Secretary of the Department of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, to establish and implement a birth defects prevention and public awareness program about pregnancy and breastfeeding information services. It requires CDC to award grants for the provision of, or campaigns to increase awareness about, pregnancy and breastfeeding information services. The bill also requires CDC to award grants for research on maternal exposures and maternal health conditions that may influence the risk of adverse pregnancy outcomes. It authorizes the following to carry out the bill's activities: $5 million for fiscal year 2011; $6 million for fiscal year 2012; $7 million for fiscal year 2013; $8 million for fiscal year 2014; and $9 million for fiscal year 2015.

A manager's amendment in the nature of a substitute is anticipated that would do the following:

- Eliminate the requirements regarding surveillance, research and a national media campaign.
- Reduce the authorization level by $.5 million for each fiscal year.

XIV. H.R. 5986, NEGLECTED INFECTIONS OF IMPOVERISHED AMERICANS ACT OF 2010

H.R. 5986, sponsored by Rep. Henry Johnson, requires the Secretary of the Department of Health and Human Services to develop a report on the epidemiology and impact of neglected infectious diseases of poverty in the United States. The bill provides that the report should also examine appropriate funding required to address these issues.

No manager's amendment is anticipated.

XV. H.R. 6012, DIABETES SCREENING UTILIZATION

H.R. 6012, sponsored by Rep. Zachary Space, addresses the growing concern about utilization rates of diabetes screening programs. Such programs can be very helpful in identifying patients with diabetes and directing them to appropriate care. This bill directs the Secretary of the Department of Health and Human Services to review the utilization of diabetes screening benefits and identify existing efforts by HHS agencies, and private and non-profit sectors to increase awareness of diabetes screening benefits. An annual report to Congress on these activities is required.

A manager's amendment in the nature of a substitute is anticipated that would do the following:

- Eliminate the requirement that HHS establish an outreach program on diabetes. Instead, it requires HHS to conduct a review of the utilization of existing HHS diabetes screening programs.
- Limit the number and timeframe for HHS reports to Congress on utilization of HHS diabetes screening programs.

XVI. H.R. 6081, STEM CELL THERAPEUTIC AND RESEARCH REAUTHORIZATION ACT OF 2010

H.R. 6081, sponsored by Rep. C.W. Bill Young, reauthorizes the C.W. Bill Young Cell Transplantation Program, which includes the National Registry for adult donors of bone marrow, peripheral blood adult stem cells, and umbilical cord blood units; the Office of Patient Advocacy; and the Stem Cell Therapeutic Outcomes Database. It authorizes $30 million for each of fiscal years 2011- 2014 and $33 million for fiscal year 2015 for the program. The bill also reauthorizes the National Cord Blood Inventory (NCBI), a program that provides grants to public cord blood banks to assist them in collecting donated cord blood units that are then listed on the National Registry. $23 million for each of fiscal years 2011- 2014 and $20 million for fiscal year 2015 is authorized for the NCBI.

No manager's amendment is anticipated.

XVII. H.R. 6109, HEALTH DATA COLLECTION IMPROVEMENT ACT

H.R. 6109, sponsored by Rep. Tammy Baldwin**,** addresses current gaps in the nation's health data collection efforts. This bill provides for the voluntary collection of data on sexual orientation and gender identity, as appropriate and practicable, in programs and surveys supported by the Department of Health and Human Services. It requires the HHS Secretary to develop standards for the development of questions and the appropriate and confidential collection of such information. It also directs that this information be analyzed to assess disparities in health status and access to healthcare.

No manager's amendment is anticipated.

XVIII. H.R. 211, CALLING FOR 2-1-1 ACT OF 2009

H.R. 211, sponsored by Rep. Anna Eshoo, addresses the need to improve access to 2-1-1 information and referral telephone service across the country. This bill requires the Secretary of Health and Human Services to award a grant to each state (based on a formula to-be-developed by the Secretary) to make the 2-1-1 health and human services referral service available throughout the state. The bill specifies that the 2-1-1 service will be operated through a lead entity that either has previously had responsibility to carry out this service or meets certain criteria. It authorizes $150 million for each of fiscal years 2009 and 2010 and $100 million for each of fiscal years 2011-2014 to carry out the bill's activities.

No manager's amendment is anticipated.

XIX. H.R. 6110, TELEHEALTH IMPROVEMENT AND EXPANSION ACT OF 2010

H.R. 6110, sponsored by Rep. G.K. Butterfield, reauthorizes three telehealth programs currently administered by HRSA, including (1) the telehealth network program, (2) the telehealth resource center program, and (3) incentive grants to coordinate telemedicine activities among the states. The bill also revises the requirements for funding priorities within both the telehealth network and telehealth resource center programs. It authorizes each of the three programs at $10 million for each of fiscal years 2012-2016.

No manager's amendment is anticipated.