On December 16, the President signed into law the massive 1,600 page, $1.1 trillion FY 2015 Omnibus Appropriations bill that will fund the federal government operations through September 2015. The hybrid “Cromnibus,” as the bill has been referred to inside the Washington Beltway, includes two types of funding legislation: (1) a continuing resolution, which is generally a clean statement of funding at the current levels for each department or agency with no adjustments, restrictions, or other explanations; and (2) an omnibus appropriations bill that includes commentary and possible policy “riders” directing the agencies as to the use of funding to develop or enforce particular regulations.

Congress also passed a bill that will extend about 45 business and individual tax breaks — including the so-called charitable IRA rollover, but for 2014 only. Independent Sector lobbied hard for a permanent extension of the charitable provisions on our behalf, but was forced to settle for another one-year extension. There are rumblings that the Administration may include tax reform proposals in the 2016 Budget. Congress also confirmed Dr. Vivek Murthy on December 15 as the 19th Surgeon General of the United States. The association supported Dr. Murthy’s nomination and helped contribute to this outcome.

And finally, the House and Senate passed the Newborn Screening Saves Lives Reauthorization Act. Once signed into law, the bill will renew for five years federal initiatives that assist State newborn screening programs; support parent and provider education; and ensure the accuracy and quality of newborn screening tests.

After a slow year, the Congress managed to get a lot accomplished in the last couple of weeks and days including numerous provisions of interest to the association. We have described those for which we advocated along with many we supported less actively, and have included language provisions that may be indicative of congressional intent in a number of areas. This report begins with a brief summary of our most significant wins and losses followed by more detailed information on provisions of interest to the association in the areas of research, prevention, access, quality and value and the nonprofit sector.

**Highlights and Commentary**

- **NIH** overall received a 0.5% increase compared to 0.3% for **NHLBI** and 1.08% for **NINDS**. These increases were higher than many programs in the bill received, but still disappointing. However, of greater concern were the specific
increases singled out for other disease groups: Alzheimer’s, cancer, and brain health (which may include stroke to

- some extent). Based on the number of directives NIH will be forced to respond to in the legislation, the next Congress will be more interested in micromanaging their activities than the previous two. As a disease with more effective treatments and prevention strategies, we will have to work harder to compete in “disease wars.” And it’s also not clear if we want to take on the NIH as aggressively as other disease groups are willing to do. This would be a good topic to discuss with the NIH as well as some of our partners in similar situations, such as diabetes.

- The **CDC-administered programs** we support fared well. The division received $130.037 million including, WISEWOMAN ($21.114 million) and Million Hearts® ($4 million) and maintained the unexpected $73 million increase that was included in FY 2014. However, there are numerous directives focused on the ability of the CDC to produce measureable results. In a Republican Congress there will be a higher level of accountability demanded for expenditure of dollars or these funding levels may not last.

- Funding for **HRSA’s Rural and Community Access to Emergency Devices Program** was increased from $3.364 million to $4.5 million, but not for AEDs. The increase was designated for the purchase of other emergency devices used to rapidly reverse the effects of opioid overdoses, as well as training licensed healthcare professionals and emergency responders in their use. The AED part was level funded but remains an extremely vulnerable programs. Its mere survival was an accomplishment.

- The most contentious battle we fought in the Cromnibus was over potential **school meals** riders. Some schools are having difficulty complying with the 100% whole grain requirement that went into effect July 1, 2014, and there is concern about further reductions in the sodium requirements for school meals. As a result, the agreement includes legislative language pertaining to whole grain and sodium standards that directs the USDA Secretary to allow States to grant an exemption from the whole grain requirements to those school food authorities that demonstrate a hardship, including financial hardship, in procuring whole grain products. Additionally, sodium standards cannot be reduced below Target I until the latest scientific research establishes the reduction is beneficial for children.

We can manage this outcome and our hope is that these small changes will allow the program to move forward without more significant alternations in the law in the next Congress. And on the positive side, the issue also provided
AHA with a perfect opportunity to highlight the issue of sodium in the food supply. A quote from Nancy generated millions of media impressions. However, the Member of Congress most engaged in this effort (Representative Aderholt (R-AL) expressed optimism that the GOP may get more of what it wants when the party controls both chambers next year.

The Cromnibus portends battles that we are likely to face in the 114th Congress. These include: (1) more scrutiny over the NIH research portfolio; (2) a higher level of accountability and outcomes demanded for Federal involvement in State and community chronic disease prevention efforts; and (3) extreme antipathy towards regulations (particularly if they impose a financial burden on companies) and tax reform. On the bright side, we have a new Surgeon General who may be able to bring new energy to the prevention movement.

The specter of earmarking funding by disease has once again emerged and should be a concern to a disease like CVD that has real treatments – if not cures – for many CVD conditions. Language provisions in the bill decry earmarking, stating that, “In accordance with longstanding tradition, funding is not directed to any specific disease research area.” There is also language, however, that addresses disease burden and “urges NIH to ensure research dollars are invested in areas in which Americans lives may be improved.” We will have to monitor this issues carefully.

The remainder of this document provides details on both the funding levels and key language provisions included in the measure. It’s important to note, that report language is not binding on the agencies. However, they do take it seriously and generally respond to it in some fashion.

**Research**

**Funding levels**

- **National Institutes of Health** – The NIH received $30.1 billion in core funding, or a $150 million or 0.5% increase in core funding, a big disappointment to the research advocacy community. (These levels exclude funding requested for Ebola.) Within this total, $25 million was added to the budget of the National Institute on Aging (NIA) and the agreement “expects that a significant portion of the recommended increase for NIA should be directed to research on Alzheimer’s disease.” NIH also received $25 million in new money for the BRAIN Initiative and the National Cancer Institute received a slightly higher percentage increase than the other institute – 0.55% increase, or $27.158 million increase compared to a 0.30% increase, or $9.065 million increase for NHLBI. Some of these increases were for building and facilities. Most institutes
received between a 0.30 to 0.31% increase. The Gabriella Miller Kids First Research Act received $12.6 million from the Common Fund.

• **NHLBI** – The Institute received a .30 % increases.

• **NINDs** – The addition of “specific increases” for brain research, resulted in a 1.08% increase for NINDS. We do not know how much of that increase will be allocated specifically for stroke research.

Table 1 compares the budgets for each Institute and Center to the 2014 level and the President’s budget request.

• **Agency for Healthcare Research and Quality.** AHRQ would be provided budget authority for its base budget ($364 million) and $106 million in FY 2015 from the Patient-Centered Outcomes Research Trust Fund. This is a change. In prior years, AHRQ was funded entirely through various taps and transfers, most notably, the “evaluation tap.”

**Language provisions**

• **Alzheimer’s budget.** A new provision of law (SEC. 230) states, “Hereafter, for each fiscal year through fiscal year 2025, the Director of the National Institutes of Health shall prepare and submit directly to the President for review and transmittal to Congress, after reasonable opportunity for comment, but without change, by the Secretary of Health and Human Services and the Advisory Council on Alzheimer’s Research, Care, and Services, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institutes) for the initiatives of the National Institutes of Health pursuant to the National Alzheimer’s Plan, as required under section 2(d)(2) of Public Law 111-375.” Unlike report language, this provision is binding. The objective is to make visible the commitment NIH has to Alzheimer’s research although it does override the criteria NIH uses to allocate resources.

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<tr>
<th>IC</th>
<th>2014</th>
<th>President</th>
<th>Omnibus</th>
<th>% Change President</th>
<th>Omnibus</th>
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### Table

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#### (Meetings) Cardiovascular Disease

The agreement reflects awareness that in March 2014, Cambridge University researchers reported that current evidence does not clearly support cardiovascular guidelines that encourage high consumption of polyunsaturated fatty acids and low consumption of total saturated fats. The agreement recognizes that these findings create conflicting information being provided to the public. The agreement requests NHLBI convene a State of the Science Meeting within 180 days after enactment with participants from CDC and other appropriate scientists from all sides of this debate to identify the open questions arising from this new study.

#### (Meetings) Rehabilitation Research

The agreement expects the NIH Rehabilitation Coordinating Committee (NIH RCC) to: (1) host a trans-NIH State of the Science Conference on Medical Rehabilitation Research; (2) develop and regularly update a trans-NIH plan for medical rehabilitation science; and (3) better coordinate the grants to adhere to the definition of rehabilitation research recommended by the Blue Ribbon Panel on Medical Rehabilitation Research. NIH is urged to establish certain benchmarks to assess whether the coordination proposals being implemented are having a
positive impact on NIH rehabilitation science. Finally, the agreement requests the National Institute of Child Health and Human Development (NICHD) and the NIH Director receive an annual briefing to discuss progress in rehabilitation research and the level of trans-NIH activity in this area of research.

- **Big Data.** The agreement continues to expect NIH to protect the privacy of individuals who are the subject of research. As the *Big Data to Knowledge Initiative* (or any similar initiative) creates new methods of collecting data from research, attention must be paid to new ways of protecting the data of individuals involved. NIH is directed to include requirements related to privacy protections in every grant that involves human research, such as the issuance of certificates of confidentiality.

- **Improve Data Availability.** The agreement directs that within 90 days after enactment, the NIH Director should submit a report that assures the House and Senate Committees on Appropriations that all journals supported with NIH resources are consistent with the February 2013 memorandum from the Director of the White House Office of Science and Technology Policy, which states that data sets used in publications supported by government grants should be made available to the public where possible. The agreement expects NIH to take immediate actionable steps to ensure all data from NIH supported journals is available and reproducible.

- **Earmarking by disease.** The NIH is expected to base its funding decisions only on scientific opportunities and the peer review process. In accordance with longstanding tradition, funding is not directed to any specific disease research area.

- **Earmarking by disease burden.** Recent GAO reports (GA0-14-490R and GA0-14-246) on NIH research allocations highlight that NIH’s research allocation process does not significantly take into account any method related to burden of disease on the American public, such as death or prevalence rate. Therefore, the agreement urges NIH to ensure research dollars are invested in areas where Americans’ lives may be improved.

- **Clinical Trials.** The agreement requests GAO to conduct a review of how NIH applied the recommendations from the 2010 Institute of Medicine (IOM) report on NCI’s clinical trials across all NIH Institutes and Centers (ICs) to improve NIH-wide clinical trial activity. Specifically, the review should provide recommendations related to administering, monitoring, managing, and supporting an appropriate NIH-wide portfolio of clinical trial activity. Further, the agreement expects NIH to review its policies and make changes as appropriate to ensure appropriate minority participation in clinical trials across all NIH ICs.
• **Common Fund.** NIH is expected to continue the long-standing policy for Common Fund projects to be short-term, high-impact awards, with no projects receiving funding for more than 10 years. Funding is not included for research within the Common Fund specifically related to health care financing reform and insurance incentive activities related to the Affordable Care Act. The agreement continues to encourage NIH to consider research related to new treatments, diagnostics, and the impact of widespread adoption of the results of biomedical science funded by taxpayer dollars.

• **Health Disparities.** The principles that serve as the foundation of the National Center for Advancing Translational Sciences (NCATS), such as public-private partnerships, community outreach, and faster access to clinical trials have tremendous potential for addressing the long-standing diseases associated with health disparities. NIH is encouraged to support NCATS centers with a history of serving health disparity populations so that research funding provided through the various institutes can be leveraged to address the disproportionate higher incidence of cancer, stroke, and heart disease among minority populations.

• **Moderate Drinking.** Numerous epidemiological and basic science studies have demonstrated that moderate drinking can be beneficial to health by reducing risk for coronary artery disease, type 2 diabetes, and rheumatoid arthritis, among others. However, these studies used different protocols or questionnaires, and may be difficult to compare. The agreement encourages the National Institute on Alcohol Abuse and Alcoholism (NIAAA) to undertake a multi-center, multiyear clinical study to clarify the health impact of moderate alcohol consumption.

• **Office of the Director.** The agreement encourages the NIH Director to ensure all ICs continue to support the Pathway to Independence Award program, which provides new investigators with mentored grants that convert into independent research project grants. In addition, the agreement continues to support new innovator awards, pioneer awards, and the transformative R01 program through the Common Fund. The agreement has provided bill language for specific funds authorized by the recently-enacted Kids First Research Act within the Common Fund to support the first year of the 10-year Pediatric Research Initiative.

• **Young Investigators.** The agreement requests NIH review the grant success rates for early stage investigators in their first two grant submissions. The objective is to consider whether the grant applications submitted by all early stage investigators, regardless of whether they successfully achieved their first submission, should compete against other early stage investigators instead of all submissions.
• **Prioritization of Funding.** NIH is expected to prioritize Federal funds for medical research over outreach and education. The agreement expects NIH to distribute grant funding in the spirit of its long-standing reputation as a meritocracy, basing eligibility requirements on the merit of the researchers’ ideas and productivity, with no discriminatory review requirements, and supporting both research institutes and team-based research.

• **Reproducibility of Research Results.** The agreement expects NIH to stress the importance of experimental rigor and transparency of reporting of research findings in order to enhance the ability of others to replicate them. The agreement concurs that the gold standard of good science is the ability of a lab to reproduce a method and finding. It voices concern with reports that much published biomedical research cannot be easily reproduced. The agreement expects that NIH will develop incentives for scientists to undertake confirmation studies, best practice guidelines that would facilitate the conduct of replicable research and guidelines to encourage research transparency in the reporting of methods and findings. In addition, the agreement expects an NIH-wide policy and trans-NIH oversight to address the replication concerns. The agreement requests an update in the FY 2016 budget request on the on-going activities NIH has toward this effort, the annual measure, and the amount of resources spent or estimated each year toward this effort.

• **Study Sections Pediatric Expertise.** The agreement expects NIH to ensure that when study sections are reviewing pediatric research applications, they have permanent or ad hoc members who are experts in the field as part of the review.

• **Transforming Basic Science to Preventive Medicine through Technology.** The agreement requests NIH develop an NIH-wide approach (including all ICs) to rapidly improve the speed and validity of personalized preventative medicine through the convergence of technology and biomedical science. The agreement requests NIH hold a joint forum with these types of industries, academic engineers, and appropriate biomedical research organizations to develop a range of potential scientific question, capabilities, gaps, and related biomedical scientific constraints.

• **Women’s Health Research.** The agreement notes the recent 25th anniversary of the NIH’s Office of Research on Women’s Health. This office was authorized by Congress to correct the gender imbalance in research and highlight the importance of women’s health issues to the larger scientific community. The agreement congratulates the office on its longevity and success. In that vein, the agreement supports NIH’s recent shift toward achieving balance between females and males in preclinical research and encourages the NIH to ensure this applies to experimental models used for basic science research and that
both males and females are utilized to investigate diseases that affect the two. It is further recommended that the NIH expand its current policies to require NIH-funded investigators to prominently indicate the sex of their experimental model in their grant application and progress reports. Further, those investigators studying both sexes, should be required to report, and when appropriate, analyze their data by sex as part of grant progress reporting to the Agency. The same should be encouraged in all published results that come from NIH funding.

When it is unknown what proportions of women and men are affected by a specific disease, NIH is encouraged to require investigators to utilize valid experimental design including consideration of sex as a biological variable in relevant research on animals, cells, and human subjects, as scientifically appropriate. The agreement recognizes NIH’s efforts to include female participants in all phases of pre-clinical and clinical trials, as scientifically appropriate. The agreement also supports requiring investigators to analyze study results by sex/gender and minority subpopulations as appropriate, based on the scope of the research. Proposals that include adequate numbers of women and men and a robust plan for analysis, publication, and distribution of findings should be given priority in funding decisions, when appropriate. NIH is directed to include in its biannual report the proportion of women and minorities as subjects in clinical research participant enrollment by trial phase and in all studies of human subjects. The NIH is also directed to report on preclinical research in terms of the proportion of studies that incorporate sex as a biological variable and of those studies that analyze data by sex as part of grant review, award, and oversight processes. This data should be reported by Institute and Center across the Agency. The National Library of Medicine is urged to implement changes to Clinicaltrials.gov that will require users to input the number of participants that drop out of trials and break out those participants by sex/gender and race.

There were also a number of reports and working groups requested under the explanatory statement accompanying the bill.

- **Report.** The agreement continues to support NIH biomedical research activities in the following areas and requests an update for each listed disease, condition, or topic in the FY 2016 budget request to describe the latest efforts ongoing and planned for the fiscal year 2016 request. Many items are listed, including the BRAIN Initiative, chromosome abnormalities, congenital heart disease, Jackson Heart Study, National Pediatric Research Network, palliative care, stroke, and telemedicine.

- **Enhanced NIH Reporting on Research Spending by Disease and Affected Populations.** The NIH reports and makes available to the public on an annual
basis the amount of research spending by disease. This information is helpful and provides insight to the public and the research community about overall NIH research. The agreement requests that NIH include, no later than 180 days after enactment and thereafter, the number of Americans affected by each category listed in the Research, Condition and Disease Categorization (RCDC) database, according to CDC or another federally-sourced data file.

- **Dissemination of health information to the public.** The agreement directs the NIH Director and each IC Director to ensure a process is in place to make certain new scientific information reaches the public and health care providers through the various other HHS outreach programs. The agreement requests a report within 180 days of enactment to the House and Senate Committees of Appropriations on how this process operates across each IC and the HHS agencies, with an eye toward reducing duplication, and improving dissemination of information.

- **Administrative Burden Workgroup.** The agreement for FY 2014 requested that the NIH Director initiate an Administrative Burden Workgroup that included relevant stakeholders to develop a plan to reduce the administrative burden on grantees and their organizations. The NIH has not yet chartered this workgroup and is directed to do so within 60 days of enactment and conduct the first meeting within 30 days of that date. The agreement requests a copy of the plan and any applicable goals or reduction targets within 180 days of enactment to the House and Senate Committees on Appropriations.

- **Blue Ribbon Commission on Scientific Standing.** The agreement directs the NIH Office of the Director to fund, in consultation with the National Science Foundation and Department of Education, a contract with the National Academy of Sciences to establish a Blue Ribbon Commission charged with determining American public opinion on, understanding and acceptance of scientific research. The Commission shall examine the present state of scientific repute in the United States and present recommendations on how to improve scientific literacy, education, and enhance scientific regard amongst the American public.

- **Commitment to New and Early Stage Investigators.** The agreement appreciates NIH’s commitment to identifying and attracting new biomedical researchers, and expects it will continue to explore novel ways to encourage early transition to independence. The agreement reflects significant concern that the average age at which an investigator first obtains R01 funding from NIH remains around age 42. Therefore, NIH is directed to develop a new approach with actionable steps to reduce the average age at which an investigator first obtains R01 funding. The agreement requests NIH to provide the House and Senate Appropriations Committees a report within 120 days of
enactment on the steps it will take, measurement methods, and a senior level IC Director monitoring plan. Further, the plan should include an analysis of the role of the universities in this effort. It is also requested that future budget requests include the past 10 years of actual data on the average age at which an investigator obtains R01 funding and the next three years of future estimates.

- **NIH Workforce Study.** In 2008, NIH performed a workforce study that examined the state of the biomedical workforce in the United States and provided insight into the future workforce capacity and the need for new investigators to sustain the enterprise. The agreement requests NIH update the NIH New Investigator Projection report developed by the NIH Office of Budget, assuming level funding. It should consider the historical data, success rates of new investigators, the success rates of second R01 (first renewal) applications for early stage investigators, trends in the workforce, data and actuarially sound assumptions with updates on the number of researchers who receive NIH F or K funding who then go on to work in industry. In addition, the report should survey the historical change over time of university policies that feed into the length of time to become a Principal Investigator (PI) and use that data to update the PI projection model to ensure it has the correct mix of new and experienced PIs in the workforce.

- **National Children's Study (NCS).** The recommendations of the Institute of Medicine's (IOM) June 2014 NCS assessment provided valuable insight. The NCS' goals and mission have the potential to add immeasurably to the scientific knowledge on children’s health; the House and Senate Committees on Appropriations have supported this project for numerous years. The IOM provided a framework of recommendations and concerns about the recent changes to the NCS. The NCS Director is expected to use this framework to ensure the NCS’ mission and goals are realized to generate the anticipated returns from the years of taxpayer support. NIH has an on-going workgroup reviewing the NCS that will provide input to the NIH Director who will then consider the NCS’ next phase over the coming weeks. In particular, the NIH decision process should ensure full consideration of IOM comments prior to any changes. The NIH Director is to provide the House and Senate Committees on Appropriations, within 90 days of enactment, a detailed report and plan about the actions taken, decision making process, options under consideration, and other similar structural issues identified by the IOM.
State and Community Based Prevention Funding

Funding Levels

- **CDC Division for Heart Disease and Stroke Prevention.** The division received $130.037 million including WISEWOMAN ($21.114 million) and Million Hearts® ($4 million). However, the funding level for the Division maintains the $73 million unexpected, never-to-happen-again increase that was included in FY 2014. So, that in itself is a coup.

- **Surveillance of Congenital Heart Defects.** CDC’s National Center on Birth Defects and Developmental Disabilities Surveillance program received $4 million ($1 million more than 2014) to expand CDC’s surveillance of congenital heart defects among adolescents and adults in order to better understand issues relating to congenital heart defects, incidence, prevalence, disparities and barriers to optimal care for those suffering from them.

- **CDC’s Preventive Health and Health Services Block Grant.** The block grant received $160 million, the same as FY 2014.

- **Prevention and Public Health Fund.** The Prevention Fund received $927 million. Amounts allocated from the fund to specific activities included: *(Note, these are the amounts these initiatives get from the Fund, not total amounts.)*
  - $887 million for the Centers for Disease Control and Prevention.
  - $72 million for the Heart Disease and Stroke Prevention Program.
  - $4 million for the Million Hearts® Initiative.
  - $35 million for Nutrition, Physical Activity and Obesity base activities.
  - $110 million for the Office of Smoking and Health
  - $30 million for Racial and Ethnic Approaches to Community Health (REACH)
  - $452 million for Chronic Disease Prevention and Health Promotion

Language Provisions

- **Burden of Disease.** The agreement directs the CDC Director to implement a population-adjusted burden of disease criteria as a significant factor for new competitive awards within the Chronic Disease portfolio for Heart Disease, Stroke, and Diabetes.

- **Chronic Disease.** The agreement directs that the CDC Director shall not consolidate programs under Chronic Disease Prevention & Health Promotion in
any manner, including through use of contracting, grant, cooperative agreement, or other such mechanism, which does not allow for an auditable accounting process to certify that all the funding provided supported the programs and activities at the levels identified in this statement.

- **Diabetes, Heart Disease, and Stroke.** The agreement expects a significant portion of resources will support local communities with the highest burden of these diseases. Further, CDC shall conduct an evaluation of supported activities to ensure they are effective and achieve the anticipated results. The agreement requests a report within 180 days of enactment on how much of the funding directly supported local communities with the highest disease burden and an analysis of how CDC evaluates its program effectiveness.

- **Mississippi Delta Health Collaborative (MDHC).** The Mississippi Delta Region experiences some of the Nation’s highest rates of chronic diseases, such as diabetes, hypertension, obesity, heart disease, and stroke. The agreement recognizes CDC’s expertise in supporting evidence-based programs to prevent the leading causes of death and disability and commends their partnership with the MDHC. The CDC is urged to continue to support MDHC’s work to strengthen linkages between the community and clinical services in the region and to continue CDC’s support for implementation of strategies that increase prevention efforts and improve access to physical activity and healthy nutrition.

- **Moderate Drinking.** The agreement notes that numerous epidemiological and basic science studies have demonstrated that moderate drinking can be beneficial to health by reducing risk for coronary artery disease, type 2 diabetes, and rheumatoid arthritis, among others. However, these studies used different protocols or questionnaires, and may be difficult to compare. The agreement urges the Center to work with the National Institute on Alcohol Abuse and Alcoholism on this issue.

- **Obesity.** The agreement expands support for the rural extension and outreach services pilot to support additional grants for rural counties with an obesity prevalence of over 40 percent. The agreement expects CDC to work with State and local public health departments to support measurable outcomes through evidenced-based obesity research, intervention and prevention programs. CDC should focus its efforts on areas of the country with the highest burden of obesity and with the co-morbidities of hypertension, cardiac disease and diabetes from county-level data in the Behavioral Risk Factor Surveillance System. The agreement encourages CDC childhood obesity efforts to support only those activities that are backed by scientific evidence.
• **Special Interest Projects.** The agreement directs the CDC to ensure that any funds used to support Special Interest Projects will be competitively awarded through an open process that is available to all qualified entities, including non-profit organizations, small businesses, and for-profit organizations.

• **Birth Defects Prevention.** The Center for Birth Defects Research and Prevention is commended for its work toward greater understanding of the causes of birth defects and for expanding the National Birth Defects Prevention Network to include the work of the Birth Defects Study to Evaluate Pregnancy Exposures (BD-STEPS) program. CDC is encouraged to allocate additional resources to expand the BD-STEPS program, with the goal of incorporating States that do not currently have a birth defects surveillance system. Priority should be given to programs in those States that have previously submitted meritorious applications, but did not receive grant funding due to budget constraints.

• **Preventive Health and Health Services Block Grant (PHHSBG).** The agreement rejects the Administration’s proposed elimination of the PHHSBG. The agreement restores the PHHSBG to a level of $160,000,000. CDC is expected to provide these flexible funds to State public health agencies. CDC is urged to enhance reporting and accountability for the PHHSBG, such as providing technical assistance to States regarding using funds for core public health capacities that may not be supported through other CDC categorical funding streams, such as information exchange systems, health information technology, billing capacity, public health accreditation preparation, and implementation of evidence-based practices.

• **Grant table.** The agreement directs the CDC Director to include in the FY 2016 and future budget requests a table that identifies each type of grant awarded under each CDC program. It should clearly include for each program the percentage of funds awarded by formula and non-formula for each type of competitive grant for each of the past three years, current year, and budget year.

• **Scientific Research Coordination with NIH.** The agreement directs CDC programs to coordinate with the Institutes and Centers of the National Institutes of Health and share scientific gaps to accelerate knowledge research related to disease and prevention activity supported through NIH’s research portfolios. The Director shall include an update in the FY 2016 budget request on this effort.

• **CDC environmental health.** In the explanatory statement under CDC Environmental Health, the language states that: “Laboratory professionals use
a variety test methods to obtain accurate and informative results to diagnose and treat patients, which may result in the reporting of different numeric values for the same test. CDC is urged to partner with the private sector in ‘harmonizing’ clinical laboratory test results.”

- **Strategic Plan.** The agreement includes language to require CDC to establish a budget based on measurable public health goals and objectives. Further, CDC is expected to develop a report examining options on how to align funding based on measurable public health and preparedness goals to address counties with the highest burden of each disease.

**Nutrition**

**Funding levels**

- **Child nutrition.** The child nutrition program received $21.3 billion in mandatory funding for child nutrition. This is an increase from both the FY 2014 enacted and FY2015 requested.

- **School food equipment grants.** The bill provides $25 million for competitive grants for schools to purchase equipment needed to serve healthier meals, improve food safety, and help support the establishment, maintenance, or expansion of the school breakfast program. This is level funding from FY 2014 enacted and below the FY 2015 requested.

- **Summer food demonstration programs.** The agreement includes $16 million to continue summer food demonstration projects, including summer EBT (Electronic Benefit Transfer). This project did not exist in FY 2014 and is below the FY 2015 requested level.

- **Women, Infants and Children Program.** WIC received $6.623 billion, a decrease from both the FY 2014 enacted and FY 2015 requested levels.

- **SNAP.** The bill includes $81.8 billion in mandatory funding for SNAP. This is a decrease from both the FY 2014 enacted and FY 2015 requested levels.

**Language Provisions**

- **School meals:** The bill included both legislative and report language pertaining to school meals. The language does the following: (1) allows States to waive the 100% whole grain enriched requirement that went into effect on July 1, 2014 if they can demonstrate difficulty in implementation or financial hardship; and (2) prohibits USDA from moving forward on implementing the Tier II sodium standards until the latest science shows benefit in sodium reduction in
kids. There is no language rescinding the ½ cup fruit and vegetable requirements; no riders on competitive foods (Smart Snacks); and no blanket waiver that was in the House version of the bill. These are big wins for us.

Legislative Provisions

- **SEC. 751.** For the period beginning on the date of enactment of this Act through school year 2015-2016, with respect to the school lunch program established under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.) or the school breakfast program established under the Child Nutrition Act of 1966 (42 U.S.C. 1771 et seq.) and final regulations published by the Department of Agriculture in the Federal Register on January 26, 2012 (77 Fed. Reg. 4088 et seq.), the [USDA] Secretary shall allow States to grant an exemption from the whole grain requirements that took effect on or after July 1, 2014, and the States shall establish a process for evaluating and responding, in a reasonable amount of time, to requests for an exemption: Provided, That school food authorities demonstrate hardship, including financial hardship, in procuring specific whole grain products which are acceptable to the students and compliant with the whole grain-rich requirements: Provided further, That school food authorities shall comply with the applicable grain component or standard with respect to the school lunch or school breakfast program that was in effect prior to July 1, 2014.

- **SEC. 752.** None of the funds appropriated or otherwise made available by this or any other Act shall be used to pay the salaries and expenses of personnel to implement any regulations under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.), the Child Nutrition Act of 1966 (42 U.S.C. 1771 et seq.), the Healthy, Hunger-Free Kids Act of 2010 (Public Law 111-296), or any other law that would require a reduction in the quantity of sodium contained in federally reimbursed meals, foods, and snacks sold in schools below Target 1 (as described in section 220.8(f)(3) of title 7, Code of Federal Regulations (or successor regulations)) until the latest scientific research establishes the reduction is beneficial for children.

- **SEC. 753.** (a) None of the funds made available by this Act or any other Act may be used to exclude or restrict, or to pay the salaries and expenses of personnel to exclude or restrict, the eligibility of any variety of fresh, whole, or cut vegetables (except for vegetables with added sugars, fats, or oils) from being provided under the Special Supplemental Nutrition Program for Women, Infants, and Children under section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786) (in this section referred to as the “program”). (b) Not later than 15 days after the date of enactment of this Act, each State agency shall carry out the program in a manner consistent with subsection (a). (c) Not later than 90 days after the date of enactment of this Act, the Secretary of Agriculture...
shall commence under section 17(f)(11)(C) of the Child Nutrition Act of 1966 (42 U.S.C. 1786(f)(11)(C)) the next regular review of the supplemental foods available under this program, including a review of the nutrient value of all vegetables. (d) If, upon completing the review under subsection (c), the Secretary of Agriculture recommends that a vegetable be eligible for purchase under the program, none of the funds made available under this Act or any other Act may be used to exclude or restrict the eligibility of that variety of vegetable (except if that vegetable has added sugars, fats, or oils) from being purchased under the program, and subsection (a) shall continue to be effective. (e) If the review in subsection (c) recommends that any vegetable shall not be available for purchase under the program, based upon the nutritional content of the vegetable and the nutrition needs of WIC participants, subsection (a) shall expire upon the publication of the regularly scheduled review. (f) Not later than 90 days after completing the review under subsection (c), the Secretary of Agriculture shall make publicly available all scientific research and data used to make the final recommendations and explain the results of the review by submitting a report containing such information to the Committee on Agriculture, Nutrition, and Forestry of the Senate, the Committee on Education and Workforce of the House of Representatives, and the Committees on Appropriations of the Senate and the House of Representatives. (g) Upon completion of the review under subsection (c) by the Secretary of Agriculture, the Comptroller General of the United States shall conduct an audit of the review which shall include an audit of the scientific research and data used to conduct the review.

Explanatory Statement

- Some schools are having difficulty complying with the 100 percent whole grain requirement that went into effect July 1, 2014, and there is concern about further reductions in the sodium requirements for school meals. In lieu of the language in the House and Senate reports on School Meals, the agreement provides bill language pertaining to whole grain and sodium standards. The USDA Secretary is directed to allow States to grant an exemption from the whole grain requirements to those school food authorities that demonstrate a hardship, including financial hardship, in procuring whole grain products. Additionally, sodium standards cannot be reduced below Target I until the latest scientific research establishes the reduction is beneficial for children.

- The agreement directs the Secretary to use the authority under the Healthy, Hunger-Free Kids Act of 2010 to allow States to vary the frequency of monitoring and compliance reviews of each school food authority based on past school performance, with no cycle extending more than five years. The Secretary shall submit a report to the House and Senate Appropriations
Committees that describes the Department’s process for allowing States to prioritize monitoring and compliance reviews.

- USDA issued a proposed rule in the Federal Register on February 4, 2014, titled "Professional Standards for State and Local School Nutrition Programs Personnel." As this process moves forward, USDA is encouraged to work with schools to ensure this regulation does not result in unintended consequences.

- Language included for WIC allows white potatoes to be an eligible food, against current scientific recommendations.

**Tobacco**

**Funding levels**

- **Office of Smoking and Health.** The CDC received $216.5 million for tobacco (including $110 million from the Prevention Fund). This is in line with this year’s spending and includes enough money to continue the mass media TIPS [From Former Smokers] campaign next year.

- **Tobacco user fee.** FDA will receive $566 million in tobacco user fees. This too is consistent with this year’s funding level and is the amount called for in the 2009 legislation for FY 2015. Based on our review, there are also no riders restricting FDA’s authority. We were pushing hard to prevent any riders to restrict FDA’s authority over cigars, e-cigarettes or other restrictions on FDA’s authority to regulate tobacco products.

**Language provisions**

- There are no cigars or e-cigarette riders.

- **Tobacco products on military bases.** There is language that eliminates the current 5% discount on tobacco products sold on military property so prices will be at the same price in the local community. The language was also found in the National Defense Authorization Act that recently passed. The House bill contained no similar provision. (See below)

**SEC. 8073.** The Secretary of Defense shall issue regulations to prohibit the sale of any tobacco or tobacco-related products in military resale outlets in the United States, its territories and possessions at a price below the most competitive price in the local community: Provided, That such regulations shall direct that the prices of tobacco or tobacco-related products in overseas
military retail outlets shall be within the range of prices established for military retail system stores located in the United States.

- **Trade.** For more than a decade, there has been language in the spending bill to prevent the US government from using its trade power to promote tobacco overseas. It was originally proposed by Rep. Lloyd Doggett of Texas. The last three years we have had to fight to get it included. The good news is that the Doggett trade language was included.

**Other prevention funding**

- **PEP Grants.** The bill provides $47 million for Carol M. White Physical Education Program. This is a $27.577 million cut from FY 2014 enacted – nearly 37%. There is no comparable for FY 2015 as the requested budget called for a consolidated Successful, Safe and Healthy Students program.

- **Transportation Alternatives Program.** This program, which funds Safe Routes to School and other active transportation initiatives, remained at current MAP-21 levels.

- **National Park Service/Land and Water Conservation Fund.** The NPS received $2.275 million. This is an increase from FY 2014 enacted, but less than the FY 2015 request. There were no changes to the Land and Water Conservation Fund allocations.

**Access to Care**

**Funding Levels**

- **ACA.** The Cromnibus legislation contains a number of provisions that relate to the implementation of the Affordable Care Act (ACA). The agreement does not de-fund or undermine HHS implementation of the ACA. However, the bill does rescind $10 million in appropriations for the Independent Payment Advisory Board (IPAB). The original ACA appropriated $15 million a year for the IPAB, adjusted for inflation. As the IPAB has never been made operational, and Medicare spending projections indicate that it will not need to make a recommendation in the near future. This action seems largely symbolic.

- **Highway safety programs.** Highway safety program received $235,000,000, the same as the FY 2014 enacted level. This program includes funding for the National 911 Program and the National EMS Information System (NEMSIS).
Language Provisions

- **ACA.** In what is likely preparation for further attention to ACA funding for 2016, the Cromnibus requires the Centers for Medicare & Medicaid Services (CMS) to detail in its 2016 budget all funds that have been spent since the enactment of the ACA and what spending is anticipated for 2016 on a list of activities specified in the Cromnibus explanatory statement, as well as milestones completed for data hub functionality and readiness.

Quality and Value

Funding Levels

- **Rural AED program.** HRSA’s Rural and Community Access to Emergency Devices Program received $4.5 million – a $1.136 million increase over the $3.364 million FY 2014 level. However the increase over FY 2014 “should be competitively awarded for the purchase of other emergency devices used to rapidly reverse the effects of opioid overdoses, as well as training licensed healthcare professionals and emergency responders in their use.” So, the AED part was level funded.

- **ONC.** The Office of the National Coordinator for Health IT received $60 million, compared to the $75 million requested by the President.

- **Telehealth.** Increases for telehealth included:
  - $4 billion for the Veterans Administration
  - $14.9 million for the Health Resources and Services Administration to help small, rural hospitals adopt health IT;
  - $1 million in additional funding to HRSA
  - $10.3 million for the Department of Agriculture to fund broadband transmission in rural areas for telehealth and distance learning programs

Language Provisions

- **Office of the National Coordinator for Health Information Technology (Information Blocking).** The Office of the National Coordinator of Health Information Technology (ONC) is urged to use its certification program judiciously in order to ensure certified electronic health record technology provides value to eligible hospitals, eligible providers and taxpayers. ONC should use its authority to certify only those products that clearly meet current
meaningful use program standards and that do not block health information exchange. ONC should take steps to decertify products that proactively block the sharing of information because those practices frustrate congressional intent, devalue taxpayer investments in Certified Electronic Health Record Technology (CEHRT), and make CEHRT less valuable and more burdensome for eligible hospitals and eligible providers to use. The CMMI [Center for Medicare & Medicaid Innovation] requests a detailed extent of the information blocking problem, including an estimate of the report from ONC no later than 90 days after enactment of this act regarding the number of vendors or eligible hospitals or providers who block information. This detailed report should also include a comprehensive strategy on how to address the information blocking issue

- **Ventricular Assist Devices.** The agreement is concerned with the Medicare National Coverage Analysis for Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy (CAG-00432R) Decision Memo dated October 30, 2013. CMS is encouraged to review the decision, and upon receipt of appropriate new evidence, to consider whether to cover ventricular assist devices for: (1) individuals who are undergoing an evaluation to determine candidacy for heart transplantation; and (2) individuals who would be potential heart transplant candidates, but are not eligible because of a contraindication that may be favorably modified by the use of a ventricular assist device.

- **Rehabilitation Innovation Centers.** Comprehensive rehabilitation research centers in the United States serve a unique role in complex fields such as brain injury, strokes, multiple traumas, and wartime injuries. Given the high volume of Medicare and Medicaid patients served by these centers, HHS is urged to evaluate the current prospective payment rate with the goal of maintaining these centers of excellence and continuing the high quality of care provided by them.

**Nonprofit**

- **IRA Rollover.** The Senate signed off on legislation (H.R. 5771) on December 16, 2014 to reinstate retroactively dozens of expired tax provisions, including the IRA charitable rollover and the enhanced deductions for donating land conservation easements and food inventory. While taxpayers will be able to employ these provisions in the upcoming tax filing season for the 2014 tax year, the package will expire again on January 1, 2015. The House passed the measure on December 3 and the President signed it into law on December 19. Unfortunately, the House failed to advance the Supporting America’s Charities Act (H.R. 5806), a bill that would have made permanent the IRA charitable
rollover and the enhanced deductions for donations of land conservation easements and food inventory. The vote was 275 in favor and 149 opposed, just eight votes shy of the two-thirds supermajority needed under the expedited procedural rule used to consider the legislation.