AGS | THE AMERICAN GERIATRICS SOCIETY
Geriatrics Health Professionals.
Leading change. Improving care for older adults.

40 FULTON STREET, 18TH FLOOR
NEW YORK, NEW YORK 10038
212.308.1414 TEL 212.832.8646 FAX
www.americangeriatrics.org

February 20, 2015

The Honorable Fred Upton
Chairman
U.S. House of Representatives
Committee on Energy and Commerce
2368 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Representative DeGette,

The American Geriatrics Society (AGS) greatly appreciates the opportunity to comment on several important aspects of the 21st Century Cures Discussion Draft. The AGS is a not-for-profit organization comprised of more than 6,000 health professionals who are devoted to improving the health, independence and quality of life of all older people. Our vision for the future is that every older American will receive high quality patient-centered care. Research is a key avenue for achieving this vision. We greatly appreciate your interest in and support for health research that will promote medical innovation and impact the way we treat disease. This is an important opportunity to think about ways in which we can improve on and address the health care needs of aging Americans. Below we have made some recommendations on select provisions that we hope you consider as you work to further develop this discussion draft.

TITLE II - BUILDING THE FOUNDATION FOR 21ST CENTURY MEDICINE INCLUDING HELPING YOUNG SCIENTISTS

Subtitle F - Building a 21st Century Data Sharing Framework

Section 2092 of Subtitle F requires the Secretary of Health and Human Services make recommendations for the development and use of clinical data registries, including recommendations for a set of standards that "would allow for the bidirectional, interoperable exchange of information between the electronic health records of reporting clinicians and such registries." AGS supports the sharing of data and recognizes the vast potential for electronic health records (EHRs) to improve the quality and coordination of care for geriatric patients.

However, we are concerned that single disease registries may not meet the needs of patients living with multiple chronic conditions (MCC). Chronic conditions are common among older adults, and many older adults have more than one chronic condition. Single disease registries should include data adequate to distinguish patients with multiple chronic conditions. A patient with congestive heart failure and hypertension in mid-life has very different healthcare needs and outcomes than a patient with congestive heart failure, chronic lung disease, moderate dementia and diabetes.

Additionally, efforts to promote the interoperable exchange of information should take into account that Medicare beneficiaries are often cared for in multiple care settings, including the office, hospital, post-acute and long-term care facilities. Integrating their care and treatment across settings is an important goal and one that needs to be addressed.

Subtitle G - Utilizing Real-World Evidence

AGS is concerned about the FDA program established in Section 2101 of Subtitle G that would use "real-world evidence," including data from registries, to support regulatory decision-making because currently there is no consensus on the best methods for collecting such evidence for this purpose. We believe that due to the limitations of registry data in particular, this section would need to include an effort to further specify how the data would be used, including but not limited to, identifying potential rare harms and informing funding for subsequent trials with appropriate methodologies to reduce bias. Given the need to further understand how to utilize these data, we strongly suggest that the FDA create a program that will research the best method for collection rather than issuing public guidance.

Subtitle O - Helping Young Emerging Scientists

AGS members include medical researchers specializing in the field of aging. These researchers are working on pioneering projects on issues such as the effects of sleep medication on hip fractures and postoperative delirium in the elderly, to name a few. We have heard, first-hand, about the particular difficulty of new investigators to remain in medical research because of a lack of, or uncertainty regarding sustained funding. We recognize the importance of increasing National Institutes of Health (NIH) support for investigators with innovative and creative ideas in the early stages of their career.

AGS recently sent a survey to investigators, which can be accessed here, to better understand the impact of federal budget cuts to aging-related research on investigators, institutions and medical progress. We found that investigators are overwhelmingly "very worried" or "moderately worried" that federal funding limitations will prevent them from maintaining their lab or research agenda over the next ten years. Of note, over 57 percent of respondents said that compared to five years ago the pipeline of new investigators planning a career in aging research has decreased in their research program or center.

We wholeheartedly support efforts to enhance the academic and career development of new investigators, and appreciate Congressman Andy Harris' leadership on this issue. We are, however,, concerned about the funding mechanism.

Specifically, the proposal in Sections 2261-2262 to redirect funds from the Public Health Service Evaluation Set-Aside, known as the "evaluation tap," that totals about $700 million per year, back to the NIH to support grants for emerging scientists would come at the expense of many important programs critical to assessing and improving health.

We urge the Committee explore other sources of funding for this important initiative, which will make an important difference in recruiting and retaining researchers with deep expertise in aging matters.

Subtitle N - 21st Century Chronic Disease Initiative Act

AGS shares the concerns expressed by the Friends of the National Institute on Aging (FoNIA) regarding the 21st Century Chronic Disease Initiative Act, which would implement a plan to carry out a longitudinal study designed to improve the outcomes of patients with chronic disease. As stated by the coalition, "a new study would be redundant to existing similar projects, would risk diverting scarce resources (capital, researchers and study participants) from other chronic disease research. For Alzheimer's disease in particular, we believe that the established national goal of preventing and effectively treating Alzheimer's by 2025 serves us well.

Title III - Modernizing Clinical Trials

Subtitle A - Clinical Research Modernization Act

Sections 3001-3002 would help streamline the institutional review board (IRB) process, particularly for clinical trials conducted at multiple sites, by minimizing regulatory duplication and unnecessary delays. AGS is supportive of efforts to streamline this process and supported in December 2014, the NIH draft policy that would require the use of a single IRB for multi-site clinical trials conducted or supported by NIH. We understand that IRBs are an important component of the clinical trial process. We believe that a modernized process as outlined in the NIH proposed policy will reduce inefficiencies so that research can move forward efficiently and avoid costly delays in study approval and start up while following all ethical principles and guidelines. Any additional plans to streamline data reporting and clinical trials should truly streamline the process and not simply create new procedures, as the existing framework is already overly burdensome for researchers.

General Comments - Clinical Trials

While not directly addressed in the discussion draft, AGS strongly urges you to consider the addition of language under this section to help guide the development of new policies to foster the participation of diverse patient populations in clinical trials. Older adults with poor health, disability and multiple morbidities are frequently excluded from randomized clinical trials; however, these are the individuals who generate a large share of health care costs, for whom there is little guidance on comparative effectiveness, and are most vulnerable to the adverse effects of medication.

Despite several decades of calls to action, the gaps in the evidence base for guidelines have never been larger. Among 22 Late-Breaking Clinical Trials presented at the 2011 American Heart Association Scientific Session, 8 trials did not include a single patient older than 65 years of age.[1] More than 50 percent of all trials for coronary artery disease in the past decade did not enroll a single patient ≥75 years of age. The geriatric population represented just 9 percent of all patients enrolled in such trials.[2] In October 2012 the American Diabetes Association published a "Consensus Statement on Diabetes in Older Adults" and concluded that "despite having the highest prevalence of diabetes of any age group, older persons…have often been excluded from randomized controlled trials…of diabetes."[3]

AGS has made several recommendations; most recently in a letter[4] to the Food and Drug Administration (FDA) request for comment on the issues and challenges associated with the collection, analysis, and availability of demographic subgroup data for FDA approved products. Our feedback outlines ways in which the FDA could increase awareness, improve processes, and eliminate barriers to enrollment. A link to our letter can be found in the footnote below. We would welcome the opportunity to speak with you about this issue in further detail.

---

1 Green P, et al. Representation of Older Adults in the Late-Breaking Clinical Trials American Heart Association 2011 Scientific Sessions. JACC 2012; 60; 869-870.

2 Lee PY, Alexander KP, Hammill BG, Pasquali SK, Peterson ED. Representation of elderly persons and women in published randomized trial of acute coronary syndromes. JAMA. 2001; 286: 708–713

3 Kirman S, et al. Diabetes in Older Adults: A Consensus Report. J Am Geriatr Soc 2012.

4. American Geriatrics Society Comments to FDA. Docket No. FDA-2013-N-0745, Action Plan for the Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Human Medical Products, Public Hearing. May 2014.
http://www.americangeriatrics.org/files/documents/Adv_Resources/Comment.Letter05.15.14.pdf

TITLE IV - ACCELERATING THE DISCOVERY, DEVELOPMENT, AND DELIVERY CYCLE AND CONTINUING 21ST CENTURY INNOVATION AT NIH, FDA, CDC, AND CMS

Subtitle A - National Institute of Health

AGS strongly supports Section 4007 to authorize additional funding for the NIH Common Fund. The NIH Common Fund supports high impact cross-cutting research across multiple Institutes. The National Institute on Aging (NIA) is involved in several of these efforts, which are designed to overcome major research barriers. The Healthy Brain Project is one of the many important initiatives that have been funded through the NIH Common Fund. The ultimate goal of this effort is to ascertain effective and practical measures that can be utilized by the public and healthcare providers to promote cognitive and emotional health in older adults. This is a joint initiative of the NIA, the National Institute of Mental Health (NIMH) and the National Institute of Neurological Disorders and Stroke (NINDS).

AGS also supports additional funding for NIH Brain Research and specifically the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative. This is an important initiative aimed at revolutionizing our understanding of the human brain. This groundbreaking program could help researchers find and create effective ways to care and treat those suffering from various neurological and psychiatric disorders, including Alzheimer's, depression and Parkinson's Disease, to name a few.

More resources will allow the NIH to continue to prioritize aging research across institutes. The Institutes that make up the NIH, and in particular the NIA, lead the national scientific effort to understand the nature of aging and to extend the healthy, active years of life. Robust medical research in aging is critical to the development of medical advances which will ultimately lead to higher quality and more efficient healthcare. Continued federal investments in scientific research, including comparative effectiveness initiatives, will ensure that the NIH has the resources to succeed in its mission to establish research networks, assess clinical interventions and disseminate credible research findings to patients, providers and payers of health care. One example of research specific to older adults is the PCORI-NIA comparative effectiveness project, *Strategies to Increase confidence, InDependence and Energy (STRIDE)* that is looking at falls in older adults. We believe that increased investment in projects that focus specifically on older adults will lead to improved health and, perhaps more importantly, quality of life for this population.

Subtitle I - Telemedicine

AGS supports policies and regulations that bring the expertise of geriatrics to patients and families, and therefore agrees with the proposal outlined in Section 4181 of Subtitle I to expand the number of teleheath services covered by Medicare and limit geographic restrictions. Telehealth services play an important role for home-bound older adults and those living in rural and underserved communities. About 62 million Americans rely on rural health providers, and rural areas of the U.S. have fewer than half as many primary care physicians per 100,000 people as urban areas of the U.S. Rural patients often have to travel long distances to reach a physician, which can be especially challenging for older adults who often have more medical appointments and difficulty traveling compared to younger persons.

Subtitle N - Medicare Part D Patient Safety and Drug Abuse Prevention

Sections 4281-4284 under Subtitle N outlines a proposal aimed at preventing high-risk Medicare beneficiaries from abusing controlled substances. AGS shares your concern about the misuse of scheduled medications; however, any proposal to address potential abuse will need protections in place to ensure that beneficiaries who need these medications for legitimate reasons have access to them. Specialists with knowledge in treating conditions that require the use of frequently abused medications

should play a key role in developing the criteria that will be used to identify at-risk beneficiaries. This and other important recommendations, including how to handle multiple prescribers, have been outlined in detail in a November 2014 issue brief[5] developed by the Leadership Council of Aging Organizations (LCAO), of which AGS is a member. The brief highlights several important beneficiary protections that we support and believe you should consider.

A further concern that AGS has includes situations where a beneficiary may live in a rural area where the designated pharmacy is not conveniently located to patients. There should be protections in place to ensure access for these beneficiaries who may only have access to one pharmacy due to their geographic location and travel time.

Another concern is the issue around multiple prescribers. Multiple prescribers would need to be defined to allow for prescribers from the same practice cross-covering one another as well as teaching facilities where providers rotate. The other issue is the use of multiple pharmacies. If the "locked in" medications are filled in one pharmacy and all the other medications are filled in the patient's usual pharmacy, there is the potential to miss drug interactions. Further, the patient's doctor may resort to prescribing other - and maybe less effective or appropriate - medications that do not fall into the "locked in" list.

Again, we appreciate the need to address the misuse of scheduled medications but urge you to develop the program in a way that will ensure no harm to the Medicare beneficiaries that need these medications.

TITLE V - MODERNIZING MEDICAL PRODUCT REGULATION

Subtitle D - Medical Device Reforms

Section 5068 under Subtitle D creates processes to ensure that an advisory committee selected to review a medical device submission has adequate expertise to assess "the diseases or condition for which the device is intended to cure, treat, mitigate, prevent, or diagnose." AGS believes that any effort to strengthen and improve the advisory committees should require the FDA to safeguard the unique health care needs of older adults by establishing a Geriatrics Advisory Committee.

While older adults represent a significant percentage of the population treated, the FDA continues to approve devices and therapeutics with little, if any, data in this population. We envision that a newly formed Geriatrics Advisory Committee would act in a manner similar to the already-established Pediatric Advisory Committee to the FDA. This group would serve a valuable role to (1) advise and make recommendations to the Commissioner of Food and Drugs regarding geriatrics research; (2) identify research priorities related to the need for additional treatments for specific conditions of aging; (3) review the ethics, design, and analysis of clinical trials related to therapeutics to be used in older adults; (4) help mediate geriatric labeling disputes; (5) assist in mediating geriatric labeling changes; (6) survey adverse event reports for drugs used in older adults; and (7) serve in any other matter involving older adults for which FDA has regulatory responsibility.

---

[5] Leadership Council of Aging Organizations. *Medicare Part D "Lock-In" Proposals Must Include Beneficiary Protections.* November 2014. http://www.lcao.org/files/2014/11/FINAL-LCAO-LockIn-Part-D-Brief.pdf

We thank you for this opportunity to comment. Should you have any questions or would like to discuss anything in greater detail; we welcome the opportunity to speak with you. Please contact, Alanna Goldstein at agoldstein@americangeriatrics.org or 212-308-1414.

Sincerely,

Wayne C. McCormick, MD, MPH, AGSF
President

Jennie Chin Hansen, RN, MS, FAAN
Chief Executive Officer