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

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August 14, 2015

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor & Pensions
U.S. Senate
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor & Pensions
U.S. Senate
Washington, D.C. 20510

Dear Chairman Alexander and Ranking Member Murray:

On behalf of the American Geriatrics Society (AGS), we commend you for the "Innovation for Healthier Americans" initiative to advance the discovery, development, and delivery of new medicines and technologies for providers and patients. The AGS is the nation's largest multidisciplinary organization of health professionals and biomedical researchers in aging 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 person-centered care.

As the Committee works on legislation to promote medical innovation we ask that you consider the recommended policies and priorities presented below. We believe that these actions will improve the treatment and care of our nation's burgeoning population of older adults.

Expand and Sustain Federal Commitment to the NIH

The institutes that make up the National Institutes of Health (NIH), and specifically the National Institute on Aging (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.

According to the U.S. Census Bureau, the number of people age 65 and older will more than double between 2010 and 2050 to 88.5 million or 20 percent of the population; and those 85 and older will increase threefold to 19 million. As our aging population increases, so too will the prevalence of diseases disproportionally affecting older people – most notably Alzheimer's disease and related dementias – and the economic burden associated with these diseases. Currently, chronic diseases related to aging, such as diabetes, heart disease and cancer afflict 80 percent of people age 65 and older and account for more than 75 percent of Medicare and other federal health expenditures.

We are very concerned that while America's aging population is growing at an unprecedented rate, funding needed for aging research is not keeping pace. The recent funding for research specific to Alzheimer's disease and related dementias is encouraging. Still, significant research gaps remain in this area as well as in other important areas of aging including clinical and basic research concerning health and disease in older people, multiple chronic conditions, and aging over the human lifespan. These research gaps are due in large part to insufficient funding levels and the ongoing uncertainty of the annual appropriations process.

AGS believes that sustained and enhanced federal investment in aging research is absolutely essential to translating discoveries into safe and effective treatments. Additionally, considering the significant amount of funds the federal government spends on health care costs associated with age-related diseases, it also makes sound economic sense to provide additional federal resources for aging research.

We also encourage you to support programs that accelerate personalized or "precision" medicine. Precision medicine, an innovative approach to disease prevention and treatment that takes into account a person's genomics, has enormous potential to improve health and how we treat disease.

To ensure the continued federal investment in promising aging research efforts, precision medicine, and to provide opportunities for early stage investigators (discussed below), AGS strongly supports the establishment of a dedicated funding mechanism for NIH such as the NIH Innovation Fund contained in the 21st Century Cures Act (H.R. 6). We ask that you consider including a similar provision in the Senate legislation.

Expand Opportunities for New Investigators

AGS members include medical researchers specializing in the field of aging. These researchers are 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 specific challenges that new investigators face to remain in medical research because of a lack of, or uncertainty, regarding sustained funding. Of note, the percentage of grant applications funded by the NIA has drastically dropped over the years.

The field of aging needs new investigators with innovative and creative ideas in the pipeline to build upon past research successes and provide future leadership in genomics, precision medicine, and other scientific discoveries.

In Congressional testimony, NIH Director Dr. Francis Collins has candidly discussed this issue, noting that the uncertainty over funding has dissuaded promising scientists and clinicians from pursuing careers in research. While the NIA and NIH have taken recent, concrete steps to provide additional funding opportunities for new investigators, more needs to be done. For example, Congress should expand loan forgiveness programs at the NIH, remove barriers that make it difficult for researchers eligible for student loan forgiveness at one agency (NIH) to accept a research position at another agency (such as VA), and ensure that new investigators have access to grant funding.

We believe that increasing NIH and NIA support, through a sustained funding mechanism, can improve the payline and success rates for new investigators. These individuals are the future leaders of the field and must be equipped with the resources to conduct new research initiatives, and to ultimately enhance the health and quality of life of older adults.

Encourage Collaboration, Professional Development

Policies should be eased that prevent NIH and the Food and Drug Administration (FDA) staff from attending scientific conferences and meetings. Such conferences and meetings are important for fostering collaboration between researchers, clinicians, and caregivers as well as for keeping staff informed about promising developments in biomedical research and patient care.

Support the Inclusion of Older Adults in Clinical Research

AGS urges the addition of language 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, eight 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 nine 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]

We would like to highlight a provision under Title I of H.R. 6 that would enhance the quality and availability of age-based subgroup data from clinical trials. Section 1083 of Subtitle E, directs NIH to convene workshops of experts on pediatrics and geriatrics to develop guidance identifying when it is appropriate to consider age as an inclusion or exclusion criteria for participation in clinical trials. This section also requires NIH to publically report every two years on the number of children broken out by age, race and gender in NIH-funded clinical trials. We strongly urge that the same type of reporting be required for older adults. Requiring a stronger focus on the enrollment of older adults among industry and other trial sponsors will help us determine the safety and effectiveness of drugs on such patients at the subgroup level. If the elderly, for example, are projected to be a larger percentage of those who use a drug, then this proportion should be reflected in the participants of the drug's clinical trials.

In addition, AGS has made several recommendations most recently in a letter[4] to FDA 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. Here is a link to the letter: http://bit.ly/1P8Ux27

Improve Health Information Technology (HIT)

Electronic Health Records (EHRs) Interoperability

AGS recognizes the vast potential for EHR interoperability to improve the quality and coordination of care for geriatric patients, many of whom are diagnosed with more than one chronic condition, prescribed more than one medication, and receive care in multiple settings, including office, hospital, post-acute and long-term care facilities. By expanding access to patients' medical records, an

[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

interoperable EHR system can help healthcare providers recommend treatments that are better tailored to these often complex patients' preferences and concurrent treatments.

Telehealth Expansion

AGS encourages you to include policies that expand access to, and promote innovation of telehealth services, especially services that will improve home-based care for frail older adults and those in rural and other underserved areas. Web-based consultations using telehealth, or shared imaging between rural primary care providers, geriatricians and specialists not in practice within the patient's catchment area, for example, would help ensure that the 62 million Americans living in these communities receive the best care possible. Patients often have to travel long distances to reach a provider and this can be especially challenging for older adults who may have multiple medical appointments and difficulty traveling. Telehealth support has shown to improve care for patients in skilled nursing facility and assisted living facilities by decreasing emergency department utilization and hospitalization. Home health monitoring systems have shown similar improvements and better compliance and patient satisfaction. Telehealth can also be used to train and educate primary care providers and other specialists with the skills needed to adequately treat their patients. We hope that the HELP Committee will collaborate with the Finance Committee to expand access to these services under Medicare.

Strengthen and Grow the Geriatrics Healthcare Workforce

Biomedical research holds great promise but, by itself, will not improve patient care.
Our nation's healthcare workforce must have the knowledge and training to deliver these new treatments to the patients who need them.

AGS members are responsible for furnishing and directing care for our nation's older adults; however the current geriatrics healthcare workforce is not large enough to meet the unique and complex needs of this rapidly growing population. Of note, our nation is facing a critical shortage of geriatrics faculty and healthcare professionals across disciplines. For example, there are currently 7,428 allopathic and osteopathic certified geriatricians in the U.S. – one geriatrician for every 2,526 Americans 75 or older. Due to the projected increase in the number of older Americans and the plateauing of the number of geriatricians over the last 10 years, this ratio is expected to drop to one geriatrician for every 4,484 older Americans in 2030.[5,6] This trend must be reversed if we are to provide our seniors with the quality care they need and deserve. Care provided by geriatrics healthcare professionals, who are trained to treat the most complex and frail individuals who account for 80 percent of our Medicare expenditures, has been shown to reduce common and costly conditions that are often preventable with appropriate care, such as falls, polypharmacy, and delirium. Additional federal investments and policies are necessary to expand the geriatrics workforce, and provide other health professionals with the knowledge and skills needed to appropriately care for older adults.

There is also an alarming shortage of geriatrics and gerontology faculty and to correct this deficit, substantial increases in mid-career academic training positions are necessary. In addition, to ensure that future physicians are prepared to care for the elderly, medical schools and residency programs need to

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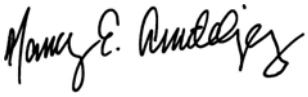
[6] Projections for 2010 through 2050 are from: Table 12. Projections of the Population by Age and Sex for the United States: 2010 to 2050 (NP2008-T12), Population Division, U.S. Census Bureau; Release Date: August 14, 2008. The source of the data for 1900 to 2000 is Table 5. Population by Age and Sex for the United States: 1900 to 2000, Part A. Number, Hobbs, Frank and Nicole Stoops, U.S. Census Bureau, Census 2000 Special Reports, Series CENSR-4, Demographic Trends in the 20th Century. Compiled by the Administration on Aging.

include geriatrics in the curriculum. Other health disciplines – such as nursing, pharmacists, physician assistants and clinical social workers who comprise the geriatrics care team – also require additional training. Due to the demographic trends, there is an increasing and compelling need for biomedical research in aging as well as a strong and sustained national emphasis in the education and training of our nation's health professionals to care for the growing geriatric population.

Should you have any questions or would like to discuss any issues in greater detail we welcome the opportunity to speak with you. Please contact Alanna Goldstein at agoldstein@americangeriatrics.org or 212-308-1414.

Sincerely,



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