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February 8, 2012

HHS Office of the Assistant Secretary for Planning and Evaluation
Room 424E, Humphrey Building
200 Independence Avenue, SW
Washington DC, 20201

Re: Draft Framework for the National Plan to Address Alzheimer's Disease

Dear Secretary Sebelius,

The Society for Women's Health Research (SWHR) is writing to the Advisory Council on Alzheimer's Research, Care, and Services in regards to the Draft Framework for the National Plan to Address Alzheimer's Disease. SWHR has key scientific recommendations that it believes the Advisory Council should consider as it is finalizing the National Plan to Address Alzheimer's Disease.

SWHR, a national non-profit organization based in Washington, D.C., is widely recognized as the thought leader in research on sex differences and is dedicated to improving women's health through advocacy, education, and research. SWHR appreciates the work the National Alzheimer's Project Act (NAPA) is and will be doing to focus our nation's resources on Alzheimer's disease.

Alzheimer's disease is a degenerative disease of the brain, and the brains of men and women are inherently different. While it is common knowledge that men and women think differently, recent scientific discoveries have demonstrated that the difference goes far beyond thought processes. Sex differences have been observed in the anatomy of the brain, behavioral traits, and in the physiological responses of the nervous system. Differences are also noted in the aging process and for degenerative diseases, such as Alzheimer's disease.

Significant differences have been found in men and women who suffer from Alzheimer's disease. Larry Cahill, Ph.D., an associate professor in the Department of Neurobiology and Behavior at the University of California, Irvine, explained in a paper published in Nature Reviews Neuroscience that "Alzheimer's disease-related neurofibrillary pathology associated with abnormally phosphorylated tau protein differs in the hypothalamus of men and women: up to 90 percent of older men show this pathology, whereas it is found in only 8-10 percent of age-matched women." Abnormalities caused by Alzheimer's disease may differ between the sexes and result in different symptoms for men and women with the disease, which may lead to the need for different treatment decisions.

In October 2011, SWHR hosted a one-day scientific roundtable of experts to discuss what is known about sex and gender differences in Alzheimer's disease. The meeting focused on basic and clinical science perspectives, as well as those of the caregiver, and included input from industry scientists. Participants were asked what research questions needed to be answered for progress to be made in the disease. Key research recommendations from the roundtable are as follows:

- Research on the rate of progression of Alzheimer's disease, specifically examining sex differences in the transition from normality to early stages of disease to dementia, and from dementia to outcomes.
- Research on the influence of sex steroids, bioenergetic vulnerabilities, synaptic function, and cognition in the brain as it relates to Alzheimer's disease.
- Re-examination of existing data for potential sex differences to help define the etiology of Alzheimer's disease and publishing sex-specific results.
- Research on the differential impact of the caregiving role on men and women and design interventions to provide more effective services

From the meeting it was clear that research on Alzheimer's disease must account for sex as a basic biological variable and include sex-specific analyses. This type of analysis would be an extremely useful component of a national strategic plan to combat Alzheimer's disease. Approximately two-thirds of all Americans currently living with Alzheimer's disease are women, which is why it is extremely important to ensure that the clinical trials evaluating pharmacologic and non-pharmacologic ways to prevent, manage and treat Alzheimer's disease include an adequate number of women within their study population to perform a sex-specific analysis.

SWHR strongly encourages that these recommendations be incorporated in the Framework goals and strategies and be a part of the continued discussions and work of the Advisory Council.

In addition, SWHR would like to provide comment on several of the specific goals and strategies. Strategy 1.B states that, "new partnerships and outreach efforts may be needed to ensure that enough people are enrolled in clinical trials to examine the effectiveness of promising interventions." SWHR agrees and advocates for appropriate representation in clinical research based on the disease prevalence in the population, with the specific goal of enrolling sufficient numbers of men and women to achieve statistical significance in the resulting sex-specific data analysis.

SWHR believes that under Strategy 1.C, identifying early and presymptomatic stages of Alzheimer's disease requires knowing whether there are any particular differences evident based on sex, race, age, or ethnicity. The reporting and analysis of such data should be a part of the strategy even if the results show no difference, as that is important to determine.

In Strategy 1.E, SWHR recommends amending the draft to require the reporting and analysis of sex, race, age and ethnicity in the research findings, as these factors directly impact the quality of the findings disseminated into medical practice. The reporting of these differences, or lack thereof, influences the knowledge and identification of disease by the public health system, including patients and caregivers.

The quality and efficiency of care under Goal 2 would be increased by the measurement of sex and gender differences as well as differences in race, ethnicity and age. SWHR further recommends that gender be a part of the timely and accurate diagnosis strategy of 2.B as well as education and support to patients in Strategy 2.C. The more accurate and informative the information that is provided to patients, family members and care givers, the more likely it will be that they understand and are able to be engaged in medical decision making.

As women age, many experience comorbid illnesses and diseases, making the coordination of care even more critical. Strategy 2.F is critically important as, “coordinating care...can help reduce duplication and errors and improve outcomes,” especially for those patients, particularly women with multiple chronic diseases. Coordinated care will also help to lessen the difficulty of decisions made by many women who are responsible for making the majority of healthcare decisions for their household.

While SWHR believes that the groups mentioned in Strategy 2.G are unequally burdened by Alzheimer’s disease, we feel that it is important to include women who are disproportionately affected in general as well as within these subgroups. We recommend that women be added as a subgroups being disproportionately burdened by Alzheimer’s disease. It is known that approximately two-thirds of all Americans currently living with Alzheimer’s disease are women. Moreover, there is a need to examine the data by sex within each population identified in Strategy 2.G, including within racial and ethnic minorities

While SWHR agrees that information and training should be given to caregiver in a culturally sensitive manner, as stated in Strategy 3.A, it is important to note that this information should include information on sex and gender differences, as well as differences in race, ethnicity and age. Providing caregivers with any information available on these differences would allow them to better support and care for persons with Alzheimer’s disease.

In Goal 4, SWHR believes that the public would benefit from being provided with Alzheimer’s disease facts and information specified by sex, race, and ethnicity. This will help ensure that they have all available knowledge, including information to address the widespread confusion and misconceptions surrounding Alzheimer’s disease. A better understanding of the disease will allow for the development of more effective preventions, diagnostic tools and treatments through support of the general public.

Data are an essential element of all research and a critical component to the advancement of our knowledge of sex and gender differences in Alzheimer’s disease. SWHR is delighted to see that in Goal 5 there will be, “efforts to expand and enhance data infrastructure and (to) make data easily accessible to federal agencies and other researcher.” SWHR would like to see that data include information on differences that may exist between sex, age, race, ethnicity and culture and that it is made accessible to the public in order to advance research, treatment and diagnosis of Alzheimer’s disease – from patients to caregivers to families.

SWHR believes the recommendations and comments it has provided to the Advisory Council on Alzheimer’s Research, Care, and Services will help to advance more targeted therapies in Alzheimer’s disease for both men and women. This will lead to a greater understanding of risk factors for both men and women and more sex-specific treatment of cognitive aging, Alzheimer’s disease and other dementias.

Should the Advisory Council have any questions or would like more information please contact me at martha@swhr.org or at 202-496-5007.

Sincerely,



Martha R. Nolan
Vice President, Public Policy

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