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TESTIMONY OF

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TESTIMONY BEFORE

the Subcommittee on Aging, Health, Education, Labor & Pensions Committee
United States Senate
Field Hearing on
"Alzheimer's Research and Care: Helping Patients and Families"

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Good morning. Let me begin by thanking you Senator Mikulski for holding this very important hearing and for inviting me to testify this morning. This is just one more example of your constant and invaluable leadership in the fight to conquer Alzheimer's disease. I am delighted to be here with my friends from the Alzheimer's Association and want to acknowledge that organization's ongoing staunch advocacy here in Baltimore, in Maryland, and across the country, on behalf of people with Alzheimer's disease and their families. It is an honor for me to serve as chair of the Medical/Scientific Advisory Committee to the Central Maryland Chapter of the Association.

I also want to acknowledge Dr. Richard Hodes, Director of the National Institute on Aging (NIA) and his Deputy Director, Dr. Judy Salerno who is also with us today. They are leading a rapidly escalating effort, not just at NIA but also across institutes throughout NIH, to find the answers to Alzheimer's disease. They have attracted the best scientists to this important enterprise – now they need the money from Congress to take advantage of the scientific opportunities that have been created.

I speak to you today as a scientist and medical school professor at Johns Hopkins, as a physician who has cared for thousands of patients with Alzheimer's disease and their families, but also as the spouse of a woman whose grandmother suffered greatly before dying from this horrible illness. Alzheimer's has touched me personally, as it has so many here in this room today.

Most of us are likely to live at least until age 65, and many of us will live to age 85 or older. In fact, when I ask audiences to whom I speak how many expect to live to be 85 years, almost everyone raises their hand. Those of us living to 65 have one in 10 chance, and those of us living to 85 have as much as a one in three chance of developing Alzheimer's disease or a related condition. Therefore the specter of Alzheimer's disease is a very personal one. It will affect us all directly or indirectly in the years to come.

Research is an essential part of the battle to conquer Alzheimer's disease. The ultimate goal must be to find treatments that will cure, prevent, or delay this illness. At the same time, we must focus our energies on research designed to improve the lives of the 4 million victims currently alive in the United States, and the countless others worldwide, for whom a prevention or cure will come too late. And, we must research ways to improve the lives of the caregivers, who are just as affected by the disease. It is critical that we as a nation dedicate adequate resources to this effort.

That is why I so strongly endorse S.2059, the Alzheimer's Disease Research, Prevention and Care Act of 2002, which you and Senator Kennedy have introduced to assure adequate resources for the essential research that must be done in the immediate years ahead. And by reauthorizing and expanding the Alzheimer grant programs to the state, you will help assure that what we learn about Alzheimer's disease is translated to better access, care and treatment for people with the disease and their caregivers.

Your bill provides the essential stimulus to help the goal set by the Alzheimer's Association and endorsed by your colleagues on the Senate Appropriations Committee, to increase federal funding for Alzheimer research to \$1 billion per year.

Good research is costly, but the potential return on investment is huge. For a Congress concerned about controlling health care spending and guaranteeing the future of Medicare, finding a way to stop Alzheimer's disease must be a very high priority.

We at Johns Hopkins are proud to be at the forefront of both research and care of Alzheimer's and related disorders. Our memory disorders clinical program, one of the first ever established in the United States, spanning the several Johns Hopkins medical institutions and our affiliated long-term care facility, Copper Ridge, provides diagnostic evaluations and ongoing care "from diagnosis to the end of life" for thousands of patients with Alzheimer's every year.

We now know a great deal about evidence-based, systematic care for people with Alzheimer's disease, which can make a substantial difference in the lives of our patients and their families. Current treatments, which include a combination of medications, counseling, and a variety of other interventions have been shown to alleviate symptoms, to delay institutionalization, and to delay the course of this progressive illness. While the cure is not yet on hand, what we have today can be of great benefit when properly

applied. While it is beyond the topic of this particular hearing, I would emphasize the urgency of incorporating this knowledge into health and long term care policy. That includes adding a prescription drug benefit and chronic care coverage to Medicare.

Alzheimer Research Opportunities and Priorities

We are here today to discuss the research needs for the future. These can be summarized in a few broad strokes.

First, we need to better understand the biology of Alzheimer's disease. This involves laboratory work to understand the complex mechanisms involved in the brain degeneration, the hallmark of the condition. My colleagues at the NIA-funded Johns Hopkins Alzheimer's Disease Research Center are working hard every day in this effort.

Second, we need to better characterize risk and preventive factors for Alzheimer's disease through epidemiologic research. Research at Johns Hopkins has already led to the identification of estrogen and NSAIDs (non-steroidal anti-inflammatories) as possible preventive factors, and to the implementation of prevention studies using both of these treatments.

Much more needs to be known about the risk and preventive factors for dementia so as to develop effective preventions or treatments. Currently under investigation are the role of genes, nutrients, medications (prescription and over the counter), and other biological factors (e.g., homocysteine) in the development of AD. Recent research out of Hopkins indicates that the incidence of Alzheimer's peaks and then declines in late life. This research also suggests that a large proportion of the population may not be susceptible to the development of Alzheimer's. The reason for this non-susceptibility likely includes some combination of protective factors involving both genes and environment. Identification of protective genes and their gene products would be a major breakthrough.

One area of enormous potential, where basic biological, epidemiological, and clinical research overlap, is the growing evidence of the connection between vascular disease and Alzheimer's. We already know about risk factors and effective prevention of vascular disease. If we can better understand these connections, we may be on the path to prevention of Alzheimer's as well. This is a particularly important field of research for people of color, particularly African-Americans and Hispanics, who are at higher risk of vascular disease.

Third, we need to improve the accuracy and ease of the diagnosis of Alzheimer's disease. In academic medical centers such as Johns Hopkins, we can achieve diagnostic accuracy of over 90% in many cases; but that level of diagnostic accuracy is not realized in most clinical settings. We know now that Alzheimer's disease has a long pre-clinical phase, where the disease is damaging the brain but when there are no symptoms. At present we do not have the capability of diagnosing the disease in these very early stages of its development. Yet, accurate diagnosis is critical to effective treatment. In addition, the earlier the diagnosis, the greater the effectiveness of treatments. Also, diagnostic tests that are accurate may provide clues to the biology of the illness. A wide range of diagnostic tests, including cutting edge imaging techniques of the living brain, must be evaluated for this purpose.

Fourth, we need to improve our understanding of the full range of clinical manifestations of the disease. Recent research from our group has found that as many as 90% of patients develop non-cognitive symptoms such as depression, agitation, delusions, hallucinations, and distressing behaviors. Most of these are a direct consequence of the brain damage that the disease brings about. These are very troubling symptoms which dramatically worsen the lives of patients, burden caregivers, and can rapidly lead to early institutionalization. They also create some of the most difficult challenges for residential facilities caring for persons with dementia. Effective management of the symptoms can have a wide range of benefits, for the patient, the family, and the formal care system.

Fifth, we must substantially and immediately increase research into the treatments of Alzheimer's disease. The most exciting possibility comes from recent knowledge of the pre-clinical phase of

Alzheimer's disease. It turns out that the disease is damaging the brain for many years before the onset of any symptoms. This offers an opportunity to intervene and stop or slow it before symptoms occur. That is the key to preventing Alzheimer's. One estimate indicates that if the disease could be delayed by five years, the number of people suffering from the disease would be reduced by half. To this end the National Institute of Aging has initiated prevention studies to find out whether certain medications can prevent the onset of Alzheimer's symptoms and other Institutes are now joining NIA in that effort.

Clinical Studies at Johns Hopkins

At Johns Hopkins we are proud to have a leadership role in these clinical studies. By way of example, I mention today the Alzheimer's Disease Anti-inflammatory Prevention Trial or ADAPT in which I have a leadership role. ADAPT is designed to find out whether healthy people 70 and older without memory symptoms, who have a family history of Alzheimer's, are less likely to develop the disease if treated with non-steroidal anti-inflammatory medications. This study has already enrolled 600 people at six sites nation-wide, one of which covers the Baltimore-Washington area. We eventually plan to enroll a total of 2,400 participants over the next year and a half. I would like to take a moment to acknowledge the presence in the room my staff of the ADAPT-Baltimore team who are working extremely hard in this critical study. This along with other studies investigating other potential treatments or preventions such as estrogen, and ginkgo, are in the field recruiting participants.

These sorts of studies are very expensive, each costing anywhere between \$15 and \$25 million, but they are the only way we will find the safe and effective way to stop Alzheimer's. Each study takes several years to complete and involves scores of clinicians as well as thousands of participants. The most promising studies involve healthy seniors, or people with mild cognitive impairment, who must be enrolled in sufficient numbers and over long enough periods of time for the symptoms of Alzheimer's disease to emerge. These studies also require substantial investment in outreach efforts to recruit and retain enough study participants, including particularly participants from the diverse ethnic and cultural backgrounds affected by Alzheimer's disease.

The success of these studies depends not just on adequate funding but also on educating our seniors about the availability of these studies and encouraging them to consider participation in them. That is another reason, Senator Mikulski, why this hearing and your very visible leadership is so important.

In addition to these efforts to find ways to prevent Alzheimer's, laboratories at universities worldwide and several pharmaceutical companies are working aggressively to find effective medications for the treatment of Alzheimer's disease. Already we have several FDA-approved treatments that have some benefits for disease symptoms. Redoubling laboratory efforts at drug discovery and bringing potential new medication treatments to clinical trials where we can assess their safety and efficacy should be a major undertaking over the next few years.

Equally important to finding ways to treat the cognitive symptoms, we need to evaluate further treatments for the non-cognitive symptoms of the disease. That will yield great benefits for patients and families and for long term care providers. For example, in the Depression in Alzheimer's Disease Study funded by the National Institute of Mental Health, we have recently found that alleviation of depression may delay the functional decline of the disease.

We must not limit ourselves to medication treatments since a variety of other interventions greatly benefit patients. With our affiliate, the Copper Ridge Institute, we are investigating the benefits of several non-medication treatments for Alzheimer's patients and their caregivers. Increased funding in this area, thus far primarily supported by the Alzheimer's Association, will also be necessary.

Finally in the area of treatment, we need to be sure that we can deliver treatments where they are needed. I specifically want to mention the long-term care environment. Currently, about one-quarter of people with Alzheimer's disease, perhaps as many as one-third, live in residential care facilities. We have known for many years that a very large portion of the nursing home population has Alzheimer's or another dementia. We are only now finding this out about assisted living. In our Maryland Assisted Living Study (funded by the National Institute of Mental Health), our initial findings indicate that as many as two-

thirds of residents suffer from memory disorders and that the detection and treatment of these disorders in that environment is sorely lacking. It is critical that we understand better the presence and course of Alzheimer's in assisted living and that we deliver the most effective available treatments to this population of patients as well.

In summary, and with my deep appreciation for your inviting me to speak at this hearing, I would like to strongly emphasize that Alzheimer's is a disease that affects us all at a personal, an economic, and a societal level. Research is the key that will allow us as society to manage this scourge. Redoubling efforts of research in the laboratory, looking for risk factors and protective factors, improving diagnosis, understanding of the course of the disease, and developing a wide range of preventive and other treatments, with a special emphasis on drug discovery, and improving care must be our mission for the future.