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A REPORT ON THE G8 DEMENTIA SUMMIT

HEARING

BEFORE THE

SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS

OF THE

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A REPORT ON THE G8 DEMENTIA SUMMIT

WEDNESDAY, JANUARY 15, 2014

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH,
GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS,
COMMITTEE ON FOREIGN AFFAIRS,
Washington, DC.

The subcommittee met, pursuant to notice, at 2 o'clock p.m., in room 2200 Rayburn House Office Building, Hon. Christopher H. Smith (chairman of the subcommittee) presiding.

Mr. SMITH. The subcommittee will come to order. And we will be joined shortly by some of my colleagues, but I thought I would start because of the delay. And, Dr. Hodes, I want to apologize to you and the other witnesses and everyone here for that delay. We did have two votes, and such is life on Capitol Hill. So thank you again for your patience. I do appreciate that.

On December 11th, the G8 convened a dementia summit in London to examine and presumably harmonize the various national action plans on the growing international crisis of Alzheimer's and other forms of dementia. The outcome appears to indicate a coalescing around the U.S. plan to make significant headway on addressing dementia by 2025, which would have significant implications globally, particularly in low- and middle-income countries where increasing aging populations and numbers of people with dementia strain limited resources.

On January 4th, 2011, President Obama signed into law the National Alzheimer's Project Act, or NAPA, requiring the Secretary of the Health and Human Services to establish a National Alzheimer's Project. Among other provisions of that law, the administration was mandated to create and maintain an integrated national plan to overcome Alzheimer's disease; coordinate Alzheimer's disease research and services across all Federal agencies; accelerate the development of treatments that would prevent, halt, or reverse the course of Alzheimer's disease; improve early diagnosis and coordination of care and treatment of Alzheimer's disease; improve outcomes for ethnic and racial minority populations that are at higher risk for Alzheimer's disease; and coordinate with international bodies to fight Alzheimer's globally.

That congressionally mandated plan apparently found favor with the G8 which endorsed that plan as being comprehensive and forward-looking. But even before the summit, the U.S. national plan on Alzheimer's led nearly a dozen other nations to adopt their own national strategies. According to the testimony at this sub-

committee on November 21st at the pre-summit hearing, this comprehensive approach is vital to meeting what is a looming global health crisis.

The World Health Organization and Alzheimer's Disease International's 2012 dementia report estimates that there were 35.6 million people with dementia, including Alzheimer's disease, worldwide in 2010. This number is projected to nearly double every 20 years, increasing to 65.7 million in 2030 and 115.4 million in 2050. The global cost of this condition totaled $604 billion in 2010, according to Alzheimer's Disease International. To put this figure in context, Alzheimer's cost would equal the gross domestic product of the 18th place country in the world ranked by GDP.

While other G8 countries may pledge funding to address Alzheimer's and other forms of dementia in the developing world, we are facing an impending global health crisis over Alzheimer's and other forms of dementia. The 2014 Federal budget request for U.S.-funded global health programs was $8.3 billion. The focus is on achieving an AIDS-free generation and ending preventable child and maternal deaths through the administration's Global Health Initiative. Under this budget, maternal and child health would receive $680 million, malaria $670 million, TB programs $191 million, and neglected tropical disease programs $85 million. Pandemic influenza and other emerging threats would receive $47 million.

WHO estimates that more than half of global dementia cases are in low- and middle-income countries where cases are projected to explode. Across Asia, Latin America, and Africa these developing countries are expected to see rapid growth in dementia cases over the next several decades. In 2010, roughly 53 percent of dementia cases were in low- and middle-income countries. By 2050, WHO expects 70 percent of all cases to be found in those countries. So how will this impact our foreign aid portfolio, especially as regards global health funding?

We need to better understand the level of international cooperation our Government can expect in the search for early detection techniques, prevention, and treatment of Alzheimer's and other forms of dementia. There has been collaboration among scientists across borders on HIV/AIDS, but how much can we expect on the various forms of dementia? Many countries in the developing world don't even have surveillance adequate to provide reliable statistics on the incidence of Alzheimer's and other forms of dementia. Given the negative impact of the brain drain, they may not be able to be the active, effective partners we need them to be in this area. However, without their help, it will be difficult to even formulate programs to help such nations cope with this growing health threat.

These are questions we hope to have addressed, if not answered, at today's hearing. The administration was unable to participate at the subcommittee's November 21st hearing, but we have the head of the National Institute on Aging to provide the administration's view on what the summit produced. We are also joined by two representatives from the NGO community, both with long and distinguished careers and advocacy efforts that have really made a difference, who also participated in the London summit to give us a private sector view of those proceedings.

We will need more than rhetoric to deal with this crisis. As more of us live longer worldwide, the threat of developing Alzheimer's or some other form of dementia grows exponentially. We cannot afford to have a robust domestic program to fight this condition and find that our international efforts are undermined by the failure of other donors to play their proper role in this effort.

I would like to now yield to my good friend and colleague Ms. Bass for any opening comments that she might have.

Ms. BASS. Thank you, Chairman Smith, once again, for your leadership of this subcommittee and for holding this hearing which is of importance to all of us. I also want to thank our witnesses this afternoon and applaud them for their ongoing contribution to the U.S. leadership and robust global engagement in this field.

I am struck by the number of people worldwide who are currently living with dementia, which I understand ranges from 36 million to some 44 million people, many of whom live in the developing world. The fact that the United States is engaged with other nations in addressing the challenges of dementia is therefore highly encouraging to me as a legislator and speaks to the common goal needed to resolve the medical conundrum that is dementia.

I believe it is fair to say that here in the U.S. all of us have been touched by stories of families—I know I certainly have—friends and neighbors caring for elderly relatives diagnosed with dementia. Many of these caregivers could not have done so without the tireless support of professional health workers and caregiver support groups. Such is the devastating impact of dementia. All of us wait in anticipation for a cure.

At this time I want to thank—I know my colleague Congresswoman Maxine Waters will be attending soon. I want to thank her for her leadership on this issue as she serves as the co-chair of the congressional caucus on dementia. Representative Waters has kindly agreed to address this hearing today in my stead. And I know both of you, you were co-chairs because I believe you founded the caucus on dementia.

Mr. SMITH. Ed Markey did, but he asked me to join him.

Ms. BASS. Oh wonderful. Well, I know that Representative Waters will be joining us soon and I will get information from the two of you when it is over. So thank you very much.

Mr. SMITH. Thank you so very much, Ms. Bass.

I would like to now introduce our very distinguished first witness, and without objection I would ask unanimous consent that the G8 dementia summit declaration as well as the summit communique be made a part of the record.

Dr. Richard Hodes, if you don't mind, Doctor, I would like to wait another minute because I know three or four other members are on their way and I would hate them to miss your testimony, if that is okay with you. So we will stand in a very, very brief recess because I know there are at least three members that are on their way.

[Recess.]

Mr. SMITH. I would like to yield to the co-chair of the Alzheimer's caucus, my good friend and colleague, Congresswoman Maxine Waters, from California.

Ms. WATERS. I would like to thank Chairman Chris Smith, the co-chair of the Congressional Task Force on Alzheimer's Disease, as well as Ranking Member Karen Bass, for organizing this hearing and inviting me here to participate. As the Democratic co-chair of the Task Force on Alzheimer's Disease, I know how devastating Alzheimer's and other forms of dementia can be for individuals and families. As populations age, more individuals are likely to be affected by Alzheimer's and other forms of dementia. According to the World Health Organization, Alzheimer's disease is the most common form of dementia accounting for 60 to 70 percent of the dementia cases worldwide.

Here in the United States Alzheimer's disease is the sixth leading cause of death and it affects over 5 million American families. One in nine Americans age 65 and older has Alzheimer's, and one in three Americans age 85 and older suffers from this disease. The Alzheimer's Association estimates that more than 7 million Americans over age 65 will have Alzheimer's by the year 2025. Every 68 seconds another person in the United States develops Alzheimer's.

Caregiving for dementia patients is especially difficult. More than 15 million Americans provide unpaid care for a person with Alzheimer's disease or another form of dementia. Caregivers include spouses, children, and grandchildren. Caregivers face a variety of challenges ranging from assisting patients with feeding, bathing, and dressing to helping them to take their medications, managing their finances, and making legal decisions.

Alzheimer's and other forms of dementia present growing challenges not just in the United States but also in many countries around the world. According to data compiled by the Congressional Research Service, more than 35 million people worldwide suffered from dementia in 2010. By the year 2050 that number is expected to more than triple to over 150 million people. The World Health Organization estimates that more than half of global dementia cases are in low- and middle-income countries. The Congressional Research Service projected that by 2050 about 9 million people in Africa, 16 million people in Latin America, 29 million people in South and Southeast Asia and 31 million in East Asia will suffer from dementia.

Alzheimer's disease and other dementias present special challenges in low- and middle-income countries. In high-income countries like the United States, institutions and programs like Medicare, Medicaid, nursing homes, adult day care, and other social services provide critical support to dementia patients, their families and caregivers. However, in most low- and middle-income countries, public medical and social services for people with dementia are rare. Consequently, care for individuals with dementia in these countries is almost exclusively the responsibility of their families.

The G8 dementia summit brought together national leaders from the United States, the United Kingdom, France, Canada, Germany, Italy, Japan, and Russia to discuss a coordinated international response to dementia. I look forward to hearing from the witnesses about their experiences at the summit. I am especially interested in plans to coordinate efforts to enhance dementia research, treatment, and caregiver support activities. I am also interested in plans to work with low- and middle-income countries to prepare

them to respond to the needs of growing numbers of families affected by dementia.

Once again I would like to thank my colleagues, Chairman Smith and Ranking Member Bass, and I yield back the balance of my time.

Mr. SMITH. Thank you so much, Ms. Waters.

I would like to now introduce Dr. Hodes. And I know that others will join us shortly, at least they told us they would. He is the director of the National Institute on Aging at the National Institutes of Health. A leading immunologist, Dr. Hodes was named director of NIA in 1993 to oversee studies of the basic clinical, epidemiological, and social aspects of aging. Dr. Hodes has devoted his tenure to the development of a strong, diverse, and balanced approach to research focusing on the genetics and biology of aging, basic and clinical studies aimed at reducing disease and disability including Alzheimer's disease and age-related cognitive change, and investigation of behavioral and social aspects of aging.

STATEMENT OF RICHARD J. HODES, M.D., DIRECTOR, NATIONAL INSTITUTE ON AGING, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. HODES. Thank you, Chairman Smith and Congress. Thank you very much for the opportunity to speak with you. What I will try to do is provide a background of the challenge we currently face in terms of a needy world and the accompanying challenges of cognitive change and Alzheimer's disease, and in particular the way in which the recent summit in London of the G8 helped to reinforce international effort and collaboration toward that end. May I have the next slide, please.

This is just a dramatic illustration of what has happened to the demographics, the age profile of the world. It just a global statistic showing here from 1950 to the present. And you can see the 1950 at the left. That upper curve began showing that the world's population under 5 was some 14 percent or so of the world's population. The lower line, which is very low in 1950, is the proportion of people over 65, and you can see that is down around 5 percent. There has been a remarkable change in these proportions over time so that somewhere within this decade for the first time in human history there will be more individuals over 65 than there are children under five. And those curves will keep on happening so by 2040 and 2050 we will have larger and larger proportions of the population at risk for diseases such as Alzheimer's, and notably, we talked about the challenge societally, fewer and fewer individuals at younger ages capable of providing the kind of care that is currently provided informally by family members in large proportion.

The next slide is last year's very careful study of the cost of Alzheimer's disease in the United States. In 2010, the first bar, illustrates the direct medical care costs over $100 billion. The next two bars, minimum and maximum estimates of informal care costs, giving a total cost, interestingly, that is in excess of what we currently pay for cardiovascular disease or cancer and with the trends, is projected to continue as you see here in 2040 as the number of people at risk for Alzheimer's increases. The next slide.

On that background is noted a very important event, was the passage of the National Alzheimer's Project Act which mandated a national plan. The goals of the plan are illustrated here. The first one highlighted is the prevention and effective treatment of Alzheimer's disease by 2025, toward which we have focused public and scientific input to the formulation of a number of goals and benchmarks. The other targeted goals refer to optimized care and quality, patient support, enhanced public awareness, and then tracking improvement along these lines.

And the next slide is an illustration of the goals that came through in the communique and declaration from the G8 summit, notably with very strong overlapping consistency with the goals espoused in the U.S. plan. An ambitious goal here of again the 2025 target for identifying a cure or disease modifying intervention or therapy. So a very important event, I think, was the coalescence of international opinion behind this goal and a commitment to do all that is necessary in order to achieve it. And the next slide.

Importantly, in order to achieve it is the sharing of information to allow the coordination of efforts. And in the next slide, an example of the very real measures that are now in place to help international collaborations of this particular effort, one which was the outcome of a collaboration between the Alzheimer's Association and the National Institute on Aging which established an ontology of a way to categorize all of the research that is supported internationally for Alzheimer's-related research. It is a database which allows investigators, nations, planners and funders to understand current cross-sectional and trends in research and to maximize the opportunities therefore for filling gaps and for maximizing collaboration. At the G8 summit itself there was a commitment to the G8 nations to participate even more fully in the establishment of this database and its use and coordinating research activities.

Next slide. To illustrate some of the ways in which broad, organized programs of international collaboration around Alzheimer's disease are currently in place, and I will just show you three examples. This is one that was based on the Health and Retirement Study, a U.S. study that looked at population of retirement age and beyond, looked at variables of health, family structure, economics, and so it became a population-based study for understanding the risks and effect, the incidence over time, trends and cognitive change in Alzheimer's disease, the family and caregiver situations involved in these populations, and importantly has provided a template then for international efforts across the world, indicated by the map here, so that a large proportion of the world's population on all continents now is engaged in studies through largely NIH support, at least the level of catalyzing these studies with coherent and harmonized measures so that we can begin to understand worldwide the incidence, the challenge, the societal and economic context in which dementia will occur over years to come.

The next slide is an example of another international effort, ADNI. This is the Alzheimer's Disease Neuroimaging Initiative, a really landmark public-private partnership in which the U.S. public support through the National Institutes of Health along with private sector and involvement both from pharma, from imaging, from biotech, has set out to understand the early changes that occur in

Alzheimer's disease to allow intervention at early stage, well before symptoms, where there is the best chance to achieve an outcome. The fact that you see reflected here worldwide is that having established this in the United States with the very important leadership of the Alzheimer's Association again, worldwide ADNI now has in all the nations, parts of the world illustrated here, parallel efforts. The same studies go on to measure, combine the power of the measurements on many people to test whether the course and characteristics of Alzheimer's is the same in the United States as well as worldwide, another effort to try to synchronize and harmonize worldwide efforts.

And finally in a third example, the next slide, one area where enormous progress has been made is in genetic discoveries. In the last year alone there was a doubling of the number of known genetic risk factors, feasible only through international collaborations involving large numbers of people in all of the nations shown here. So yet another example of understanding whether the disease and its genetics are similar worldwide, and recruiting experts worldwide into this collaborative effort. The next slide.

So there will, in terms of the most concrete mechanism of follow-up from the summit, be a series of legacy meetings. The UK will host one on social impact investment, Japan on new care and prevention models, Canada and France on academia-industry partnerships, although all nations will be participating in these. And announced and accepted at the G8 summit was the U.S. leadership in a meeting which will occur in February 2015 in association with an international summit on Alzheimer's research which will convene the broad international community to coordinate efforts that may come forward from that meeting of experts and scientists. The next slide please.

And just a reminder of that summit, February 2015, this will repeat the summit that was held in 2012 in terms of its format. It will bring national and international experts together to establish priorities for Alzheimer's research, and as noted will have the very particular feature of a session which will involve leadership from international funders and supporters of Alzheimer's research to assure the best coordination of efforts.

I thank you for the opportunity to speak and would be happy to address any questions you might have.

[The prepared statement of Dr. Hodes follows:]

Statement of Richard J. Hodes, M.D.
Director, National Institute on Aging
House Foreign Affairs Committee
Subcommittee on Africa, Global, Health, Global Human Rights,
And International Organizations

January 15, 2014

Chairman Smith and Members of the Committee:

Thank you for the opportunity to address this hearing. I am Dr. Richard Hodes, Director of the National Institute on Aging (NIA), which is one of the 27 Institutes and Centers of the National Institutes of Health (NIH) and the lead Federal Agency supporting research on Alzheimer's disease, a serious public health issue of increasing relevance and urgency to industrialized nations and the developing world alike.

In December, I had the privilege of joining NIH Director Dr. Francis Collins and Department of Health and Human Services (HHS) Acting Assistant Secretary for Planning and Evaluation Dr. Donald Moulds as a member of the American delegation to the G8 Dementia Summit in London. Other members of the U.S. delegation included Erika Elvander from the HHS Office of Global Affairs; Dr. Philip Rubin, Principal Assistant Director for Science at the White House Office of Science and Technology Policy; and Dr. John Wingfield from the National Science Foundation. The goal of the Summit was to develop a coordinated global strategy for addressing the growing issue of Alzheimer's disease and related dementias (ADRD). It is my pleasure to be here today to talk to you about the Summit, its outcomes, and our future plans.

Background: Scope of the Problem

Alzheimer's disease is an irreversible, progressive brain disease that slowly destroys memory and thinking skills and eventually even the ability to carry out the simplest tasks of daily living. In most people with Alzheimer's, symptoms first appear after age 60. Alzheimer's disease is the most common cause of dementia among older people; other forms of dementia include frontotemporal lobar degeneration, Lewy body dementia, and mixed and vascular dementias. Although treatment can help manage symptoms in some people, currently there is no cure for these devastating diseases.

As improvements in modern medicine and care delivery have facilitated a rapid and significant increase in life expectancy in the United States and around the world, we have also seen an accompanying increase in the prevalence of chronic and noncommunicable diseases, including ADRD. In the United States alone, experts estimate that as many as five million people age 65 and older suffer from Alzheimer's disease.[1] An NIH-supported team of economists recently calculated that the costs in 2010 to the U.S. health care and long-term care systems for caring for people with Alzheimer's disease were between $159 billion and $215 billion, depending on how the costs of informal care were assessed, and that those costs could rise dramatically with the increase in the numbers of older people in coming decades. The team estimated direct costs of dementia care purchased in the market in 2010 at $109 billion, exceeding direct health costs for heart disease ($102 billion) and cancer ($77 billion) that same year.[2]

[1] Hebert LE et al. Alzheimer disease in the United States (2010-2050) estimated using 2010 census. *American Academy of Neurology* 80: 1778-1783, (2013).
[2] Hurd MD et al. Monetary Costs of Dementia in the United States. *New England Journal of Medicine* 368: 1321334, 2013. See also http://www.nia.nih.gov/newsroom/2013/04/nih-supported-study-finds-us-dementia-care-costs-high-215-billion-2010

Globally, results of a recent meta-analysis[3] suggest that 35.6 million people lived with dementia worldwide in 2010, with numbers expected to almost double every 20 years, to 65.7 million in 2030 and 115.4 million in 2050. In 2010, 58 percent of all people with dementia lived in countries with low or middle incomes, with this proportion anticipated to rise to 63 percent in 2030 and 71 percent in 2050.

The National Alzheimer's Project Act

Recognizing ADRD's devastating impact on patients and families, President Obama signed the National Alzheimer's Project Act (NAPA) into law on January 4, 2011. NAPA established the National Alzheimer's Plan and requires the HHS Secretary to:

- Create and maintain an integrated national plan to overcome Alzheimer's disease
- Coordinate research, both translational and fundamental, and services across all Federal Agencies
- Accelerate the development of treatments that prevent, halt, or reverse the disease
- Improve early diagnosis and coordination of care and treatment of the disease
- Improve outcomes for ethnic and racial minority populations at higher risk
- Create an Advisory Council to review and comment on the national plan and its implementation
- Coordinate with international bodies to fight Alzheimer's disease globally

[3] Prince M et al., The Global Prevalence of Dementia: A Systematic Review and Metaanalysis. Alzheimer's and Dementia 9: 63-75, 2013.

Under NAPA, the National Plan to Address Alzheimer's Disease was released on May 15, 2012, was subsequently updated in June 2013,[4] and will continue to be updated annually. The five primary goals of the Plan are to:

1. Prevent and Effectively Treat Alzheimer's Disease by 2025
2. Optimize Care Quality and Efficiency
3. Expand Supports for People with Alzheimer's Disease and Their Families
4. Enhance Public Awareness and Engagement
5. Track Progress and Drive Improvement

To begin to implement the Plan, the Administration supported NIH investments in clinical trials and other research, enhanced training efforts focused on educating health care providers about Alzheimer's disease, and new tools to increase public education and awareness of Alzheimer's disease and the supports available.

Since the Plan was established, NIH has made significant progress on a number of fronts.

- Recommendations resulting from the NIH-hosted Alzheimer's Disease Research Summit held in 2012—which drew some 500 participants, including speakers and researchers from the world over—set overarching goals for the field. A subsequent meeting on AD-Related Dementias, similar in reach and scope, was held in 2013.
- The NIH research program has helped to support new technologies that have stepped up the pace for identifying genes associated with AD; notably, in November 2013, the International Genomic Alzheimer's Project, which is supported in part by the NIH, announced identification of 11 new genes, offering important new insights into the disease pathways. Under an intensifying research effort, we have initiated major new

[4] See http://aspe.hhs.gov/daltcp/napa/NatlPlan2013.shtml.

clinical trials, including the first primary prevention trial in people at highest genetic risk for the disease; supported intensive genetics sequencing; and initiated development of innovative new cellular models.

Other HHS components are actively working under NAPA as well to enhance care and services:

- Through its network of Geriatric Education Centers, the Health Resources and Services Administration has provided resources that have facilitated reaching 34,000 trainees – including primary care physicians – on topics from dementia diagnosis to effective management.
- HHS has also launched www.alzheimers.gov, a one-stop portal to information about Alzheimer's care and services. The site links to both public and private resources for the public and health professionals.
- An HHS Specific Populations Task Force has identified the unique challenges faced by groups unequally affected by Alzheimer's disease.[5]

International Activities and the G8 Dementia Summit

We recognize the staggering international scope of the problem of ADRD, but also the tremendous opportunity for progress if nations work together to leverage knowledge and coordinate efforts. We at NIH are particularly interested in improving coordination of research so that investments are maximized, but we are also interested in learning from other countries' successes, particularly in areas such as improving care and support, including for ADRD caregivers.

[5] The Task Force's report is available at http://aspe.hhs.gov/daltcp/reports/2013/AlzSpPop.pdf.

The G8 Dementia Summit represented an exciting opportunity to confer with global leaders in science policy on development of a coordinated approach to ADRD. Summit participants included United Kingdom Prime Minister David Cameron, World Health Organization (WHO) Director General Dr. Margaret Chan, and Organisation for Economic Co-operation and Development (OECD) Deputy Secretary General Yves Leterme, among many others. We discussed a number of topics, including improving life and care for people affected by dementia and their caregivers; preventing and delaying dementia; and social adaptation to global aging and dementia.

The Summit concluded with the publication of a declaration and communique[6] recording the joint activities decided on during the meeting. In the declaration, the participating countries stated their intention to:

- Set a shared goal to identify a cure or disease-modifying therapy for dementia by 2025
- Collectively increase the amount spent on dementia research
- Increase the number of people involved in clinical trials and studies on dementia
- Support the United Kingdom's establishment of a new global envoy for dementia innovation
- Develop an international action plan for research
- Share information and data from dementia research studies across the G8 countries to work together and get the best return on investment in research
- Encourage open access to all publicly-funded dementia research to make data and results available for further research as quickly as possible

These joint activities are fully consistent with NIH's priorities for ADRD research, and we look forward to working closely with other G8 nations to achieve mutual goals. In particular we

[6] https://www.gov.uk/government/publications/g8-dementia-summit-agreements

are delighted that our G8 partners share in our primary objective set forth under the 2012 National Plan—to find effective interventions to prevent or treat Alzheimer's by 2025. In addition, it is worth noting that NIH has already significantly boosted spending on ADRD research by redirecting existing funds within NIH toward this investment; and we will continue to support this high-priority area of research to the extent possible, striving as always to balance this and other compelling areas of scientific opportunity within our available resources.

We anticipate that several ongoing NIH initiatives on ADRD will serve as resources or models for new or expanded global initiatives. These include:

The Alzheimer's Disease Neuroimaging Initiative (ADNI). NIA launched ADNI in 2004. The largest public-private partnership to date in Alzheimer's disease research, it receives generous support from private-sector companies and foundations. ADNI's goal is to find neuroimaging and other biological markers that can detect disease progression and measure the effectiveness of potential therapies. The study expanded over the years and now involves over one thousand volunteers, a mix of cognitively healthy people and those with Alzheimer's disease or mild cognitive impairment, which is frequently a precursor condition to Alzheimer's disease. To speed the pace of analysis and findings, magnetic resonance imaging and positron emission tomography brain images as well as clinical, genetic, and fluid biomarker data are available to qualified researchers worldwide through a Web-based database. Findings from this initiative have generated excitement about using brain and fluid biomarkers to identify people at risk for developing Alzheimer's or to characterize the pace of deterioration.

ADNI has been remarkably fruitful. To date, more than 430 papers using ADNI data have been published from investigators around the world, and many more will come as more data are collected and analyzed. Accomplishments include new findings about how changes in the

structure of the hippocampus may help gauge disease progression and the effectiveness of potential treatments, and the establishment of biomarker and imaging measures that predict risk for cognitive decline and conversion to dementia. The success of ADNI has also inspired similar efforts, supported by the Alzheimer's Association, in Europe, Japan, Argentina, Australia, Taiwan, Republic of Korea, and China.

The International Alzheimer's Disease Research Portfolio (IADRP). To enhance coordination and collaboration among Alzheimer's research funders internationally, NIA, in partnership with the Alzheimer's Association, developed a public database for tracking Alzheimer's disease research and funding. Launched in 2012, the International Alzheimer's Disease Research Portfolio enables funding organizations and researchers to assess the changing landscape of Alzheimer's research, coordinate strategies, leverage resources, avoid duplication, and identify promising areas of growth. Today, 13 major Alzheimer's disease research funders in the United States, United Kingdom, Canada, and Australia have provided funding data, and many others use the IADRP database.[7]

The Health and Retirement Study. NIA has pioneered cross-national research, sponsoring collaborative international projects, and disseminating findings in aging-related conditions, including Alzheimer's Disease, and concerns affecting people worldwide. Significantly, NIA's Health and Retirement Study has served as the model for similar large-scale longitudinal studies in other countries. These include the English Longitudinal Study of Ageing; the Study of Health, Ageing, and Retirement in Europe; the Mexican Health and Aging Study; the Korean Longitudinal Study of Aging; and the Chinese Health and Retirement Survey.

Future Directions

[7] See http://iadrp.nia.nih.gov/cadro-web/.

A particularly promising area for the G8 to approach first involves the rapid and extensive sharing of data, disease models, and biological specimens, with appropriate consent and privacy protections. Alzheimer's disease is a complex disorder, and collaboration and sharing of data and samples on an international scale is crucial, especially in light of constrained budgets. Over the past few years, international collaboration and data sharing have resulted in unprecedented advances in identifying Alzheimer' s disease gene risk factors. These discoveries offer new therapeutic targets for researchers world-wide. The more we encourage collaboration and the breaking down of barriers, the more we advance our understanding of Alzheimer's disease.

In 2014, the G8 countries plan to hold a series of high-level "legacy events" in partnership with the OECD, WHO, the European Commission, the EU Joint Programme on Neurodegenerative Disease, and private partners, to develop cross sector partnerships and innovation focused on social impact investment, new care and prevention models, and partnerships between academia and industry. We look forward to participating in these important meetings, as they will represent useful opportunities to learn from other countries about what is working in each of these critical areas. The U.S. will lead one of these efforts, hosting a follow-up meeting of G8 health ministers and global experts (including WHO and OECD) in early February 2015 as part of the next NIH-hosted Alzheimer's Research Summit. Participants will review the progress that has been made on our research agenda and help provide updated direction for the way forward.

Thank you. I welcome your questions.

Mr. SMITH. Dr. Hodes, thank you very much for your testimony and for your leadership. Let me ask you a few opening questions and then I will yield to my colleagues for any questions they might have.

In reading the action plan, and you talked about it in your testimony, your written testimony as well, it does talk about, and you mentioned it, the three venues that will be held, Japan-led, UK-led and Canada and French-led. Are there dates yet for those?

Dr. HODES. I am not aware of fixed dates.

Mr. SMITH. You also note in the action plan it calls upon WHO and OECD to identify dementia as an increasing threat to global health. Now as we all know, the director general of WHO was there, Dr. Chan. And I am wondering, have they been? Has WHO made this a serious part of their portfolio or are they on the threshold of doing so? Because they have done some reports in the past and I have certainly read them and I know you——

Dr. HODES. I do not know further of any action taken by WHO since that important statement at the G8 summit.

Mr. SMITH. Okay. So that will be an ongoing case of advocacy on our part to ensure that——

Dr. HODES. Certainly we will play a role as we do in WHO affairs, yes.

Mr. SMITH. Now in the list of action items it talks about the UK establishing a new global envoy for dementia innovation. I wasn't sure what that was. I looked and I am not sure. How do you define that? Or how do they define it?

Dr. HODES. The intent here as best I understand it is that the UK will identify an envoy whose responsibility will be to attempt to correlate public-private international partnerships toward a common fund of resources in support of Alzheimer's research. And I think that outline is the extent of the notion to date. The UK will appoint. The rest of the nations were in full agreement with there being such an individual to take the lead in collaborating international public-private partnerships.

Mr. SMITH. We were all thrilled that the G8 is doing this and that the UK initiated it, but I am wondering if there are any thoughts to expand it to the G20 and then by extension to the rest of the world—Brazil, China, India, Mexico, South Africa—large populations obviously with large numbers, increasingly large numbers of dementia cases who make up G20 but not G8. Is there an effort to try to bring them into the fold?

Dr. HODES. Absolutely. As you saw in some of the examples that I cited there was international representation far beyond the G8. Our plans for the G8 legacy meeting, in fact, will call for invitations far beyond G8, and there are many more nations in that, currently involved in Alzheimer's research who are being asked to contribute to this ontology database that I mentioned. But without question, G8 was a very important set of leadership nations but all of our international efforts will extend far beyond that for broader international partnerships.

Mr. SMITH. One of the bullets in your testimony is to increase the number of people involved in clinical trials and studies on dementia. Obviously domestically that will include African-Americans. It will include all people from every ethnic group in all of the G8

countries. But is there any effort to try to include Africans and those who might not usually be part of these trials? Because we have been noticing, especially where longevity is now becoming a positive statistic, people are living longer obviously, that we are going to see a huge epidemic of dementia, for want of a better word, in places like Africa, with a decreased ability to cope with it.

Dr. HODES. The challenge, if I can summarize it quickly, in carrying out the kinds of intervention, clinical trials which are currently happening is that the greatest emphasis is on analyzing people who are at high risk for disease long before there are symptoms of the disease, and tracking biomarkers such as through brain and neuroimaging, genetic analysis and so on. It is currently challenging to do these kinds of studies tracking such markers in nations that do not have the infrastructure for that kind of imaging. The way in which we are trying to do it though is illustrated in one study that attempted to maximize this. This is a study looking at individuals with early onset of genetically determined Alzheimer's disease. Due to specific mutation they have brain changes detectable decades before they have disease. There is the largest familial cohort of these in the South American country of Colombia which is relatively less developed in terms of its biomedical research infrastructure.

So in this case, NIH, together with partners are supporting studies in which those individuals will be studied both through establishing capacity in Colombia and through travel to the U.S., as one of the examples I can cite in which a generally less well developed country can be supported for research, as demanding as it is, in cases where this is particularly important to the research effort.

Mr. SMITH. You testified that the international genomic Alzheimer's project has discovered 11 new genes connected with the condition. How will these discoveries advance identification, prevention and treatment of Alzheimer's, and with the collaboration that now has gone into a much greater area of cooperation, have we already seen some things that we were not aware of coming out of some of the other countries that are part of this initiative? Are we saying, hey, we didn't know that, give us the information on that?

Dr. HODES. Well, in fact, the information that led to the description of these 11 new genes came only when we were able to look at enough subjects with and without disease that could be provided by international investigators. No single country, no single population of available data had the power to identify these new genes. You asked the very important question about what happens next once we identify genes as risk factors. An important observation of the genes described so far is that they tend to fall into families or pathways. Many of them are related, for example, to inflammation, others to transport of membranes.

When we have these clues, this drives the next generation of research which looks at ability to intervene and change the variables that are determined by these genetic risk factors and to look for clues that these are targets then for eventual clinical intervention. This is a difficult and challenging road, but each one of these new genes and gene pathways we identify provides a new potential target for next efforts at intervention.

Mr. SMITH. Let me just ask you one final question with regards to money. Are we appropriating sufficient amounts of money for research for Alzheimer's and are the other countries doing likewise? It seems to me that one of the greatest models we have is PEPFAR because the United States led and other countries did indeed follow and now the whole world is on the same page trying to mitigate the scourge of HIV/AIDS. And I am wondering if this G8 summit was the catalyst and whether or not we do indeed have a Manhattan-type mindset to really eradicate or at least find a therapy for dementia by 2025.

Dr. HODES. Well, I think it is certainly clear that the scientific opportunities that we have before us in areas of Alzheimer's research are vast and that the current fiscal constraints that we have are without question providing an important determinant in what research we can carry forward. We are gratified by the additional funding in 2012 and 2013 which added to our ability to carry out important studies. We are hopeful that there will similarly be an increase in funding available. The scientific opportunities, I think it is fair to say, in direct answer to your question, far exceed our current ability to fund all of the meritorious ideas, and we remain committed, understanding the reality of fiscal limitations, to doing the very best we can with resources available.

Mr. SMITH. I know it is perhaps a difficult question for you to answer, but could you give us any kind of sense of how many laudable projects fall off the table because they cannot be funded because there is insufficient funding?

Dr. HODES. I can give you just an overview in the sense that currently at NIA for Alzheimer's research, as for all of NIH, the success rate for applications is in the range of 15 percent, of all applications received. I think there is wide agreement that meritorious, outstanding applications are fairly uniform through nearly double that amount. So one could safely say if we did no more than fund all the meritorious applications that we have before us, even without taking measures to more actively solicit additional applications, that we could fund twice as much research as we are currently able with the resources in hand.

Mr. SMITH. Do you have hope that the G8 summit will produce a catalyzing effect? We saw with HIV/AIDS, once the bidding war in a positive sense started, countries began to step up to the plate. The Global Fund swung into action, and in every aspect it was like, we are going to resolve this. We are going to stop this pandemic, as Henry Hyde called it, the prime sponsor of the PEPFAR program, he called it the black death of modern times. And it wasn't until that started that we moved into a situation where real resources were being brought to bear. Do you think the G8 summit may have that consequence?

Dr. HODES. I think what I can say comfortably is that we have an enormous responsibility to show in the abstract and also in specifics that there are scientific opportunities before us that are likely to provide the kind of progress necessary to achieve this goal of intervention here by 2025. I think that the G8 summit was a landmark in that it brought together scientists who could make the very specific case with specific plans underlying those aspirations, and that this was embraced as you saw by the common goal across

nations, having met, I think, the important obligation to show that there is a real plan in hand with a rational approach to conducting research that will take us to the goal in mind.

I think we now stand and are hopeful that policy makers will take maximum advantage of the information we can provide, ask us to provide more than we can and leave to your hands what we hope will be a translation of these opportunities into research and real progress toward that goal and timeline.

Mr. SMITH. Thank you, Dr. Hodes.

Mr. Weber?

Mr. WEBER. Gosh, I don't know where to start. Dr. Hodes, you said in Colombia you all had identified, was it the largest biofamilial group?

Dr. HODES. Yes.

Mr. WEBER. Okay.

Dr. HODES. So there were discoveries in the 1990s which uncovered a very rare but tragic and informative population in which a mutation in a single gene, actually one of three different genes, caused Alzheimer's disease in anyone who inherited that disease, Mendelian Inheritance so-called, 50 percent of the offspring of somebody with that gene would have the gene. If you have the gene, 100 percent certainty of getting the disease age 50s, 40s, even 30s. One such large family exists in Colombia. It is known exactly what the mutation is in those individuals.

It is known that if you look at people with no sign of disease at all and do brain scans in their 30s, that individuals who have not inherited the gene all have a normal, if you will, brain scan and particularly without evidence of amyloid plaques. But the individuals who were in their 30s, who were not destined to have Alzheimer's disease for another 15 or 20 years but who have the gene, already show clear abnormalities in their brain scans. This means there is an opportunity to try to intervene with treatments before potentially irreparable damage has been done to the brain, long before symptoms by using experimental treatments and tracking the biomarkers, like brain scans, to see if these treatments are effective. Because this is such a large population, it is an enormous scientific opportunity. It is also a population as you can imagine just desperate to be a part of a search for a goal.

So in collaboration with investigators in the United States and in Colombia, with support from private sector as well as NIH, these individuals will be studied for interventions beginning, years to a couple of decades, before they actually develop disease to see if we can make progress in arresting the underlying pathology of Alzheimer's disease.

Mr. WEBER. Okay, you said a large group. Is that, and you may not know the exact numbers, I mean is it 5,000, 20,000, 150,000?

Dr. HODES. The number of people in these families is in the range of 3,000. Approximately 500 will be studied.

Mr. WEBER. Okay. And then you said, the chairman said, and I came in late so forgive me, I didn't hear all of your testimony, but you discovered 11 new genes?

Dr. HODES. Yes. New genes that are risk factors for Alzheimer's disease. And important to distinguish the kinds of genes we just talked about, three genes which guarantee that one will unfortu-

nately, tragically, have Alzheimer's disease if you inherit that gene. These are real Alzheimer's causal genes. All the rest of the genes we talk about are risk factors. That means if you have the bad variant, the bad allele of that gene, your probability of having Alzheimer's disease increased. It is not 100 percent, but it is a signal that something about that gene is involved in the process of Alzheimer's disease.

Mr. WEBER. So these are not new genes, we have just discovered the link to Alzheimer's.

Dr. HODES. That is fair enough to say.

Mr. WEBER. Right.

Dr. HODES. Since the solving of the human genome all the genes are there, you're exactly right. What has been done is to show that these are linked to Alzheimer's disease.

Mr. WEBER. How many is that? Ninth grade physical science for me was way too far back. How many genes are there?

Dr. HODES. In the range of 25,000.

Mr. WEBER. 25,000, okay. So how do you intervene and change an individual who has inherited these genes? Does it take diet? I mean, how does that work?

Dr. HODES. Well, just as an example of the kind of logic that is followed, if one finds that a number of these genes seem to be in pathways for inflammation and if there is evidence as there is that inflammation may play a role in the brain of those with Alzheimer's disease, one takes this and uses it to design interventions that may, for example, decrease or modify inflammation in the brain to see if this will have a positive effect on the course of disease. So it isn't necessarily a sign that that person with that variant is the only one for whom that intervention makes sense, it is saying that the pathway involved in Alzheimer's is identified by these variants and mutations and it is those pathways which then become the target for experimental interventions.

Mr. WEBER. Are all the other countries involved in this, are they, and I hate to use the word co-equal partners based on population, but how do we measure their seriousness, like the chairman asked? There has not been enough money. How do we get them to the table?

Dr. HODES. Well, in some specific cases, such as the example of genetics, there are clear and strong international collaborations already. In terms of having the full scope of international collaboration in Alzheimer's research, one of the initiatives that we mentioned, an international Alzheimer's research database that was generated by NIA in collaboration with the Alzheimer's Association is in the process of compiling all of the research supported nationally, internationally, by government and private and philanthropic agencies.

This, for the first time, provides an opportunity to go online and ask any of the questions that you would like to for a given nation, a given organization, and a given area of research would change over time what is the level of support to many purposes. One is to address perhaps the question you have asked about the distribution of support internationally, but even at the level of the individual scientist or funder, want to go on to see if there are gaps, if there are important areas of research that are being under-

developed. And to look at this across nations and even coordinate the efforts of nations to invest with the same database, the same understanding of where we stand now and what the needs are.

Mr. WEBER. And part of your comments, you said we are interested in learning from other countries' successes. And so I guess my question is, are we?

Dr. HODES. I think there are categories of research carried out in an individual laboratory which then become internationally shared and inform all of us. So in that respect some of the discoveries of genes or underlying processes, whichever country they arise in, are communicated internationally and inform all of us. And this is one of the important commitments and it came out of G8 as well, to enforce or inform a culture of data sharing so that when information is made available it is made available as quickly as possible to all nations.

In the area of the underlying basic biology of Alzheimer's disease we look at diverse populations to see if there are differences in risk factors across countries. These do inform all of us. I think in that respect we are learning by international comparisons. For example, there are two that I can cite. There was one study that was called the Indianapolis-Ibaden study. African-Americans of Nigerian descent from around the area of Ibadan compared to residents in Ibadan for genetic and clinical manifestations of Alzheimer's disease have revealed different influences of genes in environment. Similar study looking at Japanese immigrants to Hawaii and comparing with their Japanese populations who remain in Hawaii.

So these are some of the examples by which we can learn the effects of environment and their influence on genetic predispositions or protective factors as well. I think these areas of research, and these are only examples, do provide the positive answer that yes, we learn from the experiences internationally. In terms of the health and retirement survey which I mentioned, we are just beginning now to have the capacity to look in countries internationally at their health status, their incidence of new cases of Alzheimer's disease, their relationship to family structure, how care is being provided.

This is the first step in learning from one another and learning lessons to even have that information, but in recent years, as that particular map that I illustrated showed, we are making enormous progress in having studies that are interpretable in a similar and common way across countries both developed and developing internationally.

Mr. WEBER. And how is that information shared? Is it done through summits, through publications quarterly, through emails instantly? How is that information shared?

Dr. HODES. Yes, I mean all of the above. And perhaps some of the more organized examples that we provide are in the databases that I mentioned. Easy to see in genetics, for example. So in 2012 as part of the Presidential initiative and enhanced support for Alzheimer's disease, there was money committed to sequencing the genomes of people with Alzheimer's disease and control people who did not have Alzheimer's. The sequencing, the DNAs collected, the sequencing is done. As soon as it is done and quality control is com-

pleted, they are posted in an international database. The first group announced in December. The next in a month or two.

So they are instantly, these data, instantly available and announced as such to the scientific communities. This is a prototype of the way we attempt to not only have the data available as quickly as possible, but in a place where people know to look for it and where the ability to manipulate those data is maximized.

Mr. WEBER. And is there a parallel track for independent companies, drug research companies? Are they at the same time racing to discover this at the same time?

Dr. HODES. Oh, there are areas of research in which there is a great deal of competition. Certainly the drug companies are doing some things independent of, for example, Federal NIH efforts, but some of the large prevention trials which are being funded in the last year or two with current and enhanced U.S. funds from and through NIH have important collaborations and co-funding by industry. This is most obvious in the cases of course where there is an intervention of something that is proprietary.

But the Alzheimer's Disease Neuroimaging Initiative, a very large initiative designed to identify the earliest changes in Alzheimer's disease—brain images, biomarkers—is being supported by extensive contribution from industry, NIH. All of that with no selective advantage to anyone, the data become immediately available and posted to all. It is perceived by all involved to be of such advantage to both private sector and public that this common good and goal, has to the credit of all, I think, led to essentially instant access to these data.

Mr. WEBER. Okay, I think I have exhausted my pea brain. Okay.

Mr. SMITH. Dr. Hodes, just a couple of final questions. The point of developing an international action plan for research, what does that look like and who would take the lead? Is that a WHO lead or is that a U.S. lead? Will there be people actually tasked for research or it will be just a broad-brush set of bullets on a piece of paper? And secondly, are existing U.S. resources sufficient to implement these goals since there will be a great deal of sharing and collaborating? You answered the question about research dollars, but what about to implement this new global summit agenda?

Dr. HODES. So just to outline the way in which the research agenda in the United States has been developed or presented, we recognized with the national plan an enhanced need to bring to bear the best of international expertise in deciding priorities and strategies in order to pursue these research areas. This was done in a summit in May 2012 and there were some 500 participants. The outcome was a series of recommendations by this international group of experts as to where the priorities lay.

Those priorities and goals were translated into milestones, what it would take to achieve them, what kind of research on what schedule. This has all been shared with the national and international research community and we are in the midst of tracking progress toward them, funding and supporting that research as best as we are able. Currently, international funders have access to the same information. Through the efforts of NIA in collaboration with the Alzheimer's Association we are convening annual meetings and more frequent than that, teleconferences, of inter-

national funders of Alzheimer's research trying to invite and encourage common planning around these milestones.

So I think a well-developed, evidence-based plan with targets, goals, milestones developed through the U.S. to the degree to which this can be implemented at an international level, I think we will see in some of these meetings to come are able to muster international support behind them. So the process, I think, is there. The international collaboration remains, I think, to be optimized, but I think the will has been expressed at G8 and subsequently in a very positive sense.

And the way in which the resources of all of these countries might contribute to this common plan and achieving these common milestones is exactly the kind of planning that one would like to see. It has not yet occurred. Again, I think the G8 is a step toward expressing international will, not just by the G8 nations but then they as emblematic of a broader international community to converge on common goals.

Mr. SMITH. Thank you. Dr. Hodes, I have some additional questions but I will submit them for the record and I know other members will as well. So thank you so much for your leadership and for your testimony today.

I would like to now ask Mr. George Vradenburg who is the chairman and cofounder of USAgainstAlzheimer's, an education advocacy campaign committed to mobilizing America to stop Alzheimer's, and convener of the Global CEO Initiative on Alzheimer's. He also directs Leaders Engaged on Alzheimer's Disease, a coalition of Alzheimer's-serving organizations. Through the Vradenburg Foundation he has supported the Alzheimer's Disease International World Alzheimer's Reports and the NIH global Alzheimer's Research Summit. He has been named by the Secretary of Health and Human Services to serve on the National Alzheimer's Advisory Council to advise on the first of a kind national strategic plan. And prior to December 2003 he held several senior executive positions in a large media of companies.

We will then hear from Mr. Harry Johns who became president and chief executive officer of the Alzheimer's Association in 2005. He has worked to build momentum for the cause by working to increase awareness and understanding of Alzheimer's, emphasizing progress through clinical studies, focusing on public policy and advocacy, and targeting high impact research in detection, treatment and prevention of Alzheimer's. The Alzheimer's Association international conference is the world's largest meeting on Alzheimer's research. In 2011 he was appointed by the Secretary of Health and Human Services to the Advisory Council, and before joining Alzheimer's, Mr. Johns spent more than 20 years with the American Cancer Society.

STATEMENT OF MR. GEORGE VRADENBURG, CHAIRMAN AND FOUNDER, USAGAINSTALZHEIMER'S

Mr. VRADENBURG. Thank you, Chairman Smith and Congressman Weber, and thank you for convening again this very important follow-up meeting to the one that you held 2 months ago just prior to the G8 summit.

You asked at the outset, Mr. Chairman, what the private sector view is toward the G8 summit. And I would say that it is a potentially transformative event, potentially transformative. It set a global goal of stopping this disease by 2025, it set in place some key landmarks in terms of an international research plan and innovation platform, and it also committed to collectively and significantly raising the level of public resources devoted to research.

Now those commitments are yet to be fulfilled, and of course one of our roles, or at least I see my role, is trying to press to make sure that those roles are fulfilled. We will have during 2014 and early 2015, a series of legacy workshops that will follow on, and each of those should be designed to set some very clear action plans in place that could be done at an international level so that we move this pile forward, not just for the 5 million Americans in the United States but for the now 44 million people around the world.

Prime Minister Cameron gave a very eloquent, very passionate speech in which he analogized this G8 summit to the one held in Gleneagles by the UK several years ago which stimulated and accelerated the efforts against HIV/AIDS. So he positioned this summit precisely as you have positioned this: That is to begin to get the globe to attack this problem as a global problem affecting tens of millions of people around the country.

Fifteen years ago, it was U.S. leadership that helped mobilize the global community to combat HIV/AIDS. The G8's embrace of a goal to develop a cure or disease modifying therapy by 2025, which is the United States' goal, signals that U.S. leadership is once again becoming critical to another global effort, this time to stop Alzheimer's. Now just a word on vocabulary here. In the United States, we tend to call this Alzheimer's and other dementias referring to the entire field. The rest of the world tends to call this dementia of which Alzheimer's is a major portion. So by use of Alzheimer's or dementia I encompass the same scope.

As we discussed in November, the parallels between the scale and scope of this disease and global HIV/AIDS are striking. Shortly after our November hearing and just before the G8 summit, Alzheimer's Disease International updated its prevalence figures based upon new studies in China, sub-Sarahan Africa and new population estimates from the U.N. Those estimates indicate that they now believe that 44 million people have this disease, a 22-percent delta over what they estimated before. And if current trends remain as they are, they estimate 75 million cases by 2030 and 135 million cases by mid-century.

To put those in context, 44 million people with dementia is larger than the populations of Canada, Poland or Argentina, and 135 million projected by 2050 is a number that exceeds the population of Japan and nearly that of Russia, the tenth and eleventh most populous countries. Those numbers somewhat understate the impact of the disease since they do not account for family and other caregivers which, based upon U.S. experience, means that the total number of persons impacted by this disease may be three or four times the numbers that are actually attributed to those with Alzheimer's themselves.

And as you have mentioned before, perhaps equally concerning is the fact that 62 percent of these cases currently are in low- and

middle-income countries with an estimate that it will move to 70 percent by 2050. Think about the scale of the disease and the caregiving burden it will have on economic development gains made in global efforts against poverty and in our efforts in women's empowerment since most of the caregiving burden is borne by women. So this is an economic development issue not just a health issue.

The HIV/AIDS epidemic spurred leaders in the U.S. and the world to respond with a global fund to treat AIDS, tuberculosis and malaria as well as PEPFAR as you have already mentioned. Often overlooked however is Congress' leadership in driving both of those programs. In the summer of 2000, Congress passed and President Clinton signed into law the Global AIDS and Tuberculosis Relief Act. That law authorized an aggressive U.S. response to HIV/AIDS and established the World Bank AIDS Trust Fund, among other things, which subsequently led to the succession of funds that we have today. So it was Congress' leadership in driving this that in fact caused those funds to come into existence.

What have we learned from the HIV/AIDS experience? Peter Piot, the former head of UNAIDS, the person responsible for driving the global effort against that disease, turning it from an epidemic to a manageable disease, calls Alzheimer's the next great epidemic and a public health time bomb. With Alzheimer's, we are on the verge of a humanitarian crisis that is potentially larger than the threat posed by HIV/AIDS. Beyond the public health challenge, we are also on the front edge of an economic and fiscal crisis. The cost of Alzheimer's to health care and social support systems is huge and growing, already at more than 1 percent of global GDP. And Alzheimer's is a significant driver of the growth in entitlement spending in the developed nations as well resulting from the rapid aging demographic.

In its 2010 report entitled, Global Aging: An Irreversible Truth, Standard & Poor's, who does rate sovereign debt quality, identified global aging as the dominant threat to global economic stability. Without sweeping changes to age related public spending they think sovereign debt will soon become unsustainable. When you overlay the spector of nearly 140 million persons with dementia by mid-century together with their caregivers, the need for a coordinated and robust action for a range of health, economic and fiscal reasons at the global level is apparent.

Now the G8 dementia summit set out the basis for a global plan and global funding mechanisms to respond to this challenge. The G8 nations including the U.S. committed to identify cure or disease-modifying therapy for the disease by 2025; to increase collectively and significantly, their words, the amount of public funding for dementia research to reach that goal; to develop a coordinated international research action plan; to encourage innovation in discovery and care; to develop national incentive structures to encourage those innovations; and to report on those commitments to ensure progress is made. The UK committed to appoint a global dementia envoy which, as Dr. Hodes mentioned, is patterned on the fact that there were global envoys around HIV/AIDS; to stimulate innovation; and to coordinate international efforts to attract new

sources of financing including a possible public-private and philanthropic fund to support global international action on dementia.

The G8 ministers did commit to a series of legacy workshops in 2014 and 2015 to assure that action plans are developed, executed, and have the intended effect. And I think it is the part of the NGOs, one of our responsibilities to ensure that those occur, that the action plans are developed and that we report them back to you, subject to your calling us again after those legacy workshops are held.

I would urge this Congress to embrace the commitments by the G8 health ministers and to lay the foundation for an aggressive engagement by this country in a global action plan and corresponding global funding mechanism just as you did nearly 15 years ago for HIV/AIDS. Just as our national plan to address Alzheimer's focuses on research, care, services and support for caregivers, so too can a global strategic plan. A global action plan should also set international norms for research, care, long-term support and services so nations can learn from each other about what is expected, what is possible and what mechanisms can be adapted from higher-performing nations for implementation in lower-performing nations.

One example of what a global action plan might embrace is a reform of the clinical trial infrastructure. At the G8 summit and related follow-on events, a clear consensus emerged from industry, academia, and government that reforms in the clinical trial process would be a major step forward to reducing the time, cost, and risk associated with developing disease-modifying Alzheimer's therapies. It takes far too long and costs way too much money to recruit and enroll patients in trials, to assemble the needed infrastructure anew with every drug candidate, and to conduct the trials only to see the hand-crafted trial infrastructure and learning for that trial dismantled and lost so it is not available to other drug companies and other drug candidates.

Recognizing this, the Global CEO Initiative, which I convened, working with the New York Academy of Sciences, has made addressing this gap to develop a global Alzheimer's clinical trial platform a top priority for 2014. Such a platform will be the type of groundbreaking initiative that could be supported with a global strategy and fund. A global funding mechanism to drive this innovation, to broaden the targets of attack on this disease and to scale improvements in quality care delivery is essential to drive this action plan. Low- and middle-income nations do not have the biomedical infrastructure needed to advance research but are necessarily experiencing the same humanitarian and economic costs of this disease, so they should contribute to a global fund even if they may not be able to conduct the research themselves in their own countries.

One thoughtful idea put forward by Drs. Ron Petersen and Nick Fox, which I would recommend as well, is to ask each nation to contribute 1 percent of the cost of care that that society is sustaining for Alzheimer's to research. Based upon current numbers that would imply a global commitment to research of about $6 billion a year. Now that sounds like a big number, but that is less than what we invest in the U.S. alone for cancer research. It is equal to the amount committed by the U.S. alone to global funds

for HIV/AIDS and other infectious diseases. So we are talking about a global fund equal to what the United States itself is investing in cancer or investing in other global funds.

At the present time, notwithstanding significant investments to research and other diseases, no individual nation or small group of nations appear to be willing alone to bear even the minimum level of investment needed to attack this disease, either because of fiscal constraints, internal political barriers, or to strategically reprioritize research investments toward Alzheimer's innovations.

Beyond traditional public investment, the Global CEO Initiative on Alzheimer's, again working with the New York Academy of Sciences, is exploring innovative funding mechanisms that will attract increasing levels of private, philanthropic, social and financial capital to the Alzheimer's efforts. New forms of crowd-sourcing, hybrid philanthropic and financial venture funds, and social impact investing models are emerging in other fields, and efforts are underway to assess their applicability to Alzheimer's. In that regard we will be working with the UK and its dementia envoy among others.

While these clinical trial and financing mechanisms are still in early development, they signal the willingness, and indeed, the eagerness of the private sector to work arm-in-arm with governments to address this global Alzheimer's epidemic. And they signal the potential power of a comprehensive global action plan and fund that unifies the diverse stakeholders invested in finding a solution to this disease. Domestically, we must continue to lead the world and deliver on our commitments at the G8 dementia summit by aggressively implementing our own national plan and increasing the level of public resources to support Alzheimer's research and other programs.

While government budgets remain constrained, our taxpayers are already paying dearly for Alzheimer's to the tune of $140 billion annually in Medicare and Medicaid costs attributable to this disease. At the same time, we spent only $500 million annually on Alzheimer's research. With that in mind, I would urge Congress to enforce the commitments in our national plan and take two actions with regard to research. Build upon the increase in Alzheimer's research included in the omnibus bill to double current levels of funding in Fiscal Year 2015. That is domestic investments. And set a marker consistent with the international norm I noted above of committing just 1 percent of the total estimated domestic cost of this disease to biomedical research.

With total public and private costs in the U.S. estimated to be about $200 billion annually, this approach would yield the U.S. national goal of $2 billion in annual research funding, a target that matches the level of funding estimated by leading Alzheimer's experts and recommended by the Advisory Council on Research, Care and Services as the level of public funding necessary to meet our 2025 goal.

Finally, I think it is worth revisiting a recommendation I and other members of the Advisory Council have long supported, a White House-level official tasked with coordinating our domestic and international efforts against Alzheimer's and dementia. While I am not a fan of layers of democracy, I believe strongly in account-

ability. Congress should consider creating such a position to coordinate both domestic interagency efforts, because they are not just HHS, they are DoD and they are VA, so they are major interagency efforts domestically, and to coordinate our global leadership role much as we did with respect to HIV/AIDS.

Chairman Smith, Mr. Weber, I thank you again for convening this hearing. I urge this committee to continue its oversight focused on this issue and to strongly consider reaching out to additional parliamentarians, particularly those in other G8 member nations who share your strong interest in and commitment to forming a global working group of parliamentarians against Alzheimer's. Such an alliance would support and indeed, I think, drive the work of government administrations in implementing the G8 commitments and expanding this effort. Thank you very much for reconvening and having me testify today.

[The prepared statement of Mr. Vradenburg follows:]

Testimony of George Vradenburg
Chairman, USAgainstAlzheimer's
Convener, The Global CEO Initiative on Alzheimer's Disease

Before the House Subcommittee on Africa, Global Health,
Global Human Rights and International Organizations

A Report on the G8 Dementia Summit
Wednesday, January 15, 2014

Chairman Smith, Ranking Member Bass and other members of the Committee. Thank you for convening this important follow-up hearing to the session you held two months ago just prior to the landmark G8 Dementia Summit. I applaud you for your prompt follow-up and thank you for inviting me to testify a second time.

I am testifying today as the Convener of the Global CEO Initiative on Alzheimer's, a coalition of 12 major global companies – including firms in the medical diagnostics, biopharmaceuticals, financial services, medical foods, and home health care sectors – that is committed to partnering with government to achieve the goal of preventing and effectively treating this disease by 2025. Our members include GE, Lilly, Sanofi, Pfizer, Takeda, Bank of America, Nestle Health Science, Merck, and Home Instead among others. In addition to convening – along with the NIH and the New York Academy of Sciences – the Path to 2025 Summit in November, we were also engaged for much of last year with the British government in the planning of December's G8 Dementia Summit hosted by Prime Minister Cameron, at which the G8 nations committed to the 2025 goal; to "collectively and significantly" increase public investment in the research needed to achieve that goal; and to advance innovations in the delivery of care for families touched by dementia, of which Alzheimer's is the most prominent cause.[1]

Much has occurred between your November hearing and today. You just heard a very comprehensive report from Dr. Hodes on our government's participation in the Summit and the plans for substantive follow-up activity over the coming months through a series of workshops

[1] See:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/265869/2901668_G8_DementiaSummitDeclaration_acc.pdf

and a planned February 2015 follow-up Summit hosted here in Washington. The CEOi convened senior leaders in business, science and government on December 12, the day following the G8 Summit, and set in place an action-oriented agenda for 2014. We will be working with the G8 governments to follow up on that agenda this year.

Fifteen years ago, it was U.S. leadership that helped mobilize the global community to combat HIV/AIDS. The G8's embrace of a goal to develop a cure or disease-modifying therapy for dementia by 2025 – a slight variation to our own bold and time-based goal set two years ago – demonstrates that U.S. leadership is once again becoming critical to another global effort, this time against Alzheimer's (a term I will use as including all forms of dementia).

As we discussed in November, the parallels between the scale of the Global HIV/AIDS and Global Alzheimer's challenges are striking. Shortly after the November hearing, Alzheimer's Disease International released an updated estimate that more than 44 million people worldwide are living with dementia today. This figure represents a 22 percent increase from the previous estimate of 36 million people issued just three years earlier. This change was driven largely by new estimates for China and Sub-Saharan Africa. If this trajectory remains unchanged, the report estimates we will have more than 75 million cases of dementia worldwide by 2030 and more than 135 million cases by the mid-century point. To put these figures in context, today's 44 million people with dementia is larger than the populations of Canada, Poland, or Argentina, and the 135 million people projected by 2050 would exceed the population of Japan and nearly reach that of Russia, the tenth and eleventh most populous nations on earth.[2]

Perhaps even more concerning than the top-line number is that more than 62 percent of persons with dementia live in low-to-middle income countries, a statistic that will exceed 70 percent come 2050 based on the current trajectory. Think, for a moment, of what this means. Most of us know and have personally experienced the immense challenges in caring for a

[2] See: https://www.cia.gov/library/publications/the-world-factbook/rankorder/2119rank.html

patient with Alzheimer's disease here in the United States, one of the richest nations in the world. Now think about how much more arduous – for the patient, his or her family caregivers, and society as a whole – this task becomes when done in the developing world? Think about how this caregiving burden will set back the gains against abject poverty that have been made in many countries in recent years, particularly gains made by women who often bear disproportionate burdens as caregivers.

At the last hearing, we discussed the many parallels that exist between the response to the global HIV/AIDS challenge and the need for a similar response to the global Alzheimer's challenge. Around the dawn of this millennium, the number of global HIV/AIDS cases were thought to be between 30 to 36 million compared to an estimated 44 million Alzheimer's cases today.[3] [4] The HIV/AIDS epidemic spurred leaders in the United States and the world to respond with the Global Fund to Treat AIDS, Tuberculosis and Malaria, as well as the President's Emergency Plan for AIDS Relief or PEPFAR. Often overlooked, however, is Congress's leadership in driving both of these programs. In the summer of 2000, Congress passed and then President Clinton signed into law the Global AIDS and Tuberculosis Relief Act. This law authorized an aggressive U.S. response to the global HIV/AIDS crisis and established the World Bank AIDS Trust Fund, among other things.[5]

The global actions led by the US and G8 against HIV/AIDS, including the Global Fund and PEPFAR, were and continue to be stunningly successful by most measures, particularly when it comes to preventing new cases of HIV and reducing the number of AIDS deaths. With regard to new cases of HIV/AIDS, we have experienced a 33 percent decline from 2001 to 2012. Deaths from AIDS have also dropped sharply, going from an estimated 2.3 million in 2005 to 1.6 million in 2012.[6] With such amazing success, it is easy to forget the dire predictions of the ravages of HIV/AIDS made a little more than a decade ago. In November 2000, the United Nations issued a

[3] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5021a3.htm#fig1
[4] http://www.unaids.org/en/dataanalysis/datatools/aidsinfo/
[5] https://www.govtrack.us/congress/bills/106/hr3519/text
[6] http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/UNAIDS_Global_Report_2013_en.pdf

release saying the more than 36 million people living with HIV/AIDS was more than 50 percent higher than the population that had been predicted in 1991.

Imagine for a moment the headlines we would be reading today had the world not responded as it did to Global HIV/AIDS. What would the face of HIV/AIDS look like today? How many tens of millions of people – at home and abroad – would be suffering, their disease going untreated? How many new cases and deaths would be reported each year? What would have been the impact on economic development? How many orphans, children who would be extremely vulnerable to the many threats of exploitation, such as human trafficking, would we see each year? Thankfully, the U.S., other nations, industry and the philanthropic community did act in time. And the result?

- More than $30 billion has been pledged to the Global Fund alone to deliver treatments and means of prevention to people throughout the world, with 6 million people receiving antiretroviral therapies alone;[7]

- The pharmaceutical industry dropped the prices for treatments to increase access;

- Seven of the 10 fastest growing nations in the world are now in sub-Saharan Africa[8]; and

- We are now able to celebrate declines in new cases and the death rate.

Even today, the global HIV/AIDS stakeholders are addressing the improvements that are still needed to eradicate this devastating disease, including improved distribution of and access to treatments, and the development of vaccines.

What Did We Learn from the HIV/AIDS Experience?

[7] See: http://www.theglobalfund.org/en/infographics/2013-11-27_Results_at_End_2013/
[8] See: https://www.cia.gov/library/publications/the-world-factbook/rankorder/2002rank.html
Nations are Zimbabwe, South Sudan, Uganda, Niger, Burundi, Burkina Faso, and Mali.

Professor Peter Piot, the former head of UNAIDS and the person responsible for turning HIV/AIDS from a global epidemic into a manageable disease, calls Alzheimer's the next great epidemic and a public health "time bomb." Noting that epidemics do not respect national boundaries, he urges a global response in the form of a coordinated global action. And it is clear that we must plan for how we will detect, diagnose, and treat populations in nations as diverse as the US, China, and Italy. This means low-cost diagnostics and therapies; it means vaccines where infrequent administration will overcome difficulties of cost, access, and administration; and it means modes of care delivery designed with ease-of-planning and adaptability to different cultural and health system environments.

While there are many similarities between HIV/AIDS and Alzheimer's, there are also some key differences. Perhaps first and foremost, when the global community decided to address HIV/AIDS, the means of treating HIV were well-known, and disease-modifying and life-saving treatments had been developed. The challenge was one of affordability, access and administration. Unfortunately, Alzheimer's lacks both a means of prevention and a disease-modifying therapy, which of course are the objective of the U.S. – and now the G8 – 2025 goal. Despite this difference, a comprehensive, robust, and coordinated Global Plan to Stop Alzheimer's and a corresponding Global Alzheimer's Fund are urgently needed. A growing chorus of leaders, including Prof. Piot and leaders of the G8, have recognized the need for global planning, coordination and funding, and we must move forward to make this a reality right now.

The Time is Now to Address the Global Alzheimer's Crisis

The time has come for the United States to once again lead the global community against the grave threat to our health and finances, the threat posed by Alzheimer's and dementia. What will the future look like if the world turns a blind eye to this crisis? We are on the verge of a humanitarian crisis that is larger than the threat posed by HIV/AIDS. Beyond the public health

challenge, we are also on the front edge of an economic and fiscal crisis. The costs of Alzheimer's to health care and social support systems is huge and growing, already at more than 1 percent of global GDP. And Alzheimer's is a significant driver of the growth in entitlement spending in the developed and developing world resulting from the rapid change in aging demographics.

In its 2010 report entitled Global Aging: An Irreversible Truth, Standard & Poors identified global aging "the dominant threat to global economic stability – without sweeping changes to age-related public spending, sovereign debt will soon become unsustainable." In their 2013 update, S&P noted that global aging "will lead to profound changes in economic growth for countries around the world – compounded by heightened budget pressures from greater age-related spending."[9] S&P noted further that increases in health care spending "will likely be the biggest driver of higher-age spending in coming decades." They also predict increased costs associated with long-term care services for this growing population. Combined, these projections will place incredible strain on the fiscal well-being of the world's nations, including the United States. When you overlay the specter of nearly 140 million persons with dementia by mid-century, the need for coordinated and robust global action for a range of health, economic and fiscal reasons is apparent.

A Global Action Plan to Stop Alzheimer's & Dementia

I urge Congress to begin by **laying a foundation for a Global Action Plan and corresponding fund, just as you did nearly 15 years ago for HIV/AIDS**. Just as our National Plan to Address Alzheimer's focuses on research, care, services and support for caregivers, so too can a global strategic plan. It should be informed by existing national plans like our own and seek to leverage scarce resources by pooling resources and coordinating efforts against the highest priorities needs. A global action plan should also set international norms for research, care, and

[9] See https://www.globalcreditportal.com/ratingsdirect/renderArticle.do?articleId=1098626&SctArtId=145185&from=CM&nsl_code=LIME

long-term supports and services so nations can learn from one another about what is expected, what is possible, and what mechanisms can be adapted for implementation in their countries. As a first step, we should expect that every country should develop a national Alzheimer's/Dementia plan. Beyond that basic foundation, we can, as the UK has done, set a norm for the percentage of a nation's dementia population which has been diagnosed with the disease. For those diagnosed, we can benchmark the percentage who have a care plan and, for those with a plan, the percentage who are receiving effective care and improved outcomes. With regard to research, can we set a norm, as recently suggested by Dr. Ron Petersen, who chairs our nation's Advisory Council on Alzheimer's Research, Care and Services, that one percent of a nation's estimated cost of caring for those with Alzheimer's be dedicated to research, either within that country or to a global fund. By setting these quantified international norms, nations will develop a comprehensive global response and be able to hold themselves, and all of us, accountable for periodic improvement in national and global response mechanisms.

But there are other transnational efforts that can add momentum to a global response. For example, at the G8 Summit and related follow-on events, a clear consensus emerged from industry, academia, and government that reforms in the clinical trial process would be a major step forward to reducing the time, cost, and risk associated with developing disease-modifying Alzheimer's therapies. It takes far too long and costs too much money to recruit and enroll patients in trials, to assemble needed infrastructure anew with every new drug candidate, and to conduct the trials only to see the hand crafted trial infrastructure dismantled. Recognizing this, the Global CEO Initiative has made addressing this gap a top priority for the year. Specifically, we will be working with other partners across multiple sectors to develop a Global Alzheimer's Clinical Trial Platform that creates sustainable, linked, and trial-ready global registries and cohorts of potential trial participants available to multiple companies and forms of clinical trials, thus avoiding the inefficiency and sluggishness of one-off trial infrastructures. A platform of this kind would be the type of groundbreaking initiative that could be supported via a global strategy and fund.

In addition, we are exploring innovative funding mechanisms that will attract increasing levels of private philanthropic, social, and financial capital to the Alzheimer's efforts. New forms of crowd-sourcing, hybrid philanthropic and financial venture investments, and social impact investing models are emerging in other fields and efforts are underway to assess their applicability to Alzheimer's. The boldest of these potential new models has been developed by Professor Andrew Lo of MIT. Building on conceptual work in the cancer field, he has posited the possibility of a large national or global fund of private capital where government either issues partial guarantees or credit enhancements justified by the potential of enormous public sector cost savings that would be produced by new disease-modifying therapies.

While these clinical trial and financing mechanisms are still in early development, they signal the willingness – indeed, the eagerness – of the private sector to work arm-in-arm with governments to address the global Alzheimer's epidemic. Just as the Bill and Melinda Gates Foundation has been critical to the success of the Global Fund, so too will philanthropic and similar commitments to the struggle against Alzheimer's.

In addition to taking these steps forward on the global front, I would submit that we must continue to lead by example by aggressively implementing our own National Plan and by increasing the level of our public resources to support Alzheimer's research and other programs. While government budgets remain constrained, as noted during the last hearing, taxpayers are already paying dearly for Alzheimer's, the to tune of about $140 billion annually in Medicare and Medicaid costs attributable to the disease. At the same time, we spend about 1/3rd of 1 percent of this amount on Alzheimer's research, about $500 million annually. With that in mind, I urge Congress to take two actions with regard to research:

- Double to $1 billion in FY 15 the amount of money committed to Alzheimer's research; and

- Set a marker, consistent with the international norm I recommend above, of committing just 1 percent of the total estimated costs of this disease to Alzheimer's biomedical research. With total public and private costs in the U.S. estimated to be about $200 billion annually, this approach would yield a U.S. national goal of $2 billion in annual research funding. This target matches the level of funding determined by leading Alzheimer's experts – and recommended by the Advisory Council – as the level of public funding necessary to achieve the 2025 goal.

Finally, I think it is worth revisiting a recommendation I and other members of the Advisory Council have long supported – a White House-level official tasked with coordinating our domestic and international efforts against Alzheimer's and dementia. At the G8 Summit, the United Kingdom committed to appointing a global Dementia Innovation Envoy to coordinate the nations' work in this space. While I am not a fan of layers of bureaucracy, I believe strongly in clear accountability. Congress should consider creating such a position to coordinate both domestic inter-agency efforts and our global leadership role against Alzheimer's.

Chairman Smith, I thank you, again, for convening this hearing and I urge this committee to continue your oversight and focus on this issue and to strongly consider reaching out to additional parliamentarians, particularly those in other G8 member nations, who share your strong interest in and commitment to forming a global working group of Parliamentarians against Alzheimer's. Such an alliance would support – indeed, drive – the work of government administrations in implementing the G8 commitments and expanding this effort. It is my hope that years from now, this committee can hold a hearing exploring the success story that was the U.S.-led global effort to stop Alzheimer's and look back to your series of hearings as seminal events toward achieving that goal.

Mr. SMITH. Thank you so very much for that very comprehensive testimony and recommendations. We will follow up on it and I thank you for it. Your testimony is chock-full of action items for us and I thank you for that.

Mr. Johns?

STATEMENT OF MR. HARRY JOHNS, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ALZHEIMER'S ASSOCIATION

Mr. JOHNS Chairman Smith, Representative Weber, first of all, let me thank you for holding this hearing, and Chairman Smith, I want to thank you for your leadership over time on these issues. The NAPA, National Alzheimer's Project Act, has made a huge difference already in the progress we are making on Alzheimer's and your leadership on that has been really important, as well as the entire Congress. It is an honor to be here. It was an honor to be on the G8 panels to speak to those ministers, as were Francis and Richard Hodes.

I just want to talk about three things very quickly in the limited time we have this afternoon: The G8 and the potential to advance the cause as a result of it; what the Alzheimer's Association is doing as a nonprofit in that regard as the leader in the nonprofit world globally on this issue; and what the United States can do to advance this cause coming off of the G8 summit. We have talked a lot about the data, the statistics. The numbers are staggering of course on this. We know already that in the U.S., as you heard from Richard Hodes, that in fact we are going to get to the point—it is already the most costly condition in the U.S.—where it is going to cost $1.2 trillion annually just for the care for this disease. So if you project that at all worldwide you see the kinds of outcomes that it is going to have. Right now the U.S., North America and Western Europe take up 70 percent of those costs, and fully a third here in the U.S. But that is, as you have already heard, going to grow dramatically across the world and in lesser-developed countries.

In terms of your question about what is the impact of the G8, I think the G8 does have the potential to be a milestone as an event in the progress against this cause, against this disease. It is ultimately up to what we all do with what occurred at the G8 to determine whether or not it will be something that was small as a milestone or much larger. The kinds of things that were on the G8 communique at the end of the meeting, the 2025 goal, it is a little less ambitious than the 2025 goal contained in the U.S. plan but important nonetheless to get at what would be a cure or treatment by that 2025 date. Again, not quite as ambitious but important, and important for us to pursue on a global basis.

The increase in research funding that is called for there is absolutely critical to all of this. If we do not continue to increase our funding of research we simply will not get there, as Dr. Hodes indicated. The clinical study participation increases that are called for in the G8 communique are also absolutely essential. The two things that hold back research progress fundamentally are adequate funding and adequate participation in clinical trials. Sharing data, which you have heard about previously already this afternoon, is essential to this. With limited resources worldwide being

spent already on this issue, to duplicate efforts unnecessarily, not in the name of advancing the science but to duplicate those efforts where we will not see the additional gains, is simply not useful to us around the world.

As you heard Dr. Hodes indicate, the Alzheimer's Association is convening groups worldwide, along with the National Institute on Aging, to look at the very specific funding being done by agencies like ours, organizations like ours, by Federal agencies across the world, so that we can coordinate and maximize the returns on investment that we are all making on these things. Through our global research program at the Alzheimer's Association, we fund into 28 countries already today and we intend to continue that kind of an effort on a private basis so that we can extend the advances worldwide from the best thinking worldwide.

You may have heard the story of the young guy in Mongolia who took one of those open access classes from MIT and aced it at 100-percent level with limited other knowledge. Now that is not an illustration of what necessarily will occur in Alzheimer's research, but by making available more of the information across the world we can tap what are the knowledge bases of those countries as well, because research historically has not been shared well.

So we are working on even another step in this process which will take the database that you heard Dr. Hodes talk about, a database of research projects, to another level which would be the sharing of all of the data from those projects worldwide. So we need the cooperation of other governments. We need the cooperation of other funders. We need our own Federal Government to see to it that all of those data are shared.

We know that from the convening of our own research roundtable with all the companies engaged in drug development and imaging and other kinds of aspects of care in Alzheimer's, along with the FDA and the European Medicines Agency, that by putting all of those people in the same room we can see new outcomes that we otherwise would not see. There is recently an FDA guidance that has made possible new clinical studies that previously would not have been a possibility under the old FDA approach caused directly by putting all of those people in the same room together to discuss what can be changed. And we will see advances from that, we believe, in the reasonably near term.

You asked questions too about what is going to happen after the summit. We are working with the Alzheimer's Disease International folks of which we are the sole member in the United States to convene workgroups across the world, particularly in our case on research. We will lead a research workgroup that will transcend the G8 and go beyond those countries to try to identify, again, how we can best utilize funding that is available in the world, but also what needs to be done in those countries where the leadership is not present the way it is in the United States today.

The worldwide ADNI project, the Alzheimer's Disease Neuroimaging Initiative that you heard Dr. Hodes talk about, is one of the best examples of what can be accomplished in a research effort by sharing those data. There are already more scientific papers, more scientific output from people who were not funded in that study than by the people who originally were. So we have

more than doubled the return on investment from that research and we can do this across all of medical research and particularly all of it in Alzheimer's.

Now what can the United States do on this? The very basic leadership of the United States is fundamental to the changes that will occur in this cause, in this particular disease. You have talked about it, Chairman Smith, in terms of what happened in HIV/AIDS, in terms of what has happened in cancer, where I worked for many years. In many ways I think the model of what has occurred in cancer has shown us the advantages of research investment, whereas the model of the HIV/AIDS cooperation worldwide has shown us how to share those data and information. The fact is, if we did not have the National Alzheimer's Project Act we would not have the G8.

In terms of the question about whether or not the G8 will become the milestone that we would hope it would be, we have to continue to show the leadership in the United States to advance this cause, to make the commitments to new research funding. Because if we do not show that leadership, I am confident at least that we will not see the kinds of advances that we otherwise are going to need to have on a timely enough basis to deal with what is the aging of the population, very specifically the boomer generation in the United States.

The timeline, as you have already heard, for the development of drugs is sufficiently long that if we don't make those commitments now, we are about to hopefully see one that will advance this, but even others beyond that it is potentially too late to get the job done for the generations that will drive the huge levels of cost that you have heard about from all of us. And seeing to it again that those data are shared worldwide will be one of the other things, I think, that this Government can do to make a very big difference in these advancements.

Just fundamentally, if we make those commitments today given the advancements that we hear from the scientific community based upon what we have already developed—you may not know that the research into Alzheimer's in particular is only about 30 years old. Cancer has been studied for about 100 years. The science community didn't make the connection between what was the woman that Alzheimer discovered the disease in who was 51 years old, so the disease was considered an anomalous condition of people in middle age. So for 65 years there wasn't any research done on this. We have a gap then in the development of the research, but we have learned a lot in those 30 years. We are at the point, potentially a tipping point, of learning enough to advance those kinds of gains very rapidly.

There is a new collaboration that is taking place with the United States Federal Government, the Alzheimer's Association, and with industry. It is called the Accelerating Medicines Partnership. And the idea of this is to have all those sectors working together with academia to identify the very best drug targets. Instead of working alone and in silos, to identify those together so that we can speed the development of drugs on the timeline that I am talking about. So if in fact we do that I believe based upon what I hear from the

science community that we have the very real possibility of making rapid gains on Alzheimer's and other dementias.

So I thank you again for holding this hearing and for your leadership on this effort, and look forward to continuing to work to advance this cause and to find the change in the course of this disease.

[The prepared statement of Mr. Johns follows:]

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U.S. House Foreign Affairs Committee
Subcommittee on Africa, Global Health, Global Human Right, and International Organizations
A Report on the G8 Dementia Summit

Testimony of Harry Johns,
President and CEO
Alzheimer's Association

January 15, 2014

Good afternoon Chairman Smith, Ranking Member Bass and members of the Subcommittee. Thank you for the opportunity to testify on the recent G8 Dementia Summit. We really appreciate your commitment to this issue -- both with the hearing prior to the Summit and this follow-up hearing.

Dementia is a condition fast becoming one of the world's largest and most expensive health issues. It is affecting lives and decimating health and social care systems across the world. Thirty-six million people worldwide have dementia and this number will double within a generation. As was stressed during the G8 Dementia Summit in London on December 11, 2013, research must be a global priority if we are to improve care, find preventions and treatments, and ultimately cure dementia. The Summit was a historic opportunity for international leaders to tackle dementia on a global scale. However, it will take concerted and sustained action from world leaders to tackle one of the world's largest and most expensive health issues.

Founded in 1980, the Alzheimer's Association is the world's leading voluntary health organization in Alzheimer's care, support and research. Our mission is to eliminate Alzheimer's disease and other dementias through the advancement of research; to provide and enhance care and support for all affected; and to reduce the risk of dementia through the promotion of brain health. As the world's largest nonprofit funder of Alzheimer's research, the Association is committed to accelerating progress of new treatments, preventions and, ultimately, a cure. Through our funded projects and partnerships, we have been part of every major research advancement over the past 30 years. Likewise, the Association works to enhance care and provide support for all those affected by Alzheimer's and reaches millions of people affected by Alzheimer's and their caregivers.

The Global Impact of Alzheimer's

Alzheimer's disease is a global crisis. This crisis is placing – and will increasingly place – an enormous strain on the health care system, families, and government budgets of nations around the world. Current estimates indicate that about 36 million people worldwide are living with dementia, and when we reach the middle of the 21st century, there will be 115 million people living with dementia on this planet.

In 2010, Alzheimer's Disease International (ADI) released the *World Alzheimer Report 2010: The Global Economic Impact of Dementia*, which explores the cost of dementia to our societies. ADI is the international federation of Alzheimer's associations around the world; the Alzheimer's Association is the sole United States member of ADI.

According to ADI's 2010 Report, the global cost of dementia consumes one percent of global Gross Domestic Product (GDP) and currently costs the world $604 billion, with 70 percent of the costs incurred by North America and Western

Europe. If dementia were a country, it would be the 18th largest economy globally. As we all live longer, dementia is spiraling out of control, holding healthcare systems ransom. This cost trajectory can only be fundamentally altered through prevention and effective treatments.

Research shows that most people currently living with dementia have not received a formal diagnosis. In the United States, as many as a half of the over 5 million individuals with Alzheimer's have not been diagnosed, while a study of India found nearly 90 percent remain unidentified. These studies suggest that nearly 28 million of the 36 million living with dementia have not been diagnosed and therefore do not have access to treatment, care and organized support that getting a formal diagnosis can provide.

The need for research was also underscored this year when ADI launched the 2013 World Alzheimer's Report. This year's World Alzheimer's Report theme focused on long-term care. The report, "Journey of Caring," emphasizes that care associated with Alzheimer's disease and other forms of dementia is a global issue that must be addressed as prevalence and costs continue to soar, placing enormous stress on families and nations alike.

As the world population ages, the traditional system of "informal" care by family, friends and community will require much greater support. Today, it is estimated that 13 percent of people aged 60 or over require long-term care. Between 2010 and 2050, the total number of older people with care needs will nearly triple from 101 million to 277 million.

The report recommends that governments around the world should make dementia a priority by implementing national plans, much like the *National Plan to Address Alzheimer's Disease*, and by initiating urgent national debates on future arrangements for long-term care. It goes further by stating that systems should be in place to monitor the quality of dementia care in all settings, while promoting autonomy and choice at all stages. These are all priorities that can strengthen the state of long-term care, and keep individuals with Alzheimer's in the best possible settings for care.

Alzheimer's Association Global Research Efforts

The Alzheimer's Association is committed to accelerating the global effort to eliminate Alzheimer's disease. No single organization can surmount a challenge as great as Alzheimer's. To help achieve our vision of a world without Alzheimer's, the Association partners with key government, industry and academic stakeholders in the global race to end Alzheimer's. We believe in the value of collaboration and work toward the day when we will have disease-modifying treatments, preventive strategies and gold-standard care for all people affected by Alzheimer's disease.

The Association formula for progress in research rests on four pillars: Funding, increasing collaborations with investigators, sharing data, and overcoming barriers to progress. The first pillar is the Alzheimer's Association International Grant Program. Typically 10 to 15 percent of our grant funds are expended outside the US. Currently, we fund active grants in 21 countries, and have funded research in 28 overall. We fund across the total spectrum of Alzheimer's research from molecular biology to medical systems investigation. Our funding is peer-reviewed by a vast international network of volunteer scientists and quality-assured by our Medical and Scientific Advisory Council, a group of distinguished professionals who represent a range of dementia research, including bench research, clinical care, community health and support services. In addition to funding research directly, we work to ensure the federal investment in Alzheimer's research is comparable with the public threat of the disease.

The second pillar of the Alzheimer's Association program is encouraging increased cooperation between scientists. The Association is responsible for the largest meeting of Alzheimer's scientists every year. This year, the Alzheimer's Association International Conference (AAIC), attracted over 5,000 scientists to Boston to compare, reveal progress, and develop new collaborations to advance research. AAIC provides a platform for presentation and discussion of all aspects of Alzheimer's research from genetics to animal models, pathology, biomarkers, interventions, and social and behavioral issues. By encouraging the attendance of researchers from around the world, the Alzheimer's Association is able to bring new innovations in Alzheimer's research to a single thought forum designed to accelerate the understanding of Alzheimer's and related dementias. Also within this pillar is the Association's International Society to Advance Alzheimer's Research and Treatment (ISTAART), an international scientific society to bring researchers together to work on understanding the causes of and potential treatments for Alzheimer's and other dementias.

The third pillar of our program is sharing of information. We publish *Alzheimer's & Dementia*, the official journal of the Alzheimer's Association. This journal allows important progress to be collected in one place to increase efficiency of Alzheimer's research. For example, the criteria defining Alzheimer's disease was published in *Alzheimer's & Dementia*. We partnered closely with the National Institute on Aging (NIA) of the National Institutes of Health to develop the first new criteria and guidelines in 30 years to diagnose Alzheimer's disease. In addition, a report, which reflected the collective views and recommendations of leaders in Alzheimer's disease research, outlined a goal-directed scientific agenda to aid in the implementation of the National Alzheimer's Project Act (NAPA)'s National Plan.

The fourth and final pillar of our program is selectively investing in projects to overcome common barriers in the field of Alzheimer's. Projects included in this effort include TrialMatch™, World Wide Alzheimer's Disease Neuroimaging Initiative (WW-ADNI), the Cerebrospinal Fluid (CSF) Quality Control Program, the Hippocampal Harmonization Project, Alzheimer's Association Research Roundtable, the Accelerating Medicines Partnership and the Global Alzheimer's Association Interactive Network (GAAIN).

TrialMatch™
TrialMatch™ is a confidential, free, and interactive tool that provides comprehensive clinical trial information and an individualized trial matching service for people with Alzheimer's disease and related dementias. Recruiting and retaining trial participants is now the greatest obstacle, other than funding, to developing the next generation of Alzheimer's treatments.

World Wide Alzheimer's Disease Neuroimaging Initiative (WW-ADNI)
WW-ADNI, which the Alzheimer's Association is the administrative home of, is a collaborative effort of scientists from around the world and is the umbrella organization for neuroimaging initiatives being carried out through the North American ADNI, European ADNI (E-ADNI), Japanese ADNI, Australian ADNI (AIBL), Taiwan ADNI and two new initiatives in Brazil and India. The Initiative unites leading international Alzheimer's investigators in a common effort to:

- Help predict and monitor the onset and progression of Alzheimer's disease
- Globally harmonize neuroimaging and other biomarker collection, analysis and interpretation
- Document cognitive changes linked to physical changes
- Share data across the international research community.

Ultimately, we aim to better understand the physical changes that occur in healthy individuals compared with asymptomatic individuals, those with mild cognitive impairment (MCI) and Alzheimer's disease. WW-ADNI focuses both on changes in the brain that can be identified with tools such as positron emission tomography (PET) and magnetic resonance imaging (MRI) and changes in fluids such as blood and cerebrospinal fluid (CSF). As its name suggests, another area of focus is to involve individuals from multiple sites around the world and to follow their progress over several years to gain a worldwide picture of the physical changes that lead to Alzheimer's disease.

Data from WW-ADNI are expected to play a key role in identifying effective treatments for Alzheimer's, as well as methods that may prevent the disease or slow its progression. Each WW-ADNI site collects participant data from MRI and PET scans. Other data on physical changes related to the onset and progression of MCI and Alzheimer's (called biomarkers) are also gathered. WW-ADNI is unique in that most of the clinical, neuropsychological, imaging, and biological data gathered is quickly made available to the scientific community worldwide at no cost, allowing researchers to use the information when designing or evaluating their own research.

International Alzheimer's Disease Research Portfolio (IADRP)
This joint collaboration between the National Institute on Aging (NIA) and the Alzheimer's Association develops a database and tools for assessing the research portfolios of international funding organizations for areas of overlap or gaps, as well as areas of opportunities in which to collaborate. Currently, 13 international funding organizations, representing 27 countries, have submitted funding profiles and grants. This database and associated tools will help to support strategic planning and can help to leverage critical resources between international organizations.

Alzheimer's Association International Efforts to Harmonize the Development of Alzheimer's Biomarkers
The Alzheimer's Association Cerebrospinal Fluid (CSF) Quality Control Program, which brings together laboratories across the globe with the aim of standardizing the measurement of potential Alzheimer's biomarkers. Several studies, including studies involving data from the ADNI, have shown that levels of biomarkers in CSF are often accurate predictors of which individuals will go on to develop Alzheimer's disease. CSF biomarkers may be useful not only in aiding early detection of Alzheimer's and improving diagnostic accuracy, but also in identifying and monitoring the effects of drugs in clinical trials, understanding the molecular changes that lead to Alzheimer's, and helping to ensure that individuals recruited into Alzheimer's clinical trials are on a path toward developing the disease.

Alzheimer's Association Research Roundtable (AARR)
The AARR is a consortium of scientists from the pharmaceutical, biotechnology, diagnostics, imaging and cognitive testing industries, and senior staff and advisors from the Association. AARR members seek to facilitate the development and implementation of new treatments for Alzheimer's disease by collectively addressing obstacles to research and development, clinical care and public health education. Begun in 2003 with four sponsors, the Research Roundtable now includes more than 26 corporate sponsors that sponsor worldwide research and clinical trials. Each company sends several senior scientists to the Roundtable to benefit from the state-of-the-field scientific presentations, collegial interactions and networking opportunities. To help address these obstacles, the dialogue and presentations also include investigators from academia and government organizations such as the U.S. Food and Drug Administration (FDA); its European equivalent, the European Medicines Agency; and the National Institutes of Health (NIH).

Accelerating Medicines Partnership
The Alzheimer's Association is also proud to be a founding Steering Committee Member of the newly formed Accelerating Medicines Partnership (AMP), formerly the Target Validation Consortium, which is a pre-competitive collaboration among government, academia and industry, convened to harness collective capabilities and scale resources toward improving current efforts to develop new therapies for complex, heterogeneous diseases. The focus of the partnership is doing the research necessary to understand these diseases more fully and identifying the right targets to pursue for drug therapy, thereby accelerating the ability to bring new medicines to patients with these diseases.

The Global Alzheimer's Association Interactive Network (GAAIN)
Tying all of these efforts and global efforts overall in the Alzheimer's ecosystem, is a new program launched by the Alzheimer's Association, the Global Alzheimer's Association Interactive Network (GAAIN). GAAIN is a project that provides Alzheimer's disease scientists worldwide, freely available access to a vast amount of federated neuroscience data. GAAIN will change the way researchers work together to answer questions related to the causes, diagnosis, treatment and prevention of Alzheimer's and other neurodegenerative diseases. Built on an international database framework already in use by thousands of scientists in North America and Europe, GAAIN makes data available for searching, downloading and analyzing across a shared network accessible from anywhere via the Internet. Alzheimer's scientists can retrieve the most current information from the world's foremost laboratories. GAAIN will allow researchers to extract specific material relevant to their own investigations, helping them arrive at more reliable and precise conclusions to speed our understanding of Alzheimer's disease and advance the discovery of new treatments, preventions and cures.

Changing the Trajectory of Alzheimer's
Until recently, there was no federal government strategy to address this looming crisis. In 2010, thanks to bipartisan support in Congress, the National Alzheimer's Project Act (NAPA) (P.L. 111-375) passed unanimously, requiring the creation of an annually-updated strategic National Alzheimer's Plan (Plan) to help those with the disease and their families today and to change the trajectory of the disease for the future. The Plan is required to include an evaluation of all federally-funded efforts in Alzheimer's research, care and services -- along with their outcomes. NAPA will allow Congress to assess whether the nation is meeting the challenges of this disease for families, communities and the economy. Through its annual review process, NAPA will, for the first time, enable Congress and the American people to answer this simple question: *Did we make satisfactory progress this past year in the fight against Alzheimer's?*

As mandated by NAPA, the Secretary of Health and Human Services, in collaboration with the Advisory Council on Alzheimer's Research, Care and Services, developed the first-ever *National Plan to Address Alzheimer's Disease* in May of 2012, with an update released in June 2013. The Advisory Council, composed of both federal members and expert non-federal members, is an integral part of the planning process as it advises the Secretary in developing and evaluating the annual Plan, makes recommendations to the Secretary and Congress, and assists in coordinating the work of federal agencies involved in Alzheimer's research, care, and services.

In addition to improving health outcomes for people living with Alzheimer's and for reducing the financial impact of Alzheimer's on families and our Federally funded programs, NAPA requires the Secretary of Health and Human Services to coordinate with international bodies to integrate and inform the fight against Alzheimer's globally. We hope that the Secretary will continue to work with her global partners to improve the treatment and care of the millions of people living with Alzheimer's.

Having this Plan with measurable outcomes is important. But unless there are resources to implement the Plan and the will to abide by it, we cannot hope to make much progress. If we are going to succeed in the fight against Alzheimer's, Congress must provide the resources the scientists need. A disease-modifying or preventive therapy would not only save millions of lives but would save billions of dollars in health care costs. Specifically, a treatment that delayed the onset of Alzheimer's by five years (a treatment similar to anti-cholesterol drugs), would reduce Medicare and Medicaid spending nearly in half in 2050.

Today, despite the federal investment in Alzheimer's research, we are only just beginning to understand what causes the disease. Americans are growing increasingly concerned that we still lack effective treatments that will slow, stop, or cure the disease, and that the pace of progress in developing breakthrough discoveries is much too slow to significantly impact this growing crisis. For every $27,000 Medicare and Medicaid spend caring for individuals with Alzheimer's, the National Institutes of Health (NIH) spends only $100 on Alzheimer's research. Scientists fundamentally believe that we have the ideas, the technology and the will to develop new Alzheimer's interventions, but that progress depends on a prioritized scientific agenda and on the resources necessary to carry out the scientific strategy for both discovery and translation for therapeutic development.

There is additional funding in the NIH budget because the scientists have determined that additional research on Alzheimer's is a priority. Their budget request reflects the changing needs of the Alzheimer's community and the scientific opportunity. It is vital that Congress support the research projects the scientists at NIH deem necessary.

The G8 Meeting: Collective Planning, Collective Goals

The first-ever G8 Dementia Summit was an unprecedented opportunity to advance progress internationally, to make Alzheimer's and dementia research a global priority and to promote increased global collaboration. The Summit also underscored the need for all nations to collectively confront the human and economic costs of dementia, and take advantage of the scientific opportunities that hold promise for better diagnosis, treatment and prevention.

As a presenter at the Summit, I outlined the most important steps to improve the lives of those with dementia - direct care and support, research investment and collaboration - all items that the Alzheimer's Association and our counterparts in the other G8 nations are actively engaging in. Additionally, there is great promise with GAAIN which will allow researchers worldwide to accelerate their efforts by sharing information.

The Alzheimer's Association is on the front lines of this epidemic, but it is clear that we alone cannot overcome it. Governments and industry must also be actively engaged and all of those affected must raise their voices.

The G8 Summit concluded with the publication of a declaration and communique setting out the agreements reached, many of which are core tenets of the *National Plan to Address Alzheimer's Disease*. The countries agreed to:

- Commit to identify a cure, or a disease-modifying therapy, for dementia by 2025;
- Significantly increase the amount spent on dementia research;
- Increase the number of people involved in clinical trials and studies on dementia;

- Establish a new global envoy for dementia innovation, following in the footsteps of global envoys on HIV and AIDS and on Climate Change;
- Develop an international plan for research;
- Share information and data from dementia research studies across the G8 countries to work together and get the best return on investment in research; and
- Encourage open access to all publicly-funded dementia research to make data and results available for further research as quickly as possible.

Moving Forward
The G8 Dementia Summit was not the end; it was the beginning. Research has transformed the lives of millions living with heart disease, stroke, HIV/AIDS and cancer. Now is the time to make dementia a priority. Working together, governments, the research community, non-profit organizations and industry need to make plans made at the Summit a reality. The Alzheimer's Association is pleased that the G8 countries have shown a commitment to increased investment and improved coordination in research that will transform the lives of people with dementia across the globe.

It will take concerted and sustained action from world leaders to tackle dementia. The declaration and communique is just the first step in advancing dementia research, and to taking collaborative global action that will meaningfully impact the lives of those affected by dementia. The Summit was the start of a process aimed at putting dementia at the top of the global health agenda and the top of the agendas of health leaders from around the world. Additional international meetings will be held in the coming year to ensure that Alzheimer's is and remains a global priority. In addition to our upcoming Alzheimer's Association International Conference (AAIC) which will be held in Copenhagen, Denmark, in July 2014 and Washington, D.C. in July 2015, meetings will be hosted by the UK and Japan; Canada and France will hold a joint meeting; and Dr. Francis Collins announced a meeting to be held in February 2015 to examine the progress of the G8 Alzheimer's research effort.

Thank you again for inviting me to participate in this important discussion about the global impact of Alzheimer's disease. The Alzheimer's Association commends the Subcommittee for today's hearing and looks forward to continued work together to do all we can to improve the lives of those contending with Alzheimer's, as well as for those who care for them.

Mr. SMITH. Thank you, Mr. Johns. Thank you so very much for your leadership and again, your very specific recommendations, as well as an elaboration of what you are doing. It was very, very helpful.

We are joined by Congressman Chaka Fattah. Chaka?

Mr. FATTAH. Thank you, Mr. Chairman. And the chairman and I have worked together on a number of health related issues including blood safety and cord blood. He has done a lot of good. And I appreciate the invitation to join you. This is a subject that I have an extraordinary amount of interest in. And I was on the floor, slightly delayed.

We just passed the appropriations bill, or we are getting ready to pass it, and included in that is language that I have authored to internationalize the collaboration that we built in at the Office of Science and Technology, Phil Rubin's work. And we have created language that would build on the G8 summit and build on the work of the EU and Israel and so many other countries and groupings of countries who have started to focus in on this.

And George, you have been way out in front of this for a very long time, but I think I wanted to focus in on what you think the Congress can do. We have the national plan, we put additional dollars. There is, as you just mentioned, Mr. Johns, a sense of a tipping point. There are some very important clinical trials that are taking place now or getting ready to be launched into second and third phases. I mean, there are some things going on, but we are not in any way yet where we need to be.

And so I note in your testimony, George, that you suggest that the Congress should in a similar fashion as we did with HIV, build a much more global approach to this effort, and if there are any other specific recommendations that the chairman and I and others who are interested in these matters may be able to focus in on.

Mr. VRADENBURG. Well, you said I was way ahead, but I am following you, Mr. Fattah. You have been in front of this issue on neuroscience and how to get a White House office focused on it across agencies and now internationally, and I commend you on your leadership on these issues. I think that we need to press forward and periodically have this committee and other committees of Congress make sure that we are moving forward during 2014.

It is a critical time as Harry has mentioned, and I agree, that we ensure that we pick this moment in time and say this is a turning point not just a dot on a long line, so that we, in fact, hold accountable for all of the commitments that are made out there and insist that the U.S. Government demonstrate how it is that they are moving this forward and using their leadership to do so. I have suggested to the chair of this subcommittee that there be a set of parliamentarians. That you meet with EU parliamentarians, UK parliamentarians, Canadian parliamentarians, and Japanese parliamentarians to ensure that there is political backbone to the commitments that are made, because it is going to take the parliaments of these countries as well as the national leaders and the health ministers to ensure that we get to a unified effort. I think that you need to invite the private sector to the table in a genuinely open and joint kind of approach, a unified approach.

HIV/AIDS in the end—I am not going to say the end—we haven't gotten to the end—but with respect to what started to drive that was the unity of purpose, the unity of effort and thus the clarity of a combined plan in which everyone's roles were well defined and where people executed against a plan and could rely on each other to execute against a plan.

So bringing together all of the stakeholders, now you can't bring Madison Square Garden, but the leaders of the stakeholders and make sure the processes are transparent, to force this development of a global action plan, to authorize the existence of a global fund, will signal that in fact this nation is prepared to continue its historic leadership on these global health efforts and actually move the needle to ensure that what happened in London doesn't stay in London.

Mr. FATTAH. Well, let me ask just two very specific, concise questions, Mr. Chairman, on this point. So one is, the EU has a joint clinical trial initiative in which they have gotten all of the EU countries engaged along with Israel, and we have not joined in yet. And as a nation I think we should, because this issue of the clinical trials, which you mentioned in the testimony as I was coming in, I think, is very, very important. We have opportunities with inside of the work that you have talked about in terms of the pharmaceutical community. I have suggested that not only do we have Alzheimer's, we have 500-plus other diseases and disorders that we haven't come up with effective treatments for. I am trying to understate this.

And I think we should be much more welcoming in terms of trying to get the pharmaceutical industry more full-throatedly involved in this, and even to the degree that we might have to adjust exclusivity issues, patent issues, in ways that could provide more of a runway for them in terms of the fiduciary burdens that they have, or find ways for them to partner, like what the Alzheimer's Association, you are doing, for them to do research separate and aside and outside of their fiduciary burdens so that we can move forward. So if you could react to just to those two things.

Mr. VRADENBURG. The Innovative Medicines Initiative of Europe has issued a call for proposals to which the response time is roughly April, to come up with consortia that will develop a Europe-wide clinical trial network system. They have invited the Global CEO Initiative, the industry coalition that I convene, to come up with a North American side to that. And whether that is a side or whether we develop a global platform and we work with them, there is enormous momentum on both sides of the Atlantic and in Japan, but right now it is focused on both sides of the Atlantic, to do something with clinical trial efforts in Alzheimer's to develop linked patient registries so that we know the characterization that has been made of patients around the world. They get into longitudinal trials that are well characterized and studied and that in fact we can populate or pre-populate, potentially, global clinical trial platforms.

So that project is underway. There is no question it is going to require some government assistance, but hopefully it will also involve some private funding since the value creation is good for industry as well as for governments. Your second point?

Yes, sure.

Mr. JOHNS. Well, certainly this issue of improving participation in clinical studies is absolutely essential. We know that already the three big prevention studies that are just getting underway in the United States are going to cause the need for many, many more people than we previously had participate. It is important to note here if you don't realize already that one of the things that has happened is a consensus in the science community on this particular condition, is that there is a belief that intervening earlier in the disease is absolutely essential. So that is going to mean actually a prevention approach to the disease. The prevention approach means that many of the people who would need to be accrued into clinical studies will not have symptoms, will not have the disease actively in terms of ability to see it other than potentially on a biomarker scan.

Mr. FATTAH. What we think of as early onset is pretty far along.

Mr. JOHNS. That is exactly right.

Mr. FATTAH. So we need to step in. But my second question was on this question about patent, lengthening the period of exclusiveness for treatments and solutions as a way of maybe taking a carrot approach to a more robust effort among the pharmaceutical industry. Because right now we are nowhere, we need to get somewhere, and I am convinced that the academic side of this is very important. But I also think that the pharmaceutical industry is going to be as essential as they were with HIV/AIDS.

Mr. JOHNS. You are absolutely right, Congressman. Both are absolutely essential. Part of the problem though has been the underfunding on the front end of the pipeline. This is critical to recognize, because the pharmaceutical companies, if we had sitting here next to us one of the leaders of one of those companies, I have sat on panels with them previously, they would also tell you that they need the fueling of the pipeline.

In all diseases, the basic research is not done by the companies because Wall Street will beat up their stock price. They won't be able to make the investments in the parts of the pipeline, the later stages of development that they need to make. So it is absolutely critical that we tie these things together, not only the kinds of considerations you are raising this particular question on but also that investment in the front end of the pipeline to make all of this work together.

Mr. VRADENBURG. You will see in the G8 commitments there is an explicit commitment: Take stock of our current national incentive structure for research working in partnership with the OECD. So there is an invitation to you, Congressman Fattah, to respond to the G8 by taking stock of our current national incentive structure. I encourage you to do so.

Mr. FATTAH. Thank you, Mr. Chairman for allowing me to participate.

Mr. SMITH. Oh, it is a privilege. And as Chaka said we have worked together on so many other issues including safe blood initiatives in Africa, so thank you for your work on Alzheimer's.

We do have another vote and it is a big vote so we are going to have to leave momentarily, but I just want to assure you, Mr. Vradenburg, that I would love to follow up with you on your idea

of this global fund. We just had Mark Dybul testify, and Mark, as you know, was President Bush's HIV/AIDS czar, then became the coordinator, and he is now the executive director of the global fund for HIV/AIDS, tuberculosis and malaria.

And he used the words very similar to what you have used, the tipping point, Mr. Johns, you have mentioned potentially tranformational. We are at a tipping point and we could lose the momentum from the G8 summit if implementation is lackluster and not optimum. So we will do a series of hearings, I think a piece of legislation that tries to galvanize not just Congress but other nations, also, I think your idea of the working group.

I will be leading the delegation to the OSCE Parliamentary Assembly in July, and I would like to reach out to my fellow parliamentarians. There are 57 countries that make up the OSCE Parliamentary Assembly. They usually send five, six members of their Parliament, depending on the country. In terms of Russia it is usually one of the top Duma members, often it is the speaker. So this would be an ideal time to form, do the advance work but do as you suggested, a working group within that venue of the OSCE PA on Alzheimer's, especially using the G8 action plan as a mobilizing influence so we all go back to our respective congresses and parliaments to fight for additional funding and to make sure that our executive branches as well as our legislative branches are doing all that we ought to be doing to mitigate and hopefully end this horrible disease.

We do have this vote so I will just ask, I have a lot of questions but maybe just if there is anything you would like to leave with us? Your testimonies again are very, very extensive, again filled with information that this subcommittee and membes on both sides of the aisle, I know, will go through again and again to pull out and to see what we can do to be of greater value in this all-important fight.

Please.

Mr. VRADENBURG. I want to just make one quite different point. One of the scarcest commodities in a field as diverse and eclectic as this is leadership. And your leadership on this——

Mr. WEBER. We have the same problem.

Mr. VRADENBURG. I know you know the problem. And thus when we see leadership on Cameron's part or on Obama's part or on your part, we need to celebrate it and say, let's go. Because we don't need 500 leaders, but we need a sufficiently motivated, limited number of leaders well positioned to do what they can do and then to have that leadership group drive action. And action is the hardest thing to get when you get some diversity like we have got here with governments globally, industry globally, care problems not just research problems globally. This is going to be a challenge of leadership. So that is the one last point I would make.

Mr. JOHNS. And certainly what I observed in talking to many of the members of Parliament from the UK who were there and the ministers who are part of the Parliament of course in that system, there was an embrace of this particular issue. From Cameron on down through that group it was pretty clear that they have embraced this issue, recognizing the human impact, the economic impact of the disease if in fact action isn't taken on a timely enough

basis. They made a commitment to double their investment in research. They are looking at the kinds of things that will speed drug discovery. They are looking at the kinds of things that will move clinical trial participation.

So that kind of leadership that you have already shown and that make up the presence of the National Alzheimer's Project Act to taking out those things to the next levels, the next steps will be absolutely critical, and the U.S. leadership again in particular will be essential.

Mr. SMITH. Let me just ask you very briefly, obviously yourselves are doing, I don't know how you could do anymore than you are doing on behalf of Alzheimer's patients, research and for respite care for those who care, as you mentioned, Mr. Vradenburg, about the women who are often the caregivers, how difficult it is for them and so it becomes an empowerment issue. But it seems to me that one of the tipping points for additional resources on HIV/AIDS was when the Gates Foundation and others joined in and saw that their money had such a multiplier effect. Are you sensing that Gates and others may be realizing that this is a place where dollars spent now will multiply many-fold for our older Americans and those of course who have early onset?

Mr. JOHNS. They are not particularly from the foundation that you have mentioned because of the way that they have defined their particular mission.

Mr. SMITH. Mandates can change.

Mr. JOHNS. Certainly. But we are certainly seeing, the Alzheimer's Association has been spending a lot of time and effort in the last several years to raise the discussion in the American populace. We know that what happened in cancer, for example, as well as in AIDS, that when it was not discussed, more so in cancer where it was taboo topic to discuss—there was a study in 1961 that asked doctors if they told their patients they had the disease when they made a diagnosis, 90-plus percent of them didn't tell them. It is unimaginable today, but it illustrates the condition at the time of what was a taboo subject to discuss.

Too much of that is still present for Alzheimer's, but we have made huge gains in changing that national discussion. We need to change that discussion worldwide too, but we need to make the advances that will continue to have people embrace dealing with this disease. Even the business community hasn't so much wanted to deal with the disease. You don't associate your product with something that people shouldn't discuss. That is the way they have seen it, regrettably, previously. We are seeing cracks in that from the efforts we have made to change that discussion, so I think that parallels the kind of question you posed.

Mr. VRADENBURG. I would say where I am seeing the appetite is on the part of the social impact investing movement. This is a movement that started in the UK but it is beginning to spread globally. And what it is is that the $10 trillion of high net worth individual asset management, they do polling of their client base, and these are everywhere from investable assets of 1 million on up. They ask them, would you like your investments to reflect your values? And the answer is yes. But guess what? We have very good systems for measuring financial return on investment. We have

lousy systems for measuring social return on investment. And if what we can do is to begin to develop a clear plan that demonstrates if you invest $1 billion, Mr. Foundation 1 or 2 or 3, you will get this movement on this unmet need of on the most unimaginable proportions.

And so what we need to do is get that clarity of plan and demonstrate how the investment of funds will actually have an impact on something that is going to be the scourge of this world if we don't get acting. And that is where I sense there is a possibility here. But what this funding now from these very high net worth investors want is something that says, I want to know when I invest I will get a social return as well as a financial return.

Mr. JOHNS. Yes, if I can say, and I know you have to go, Mr. Chairman. One last thing I would say is that in the question about what can you do, seeing to it that the administrations—this one, the next one—implement the National Alzheimer's Project Act as you wrote it, passed it and put it into place is absolutely critical oversight on your part to be able to achieve what can be done. Laying out the kind of plan that George just mentioned, which is laid out in that plan, the National Alzheimer's Project Act plan, the plan for the country as a strategic plan for Alzheimer's, is a pathway to changing this in the United States and for providing the nature of the leadership we have discussed for the world. That is one thing I would ask all of you to do. It will make a huge difference.

Mr. SMITH. Thank you. And I do appreciate your leadership——

Mr. WEBER. I am done.

Mr. SMITH. Thank you, Mr. Weber. This may sound like a minor point, but just to get it on the record I did notice that the signers of the G8 were basically ministers of health or secretary of health except for us. And Don Moulds, I am sure, is a very good man, but did anyone take away that an acting Assistant Secretary for Planning and Evaluation——

Mr. VRADENBURG. Start with the proposition that Don Moulds is a good man, that the Assistant Secretary's position is now acting, he was acting at the time, but also that Secretary Sebelius felt that she had some urgent business to attend to in this country, because she was planning to come. So it did not reflect any lack of commitment on the part——

Mr. SMITH. They——

Mr. VRADENBURG. Yes, they did.

Mr. JOHNS. I did not perceive among the ministers that there was any ill perception. I too give credit to Mr. Moulds for representing us well.

Mr. SMITH. I just wanted to get that on the record and make it clear. I thank you again and look forward to work with you on legislation, and we will see you soon.

Mr. JOHNS. Thank you, sir.

[Whereupon, at 4:03 p.m., the subcommittee was adjourned.]

APPENDIX

Material Submitted for the Record

SUBCOMMITTEE HEARING NOTICE
COMMITTEE ON FOREIGN AFFAIRS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515-6128

Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations
Christopher H. Smith (R-NJ), Chairman

January 8, 2014

TO: MEMBERS OF THE COMMITTEE ON FOREIGN AFFAIRS

You are respectfully requested to attend an OPEN hearing of the Committee on Foreign Affairs, to be held by the Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations in Room 2200 of the Rayburn House Office Building (and available live on the Committee website at www.foreignaffairs.house.gov):

DATE: Wednesday, January 15, 2014

TIME: 2:00 p.m.

SUBJECT: A Report on the G8 Dementia Summit

WITNESSES: Panel I
Richard J. Hodes, M.D.
Director
National Institute on Aging
National Institutes of Health
U.S. Department of Health and Human Services

Panel II
Mr. George Vradenburg
Chairman and Founder
USAgainstAlzheimer's

Mr. Harry Johns
President and Chief Executive Officer
Alzheimer's Association

By Direction of the Chairman

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COMMITTEE ON FOREIGN AFFAIRS

MINUTES OF SUBCOMMITTEE ON *Africa, Global Health, Global Human Rights, and International Organizations* HEARING

Day *Wednesday* Date *January 15, 2014* Room *2172 Rayburn HOB*

Starting Time *2:28 p.m.* Ending Time *4:02 p.m.*

Recesses | *1* | (*2:37* to *2:38*) (____ to ____) (____ to ____) (____ to ____) (____ to ____) (____ to ____)

Presiding Member(s)

Rep. Chris Smith

Check all of the following that apply:

Open Session ☑
Executive (closed) Session ☐
Televised ☑

Electronically Recorded (taped) ☑
Stenographic Record ☑

TITLE OF HEARING:

A Report on the G8 Dementia Summit

SUBCOMMITTEE MEMBERS PRESENT:

Rep. Karen Bass, Rep. Randy Weber

NON-SUBCOMMITTEE MEMBERS PRESENT: *(Mark with an * if they are not members of full committee.)*

Rep. Maxine Waters, Rep. Chaka Fattah*

HEARING WITNESSES: Same as meeting notice attached? Yes ☑ **No** ☐
(If "no", please list below and include title, agency, department, or organization.)

STATEMENTS FOR THE RECORD: *(List any statements submitted for the record.)*

Questions of Rep. Chris Smith for Dr. Richard Hodes for the record
G8 Dementia Summit Declaration
G8 Dementia Summit Communique

TIME SCHEDULED TO RECONVENE ____
or
TIME ADJOURNED *4:02 p.m.*

Gregory B. Simpkins
Subcommittee Staff Director

QUESTIONS FOR THE RECORD OF THE HONORABLE CHRISTOPHER H. SMITH

SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS,
COMMITTEE ON FOREIGN AFFAIRS, U.S. HOUSE OF REPRESENTATIVES
"A Report on the G8 Dementia Summit"
January 15, 2014

Dr. Richard Hodes, Director, National Institute on Aging

1. Your agency is the lead federal agency on Alzheimer's and other forms of dementia, but not necessarily the provider of foreign aid programs on health care involving these conditions. How do you think the G8 Summit might impact how the United States and other G8 countries adjust their developing country health care aid programs in developing countries in light of the global dementia crisis?

Answer: Because the National Institutes of Health (NIH) and the National Institute on Aging (NIA) do not provide direct foreign aid to other nations, it is difficult to predict how the outcomes of the recent G8 Dementia Summit will influence our – or other countries' -- foreign aid programs. Certainly, the need is pressing: results of a recent meta-analysis[1] suggest that 35.6 million people lived with dementia worldwide in 2010, with numbers expected to almost double every 20 years, to 65.7 million in 2030 and 115.4 million in 2050. In 2010, 58 percent of all people with dementia lived in countries with low or middle incomes, with this proportion anticipated to rise to 63 percent in 2030 and 71 percent in 2050.

In most developing countries, approximately three-fourths of patients live in rural areas, where medical care is frequently provided by non-physician health care providers This highlights the important role that community health care providers will play in the management of dementias, and will no doubt be an important component of care strategies among aid-granting agencies, as it has been for other disease burdens.

We anticipate that the population-based data being generated in partnership with NIH in several developing countries will assist evidence-based planning, both within national governments and overseas development agencies. In addition, the development of new tools such as the International Alzheimer's Disease Research Portfolio (see below), which provides information about ongoing research, as well as broadly-available datasets such as those available through the Alzheimer's Disease Neuroimaging Initiative and the Alzheimer's Disease Genetics of Alzheimer's Disease Data Storage Site and the National Alzheimer's Coordinating Center (which collects the Uniform Data Set from the 27 NIA funded Alzheimer's Centers and makes

[1] Prince M et al., The Global Prevalence of Dementia: A Systematic Review and Metaanalysis. Alzheimer's and Dementia 9: 63-75, 2013.

the data available to researchers), will facilitate research that crosses national boundaries and make it easier than ever to conduct research on diverse populations.

We look forward to working with our partners to optimize these datasets and bring the benefits of cutting-edge research to patients and their families everywhere.

2. The International Alzheimer's Disease Research Portfolio, about which you testified, depends on information and funding contributions from countries around the world. How much of those contributions are coming from developing countries?

Answer: NIA welcomes participation of all countries, including developing nations, in the International Alzheimer's Disease Research Portfolio (IADRP). At this time, 13 major Alzheimer's disease funders in the United States, the United Kingdom, Canada, and Australia have contributed data, and we have begun to receive data from Poland.

It is our hope that other countries will join this effort in the near future. We have invited the other G8 countries (France, Germany, Italy, Japan, and Russia) to submit data to IADRP. In addition, we expect to significantly augment the number of participating countries through the International Funders Group, attendance at the International Meeting in Copenhagen in July, and the Alzheimer's Disease International meeting in Puerto Rico in May.

It is also important to note that research from around the world is represented in IADRP. For example, NIA supports Alzheimer's related studies in several developing countries, including:

- A five-year clinical trial, conducted among members of a unique and large family population in Colombia, to determine if an antibody treatment, crenezumab, designed to bind to and possibly clear away abnormal amounts of amyloid protein in the brains of people with Alzheimer's, can prevent decline in cognitive function. Members of the Colombian cohort share a genetic mutation known to cause observable signs of Alzheimer's disease at around age 45.
- The Kerala-Einstein study, which will foster collaborative research between US and Indian investigators to study potentially modifiable risk factors for cognitive decline such as diet, physical activity, social networks, and vascular diseases among older adults living in the Indian state of Kerala. This effort has the potential to have a major impact in building sustainable research capacity in India, ultimately leading to development of treatment and prevention strategies that are applicable worldwide.
- Development of a user-friendly biosensor device to measure and promote physical activity to study the effect on cognitive function among Ethiopians.
- Assessment of the prevalence and economic costs of Alzheimer's disease internationally through construction and analysis of a large, international and harmonized dataset based on representative surveys of health and ageing in 15 high-income countries (including the United States) and 12 low- and middle-income countries. Economic analysis of this large international data set will provide robust descriptive estimates of resource use and cost, identification of key cost drivers, and estimates of the economic consequences of dementia on households.

In addition, NIA supports the Study of Global Ageing and Adult Health (SAGE) in partnership with the World Health Organization. SAGE is a longitudinal study with nationally representative cohorts of persons aged 50 years and older in China, Ghana, India, Mexico, Russian Federation and South Africa and comparison samples of younger adults aged 18-49 years in each participating country to study health and health-related outcomes, including cognitive outcomes, and their determinants. Finally, investigators with the long-running Health and Retirement Study, the Nation's leading source of combined data on health and financial circumstances of Americans over age 50, collect data on the cognitive health of older Americans, with similar surveys ongoing in Europe, Mexico, Asia, and elsewhere. A major effort is currently underway to enhance cross-comparability of these surveys and facilitate innovative cross-national research.

3. The G8 Summit apparently was a success for the United States insofar as endorsing our national plan, but how confident are you that other donors will continue to collaborate on research and research funding and on implementing developing country dementia programs?

Answer: Again, it is challenging to predict the capabilities and actions of other countries – even our partners in the G8. However, the other participants have given every indication that they are seriously committed to working with us to address Alzheimer's disease, and there is every reason to be optimistic that we will continue to collaborate effectively as we work together to address this urgent public health issue.

Notably, the December Summit concluded with the publication of a declaration and communique[2] recording the joint activities decided on during the meeting. In the declaration, the participating countries stated their intention to:

- Set a shared goal to identify a cure or disease-modifying therapy for dementia by 2025
- Collectively increase the amount spent on dementia research
- Increase the number of people involved in clinical trials and studies on dementia
- Support the United Kingdom's establishment of a new global envoy for dementia innovation
- Develop an international action plan for research
- Share information and data from dementia research studies across the G8 countries to work together and get the best return on investment in research
- Encourage open access to all publicly-funded dementia research to make data and results available for further research as quickly as possible

These joint activities are fully consistent with NIH's priorities for ADRD research, and we look forward to working closely with other G8 nations to achieve mutual goals.

[2] https://www.gov.uk/government/publications/g8-dementia-summit-agreements

In addition to the declaration and communique, the G8 nations have already planned a series of high-level "legacy events" in partnership with the Organisation for Economic Co-operation and Development (OECD), the World Health Organization (WHO), the European Commission, the EU Joint Programme on Neurodegenerative Disease, and private partners, to develop cross sector partnerships and innovation focused on social impact investment, new care and prevention models, and partnerships between academia and industry. The U.S. will lead one of these efforts, hosting a follow-up meeting of G8 health ministers and global experts (including WHO and OECD) in early February 2015 as part of the next NIH-hosted Alzheimer's Research Summit. Participants will review the progress that has been made on our research agenda and help provide updated direction for the way forward.

Other planned efforts among our G8 partners include:

- The United Kingdom will more than double the funding for research into dementia and neurodegenerative disease to over £66 million each year by 2014/2015 (compared to 2009/2010). The United Kingdom also will increase opportunities for persons with dementia to participate in research, with an aim of recruiting fully 10 percent of dementia patients into clinical trials. The United Kingdom Medical Research Council will be investing in dementia research via the BioBank and is piloting the brain scanning of a subset of this national cohort, with a view to rolling out to 50,000–100,000 participants.
- Research on neurodegenerative diseases including dementia also is a priority within the European Union 7th Framework Programme for Research and Technological Development, with EUR 401 million invested for research in this area between 2007 and 2012, or an annual investment of about EUR 67 million. Additional funding resulting from the latest call for proposals (2013) will add to this amount.
- The Canadian Institutes for Health Research is investing $30 million to support the Canadian Longitudinal Study on Aging, which will investigate neuropsychological, social and economic issues of 50,000 Canadians aged 45 to 85 over the next 20 years. 30,000 participants have already been recruited and researchers will have access to the first wave of study data over the next year.

4. In your testimony, you cited the 34,000 medical and other personnel trained to diagnose, treat or manage care for Alzheimer's victims under the Department of Health and Human Services program. Do you anticipate significant differences in their implementation of this training given the varying cultural norms globally? If so, can you provide any examples of how those differences might be manifested?

Answer: All 45 Geriatric Education Center (GEC) grantees provided Alzheimer's and Dementia-related education and training to their communities, including rural and underserved communities. While differences within the content of the material being presented did not differ significantly, these trainings were delivered to meet the specific needs of each community. For example, twelve GEC grantees translated their educational materials into other languages to improve community outreach. Additionally, all grantees provided training to physicians regarding resources in their community (*i.e.*, caregiver/respite services) as well as guidance on when and how to refer patients and their families to those entities.

MATERIAL SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY, AND CHAIRMAN, SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS

G8 UK
UNITED KINGDOM 2013

Global action against dementia

G8 DEMENTIA SUMMIT DECLARATION

Introduction

We, the G8 Health Ministers, met at the G8 Dementia Summit in London on 11 December 2013 to discuss how to shape an effective international response to dementia.

We acknowledge the on-going work occurring in our countries and globally to identify dementia as a major disease burden and to address issues related to ageing and mental health, including the World Health Organisation's 2012 report, *Dementia – A Public Health Priority*. Building upon the significant research collaborations that exist between our countries and our multilateral partners will strengthen our efforts and allow us to better meet the challenges that dementia presents society.

We recognise that dementia is not a normal part of ageing. It is a condition that impairs the cognitive brain functions of memory, language, perception and thought and which interferes significantly with the ability to maintain the activities of daily living. We also acknowledge that dementia affects more than 35 million people worldwide, a number that is expected to almost double every 20 years.

We note the socio-economic impact of dementia globally. Seventy per cent of the estimated annual world-wide cost of US$604 billion is spent on informal, social and direct medical care. Yet nearly 60 per cent of people with dementia live in low and middle income countries so the economic challenge will intensify as life expectancy increases across the globe.

These costs are expected to increase significantly if therapies to prevent dementia and improve care and treatment are not developed and implemented. We recognise the need to strengthen efforts to stimulate and harness innovation and to catalyse investment at the global level.

Therefore, and in accordance with national, sub-national and local responsibilities, we commit ourselves to:

1. Call for greater innovation to improve the quality of life for people with dementia and their carers while reducing emotional and financial burden. We therefore welcome the UK's decision to appoint a global Dementia Innovation Envoy to draw together international expertise to stimulate innovation and to co-ordinate international efforts to attract new sources of finance, including exploring the possibility of developing a private and philanthropic fund to support global dementia innovation;
2. The ambition to identify a cure or a disease-modifying therapy for dementia by 2025 and to increase collectively and significantly the amount of funding for dementia research to reach that goal. We will report biennially on expenditure on publicly funded national dementia research and related research infrastructure; and we will increase the number of people in dementia related research studies;

3. Work together, share information about the research we fund, and identify strategic priority areas, including sharing initiatives for big data, for collaboration and cooperation;

4. Develop a co-ordinated international research action plan which accounts for the current state of the science, identifies gaps and opportunities, and lays out a plan for working together to address them;

5. Encourage open access, where possible to all publicly funded dementia research and to make the research data and results available for further research as quickly as possible, while protecting the privacy of individuals and respecting the political and legal frameworks of the countries in which the research is conducted;

6. Take stock of our current national incentive structure for research, working in partnership with the Organisation for Economic Co-operation and Development (OECD), and consider what changes could be made to promote and accelerate discovery and research and its transformation into innovative and efficient care and services;

7. Hold a series of high-level fora throughout 2014, in partnership with the OECD, WHO, the European Commission, the EU Joint Programme on Neurodegenerative Disease (JPND), and civil society, to develop cross sector partnerships and innovation, focused on:

    - Social impact investment – UK-led
    - New care and prevention models – Japan-led
    - Academia-industry partnerships – Canada and France co-led

8. Call upon the WHO and OECD to identify dementia as an increasing threat to global health and support countries to strengthen health and social care systems to improve care and services for people with dementia;

9. Call upon the UN Independent Expert on the enjoyment of all human rights by older persons to integrate the perspective of older people affected by dementia into their work;

10. Call upon all sectors to treat people affected by dementia with dignity and respect, and to enhance their contribution to dementia prevention, care and treatment where they can; and

11. Call upon civil society to continue and to enhance global efforts to reduce stigma, exclusion and fear.

12. We will meet again in the United States in February 2015 with other global experts, including WHO and OECD, to review the progress that has been made on our research agenda.

G8 UK
UNITED KINGDOM 2013

Global action against dementia

Signed by G8 Health and Science Ministers on 11 December 2013

JEREMY HUNT

Secretary of State for Health, UK

RONA AMBROSE

Minister of Health, Canada

MARISOL TOURAINE

Minister of Health and Social Affairs, France

GENEVIÈVE FIORASO

Minister of Higher Education and Research, France

DANIEL BAHR

Federal Minister for Health, Germany

G8 UK
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Global action against dementia

GIUSEPPE RUOCCO

Director General for Prevention, Italian Health Ministry
on behalf of Minister Lorenzin, Italy

SHINAKO TSUCHIYA

Senior Vice Minister of Health, Labour and Welfare, Japan

VERONIKA I. SKVORTSOVA

Minister of Health, Russia

DON MOULDS

Acting Assistant Secretary for Planning and Evaluation,
US Department of Health and Human Services

G8 UK
UNITED KINGDOM 2013

Global action against dementia

G8 DEMENTIA SUMMIT COMMUNIQUE

Introduction

1. We, the G8 Health Ministers, met at the G8 Dementia Summit in London on 11 December 2013 to discuss how to shape an effective international response to dementia.

2. We acknowledge the on-going work occurring in our countries and globally to identify dementia as a major disease burden and to address issues related to ageing and mental health, including the World Health Organisation's 2012 report, *Dementia – A Public Health Priority.* Building upon the significant research collaborations that exist between our countries and our multilateral partners will strengthen our efforts and allow us to better meet the challenges that dementia presents society.

3. We recognise that dementia is not a normal part of ageing. It is a condition that impairs the cognitive brain functions of memory, language, perception and thought and which interferes significantly with the ability to maintain the activities of daily living. We also acknowledge that dementia affects more than 35 million people worldwide, a number that is expected to almost double every 20 years.

4. We note the socio-economic impact of dementia globally. Seventy per cent of the estimated annual world-wide cost of US$604 billion is spent on informal, social and direct medical care. Yet nearly 60 per cent of people with dementia live in low and middle income countries so the economic challenge will intensify as life expectancy increases across the globe.

5. These costs are expected to increase significantly if therapies to prevent dementia and improve care and treatment are not developed and implemented. We recognise the need to strengthen efforts to stimulate and harness innovation and to catalyse investment at the global level. Recognising the division of health responsibilities between national and sub-national levels of government that is unique to federated states;

Research and Innovation

6. We recognise that through research, knowledge translation and care, we can reduce the increasing impact of dementia on society and we commend all efforts in the development of breakthroughs to prevent, delay, treat or stop dementia. We want to ensure that we support the research likely to have the greatest impact and which addresses the areas of greatest need. We agree to work together, to share information about the research we fund, and to identify strategic priority areas, including sharing initiatives for big data, for collaboration and cooperation. We understand the importance of using existing evidence and knowledge to inform decision-making, as well as creating better and more robust monitoring and evaluation evidence.

7. To realise these ambitions, we must draw on the existing research infrastructure. Therefore, we welcome the offer of research funders including NIH, MRC, CIHR, and AVIESAN to act as co-convenors, building on the existing work and capability offered at the European level (through the JPND, the Innovative Medicines Initiative and the Horizon 2020 initiative) to identify priorities and to develop a co-ordinated international action plan for research which accounts for the current state of the science, identifies gaps and opportunities, and lays out a plan for working together to address them.

8. Furthermore, we commit to:-

   - The ambition to identify a cure or a disease-modifying therapy for dementia by 2025 and to increase collectively and significantly the amount of funding for dementia research to reach that goal. We will report biennially on expenditure on publicly funded national dementia research and related research infrastructure; and we will increase the number of people in dementia related research studies.

   - Encourage open access, where possible, to all publicly funded dementia research and to make the data and results available for further research as quickly as possible while protecting the privacy of individuals and respecting the political and legal frameworks of the countries in which the research is conducted;

9. Although we embrace the need to increase spending on dementia research, this will not be sufficient on its own. Mutual efforts to stimulate and harness innovation at the global level therefore need to be strengthened. Consequently, we call for greater innovation to improve the quality of life for people with dementia and their carers while reducing the emotional and financial burden. We therefore welcome the UK's decision to appoint a global Dementia Innovation Envoy to draw together international expertise to stimulate innovation and to co-ordinate international efforts to attract new sources of finance, including exploring the possibility of developing a private and philanthropic fund to support global dementia innovation.

10. We acknowledge the need to attract new investors and the need to support the disruptive technology and innovation in companies and academia that is currently being postponed or shelved because of the technical and financial threat of failure. We recognise that both public and industry-led research and capacity must be encouraged to enable new approaches to be identified and developed. We must explore all avenues of innovation. Priorities for investment include:

    - Research to elucidate the mechanisms underlying the initiation and progression of neurodegeneration as a basis for identifying new targets for therapeutic development;
    - Prevention of dementia;
    - Making timely diagnosis and early intervention feasible, affordable and cost effective;
    - Facilitating the integration of care and helping individuals and their carers access care and social services in their homes and communities; and
    - Making care homes more responsive to needs.

11. To reduce the impact of dementia on an ageing society, we need to think and act differently, and we need to stimulate new investment to help address the current innovation gap. We recognise the need to build on existing capabilities and capacities to stimulate innovation across the life science, healthcare, home care, social care, and wellbeing sectors. To this end, we agree to take stock of our current national incentive structure, working in partnership with the OECD, and consider what changes could be made to promote and accelerate discovery and research and its transformation into innovative and efficient care and services.

Leadership, Cross-Sector Partnerships and Knowledge Translation

12. We see the G8 dementia summit in London as the start of a process which will allow us to step up our efforts to reduce the human and economic impact of dementia. We are keen to continue to work together but we also want to engage other countries with a similarly strong interest in dementia.

13. To develop innovation and cross sector partnership efforts, we will hold a series of high-level fora throughout 2014, in partnership with the OECD, WHO, the European Commission, JPND and civil society, to develop cross sector partnerships and innovation, focused on:

    - Social impact investment – UK-led
    - New care and prevention models – Japan-led
    - Academia-industry partnerships – Canada and France co-led

14. We will meet again in the United States in February 2015 with other global experts, including WHO and OECD, to review the progress that has been made on our research agenda.

15. The world has been slow to adapt to population ageing and dementia and this continues to worsen fiscal and societal risks, threatening sustainable growth. We need more data on prevalence and incidence of dementia, as well as prevention and treatment. As the 'baby boom' generation of the late 1950s and early 1960s come to care for their own parents affected by dementia, there is an opportunity to offer greater involvement and support. We should explore ways to connect people affected by dementia, particularly to support collaborative problem solving.

16. Increased age is the greatest predictor of dementia. It has been estimated that delaying dementia onset by 2 years could decrease global disease burden in 2050 by 22.8 million cases. We therefore recognised that a new approach to delaying and preventing dementia is needed and requires:

    - New approaches to sharing and using data and analyses developed collectively, including the use of open access and innovative crowdsourcing strategies, collected in ways which suit local and national circumstances;
    - Collaborative efforts between countries to "pool" cases, methodologies, approaches and solutions;
    - Prevention trials to obtain evidence based conclusions.

17. Dementia is a global challenge and one which is set to intensify. History shows major diseases can be made manageable, even preventable, with sufficient political will. We therefore need to better understand risk factors for dementia in younger generations, identify available options to reduce risk, and develop and implement rigorously designed public health programmes. We recognise the importance of taking a comprehensive and coordinated approach to the prevention of dementia, tailored to national and local needs, and to take prevention measures in the near term based on existing knowledge. We will encourage countries to make dementia a public health priority as their populations grow and generations age.

18. Responding effectively to dementia requires policy makers across government to work together. Governments can also learn from one another. To learn from one another and facilitate knowledge exchange, we will strive to improve the way in which we share government policy documents on treatment, services, interventions and research for people affected by dementia.

Supporting People Affected by Dementia and their Carers

19. Depending on its cause, dementia may progress from mild cognitive impairment, including difficulties organising daily life, to significant alterations in personality, disintegration of cognitive functions, loss of self and identity, incontinence, loss of physical abilities and finally death. Dementia can be both a contributory factor to, and a primary cause of death. Progress of the disease and its impact are very distressing for people with dementia, their families and carers.

20. Dementia is our collective social responsibility. We affirm our commitment to improving the lives of people affected by dementia, regardless of nationality, identity, background, culture socioeconomic status, language or religion. Furthermore, we encourage the involvement of Indigenous peoples and communities in the development, implementation, and evaluation of dementia policies, plans and programs where appropriate, while promoting the development and strengthening of capacity at various levels and recognising the cultural heritage and traditional knowledge of Indigenous peoples.

21. Dementia requires long term health and social care support. Providing care for those with dementia can present challenges for families and carers. We need to provide better and more concrete measures for improving services and support for people with dementia and their carers, to improve their quality of life and wellbeing.

22. We pledge to disseminate successful approaches to supporting people with dementia and their carers including:-

    - Provision of advice, including on care planning, management and wellness support
    - Appropriate use of medication, particularly antipsychotics, and delaying and/or reducing secondary complications
    - Community-based programmes fostering inclusion and improved quality of life
    - Delivering services through a continuum of care, including primary care

- Individual tailoring of care
- Realisation of new, ambulant living options
- Helping care homes to meet the needs of people with dementia
- Affordable options for care and everyday support
- Addressing end of life care

23. Carers themselves are often older adults, mainly women, who may be dealing with their own health problems. We call for greater social responsibility and innovation to improve the quality of life for carers and improve care while reducing costs and financial burden including:-

    - Training for carers, including how to deal with dementia related behaviours
    - Improve the reconciliation of care and career for carers
    - Support carers in acute situations and crises
    - Local and affordable options for care and everyday support
    - Promote civic engagement and the development of social networks
    - Attract and train community representatives to support people with dementia in social environments
    - Creating better and robust evaluation evidence
    - Using existing evidence and knowledge

24. Appropriate autonomy and self-determination, including substitute or supported decision making, for people with dementia must be protected and strengthened. Therefore national and local policies should be in place to ensure appropriate autonomy and self-determination are recognised and protected.

Reducing stigma and fear

25. Dementia is not a normal part of ageing. As people age, many fear the potential onset of dementia-related symptoms or a diagnosis of dementia. Negative reactions from family, friends, and professionals can impact a person's willingness to seek assistance, as well as their well-being and ability to manage the changes brought about by dementia. We commit to improving the understanding of community attitudes towards people with dementia across generations.

26. Responding effectively to dementia requires a response from all sectors of society. Therefore, we call upon all sectors to treat people affected by dementia with dignity and respect, and to promote various forms of civic engagement on dementia awareness, and to contribute to the prevention of dementia and to improve care and treatment where they can.

27. Addressing stigma and ensuring that people with dementia are treated with dignity and respect are critical. We therefore commend the creation of the UN Independent Expert on the enjoyment of all human rights by older persons and we ask that the perspective of older people affected by dementia is integrated into their work.

28. Civil society is also well placed to play a major role in changing public attitudes. Therefore, we agreed to call on civil society to continue and to enhance global efforts to reduce stigma, exclusion and fear.

Conclusion

29. We will continue our efforts to work together in line with the commitments in this Declaration and Communiqué, but we recognise that dementia is an issue which affects people in countries throughout the world. Consequently, we encourage all countries and multilateral organisations to come together and take action to reduce the risk to health and to economic development which dementia currently presents.

G8 UK
UNITED KINGDOM 2013

Global action against dementia

Signed by G8 Health and Science Ministers on 11 December 2013

JEREMY HUNT

Secretary of State for Health, UK

RONA AMBROSE

Minister of Health, Canada

MARISOL TOURAINE

Minister of Health and Social Affairs, France

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