**Energy and Commerce Committee**
**Subcommittee on Health**

**"21st Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients"**

**June 11, 2014 at 10am**

**Testimony from**
**Kenneth L. Davis, M.D.**
**Chief Executive Officer and President**
**Mount Sinai Health System**

Chairman Pitts, Ranking Member Pallone, and distinguished members of the Subcommittee on Health, thank you for inviting me to testify.

My name is Dr. Kenneth Davis and I am here today to testify in an individual capacity.

I am the CEO and President of the Mount Sinai Health System in New York. The Mount Sinai Health System is an integrated health care system encompassing the Icahn School of Medicine at Mount Sinai and seven hospital campuses in the New York metropolitan area, as well as a large regional ambulatory footprint. The Mount Sinai Health System, serving a broad spectrum of patients, is one of the largest health systems in New York State. Mount Sinai is supported by a number of programs, including the Center for Medicare and Medicaid Innovation (CMMI), the Patient-Centered Outcomes Research Institute (PCORI) and the Medicare Shared Savings Program to encourage the change from volume- to value- based care.

By way of background, I was named CEO and President of the Mount Sinai Health System in September 2013 following the inclusion of Continuum Health Partners into our health system. For the decade prior to that, I served as President and CEO of The Mount Sinai Medical

Center which entered a new era of innovation in collaborative research, education, and clinical care. A Professor of Psychiatry and Pharmacology at Icahn School of Medicine at Mount Sinai, I received my bachelor's degree from Yale College and my medical degree from Mount Sinai School of Medicine. I completed an internship, residency, and fellowship in psychiatry, and pharmacology, respectively, at Stanford University Medical Center, and thereafter won a career development award from the Veterans Administration to pursue my research in cholinergic mechanisms and neuropsychiatric diseases.

In 1979, I joined the faculty at Mount Sinai, becoming Chief of Psychiatry at the Bronx Veterans Administration (VA) Medical Center. At that time, I spearheaded Mount Sinai's research program in the biology of schizophrenia and the therapeutics of Alzheimer's disease and directed Mount Sinai's National Institute on Aging (NIA)-supported Alzheimer's disease Research Center from 1984 through 2002. My work focused on all aspects of experimental therapeutics, including animal models, assessment instruments, and design issues in drug testing. As early as 1978, I first suggested that treatment of a particular brain chemical deficiency could be useful for the treatment of Alzheimer's disease, and shortly thereafter I conducted the first positive proof of concept study in this disease using drugs called cholinesterase inhibitors. Early on in Alzheimer's, the cells that produce a chemical called acetylcholine begin to fail, and the levels of this important chemical plummet. The medication helps restore the levels of this chemical so that the nerve cells can resume their usual conversations. Subsequently, I coordinated the first multicenter NIA-funded trial of the first orally active cholinesterase inhibitor known as tacrine. This work eventually led to the discovery, development and approval of the drugs used for Alzheimer's today. Aricept (or donepezil), Exelon (rivastigamine), and Razadyne or Reminyl (galantamine) are names that you might have encountered. Either I, or a member of my staff,

helped to direct Pfizer, Novartis or Johnson & Johnson in the development of these drugs. In 1987 I was appointed Chairman of Psychiatry, Mount Sinai School of Medicine.

I also directed the NIMH funded Silvio O. Conte Center for the Neurosciences of Mental Disorders. This multimillion-dollar Center focuses on schizophrenia and is based on the premise that white matter, oligodendrocytes and myelin may be compromised in schizophrenia. It has opened an entirely new approach to this devastating disease. Over the course of my career, I have received a number of NIH grants to study major brain diseases. In addition, I have authored or co-authored more than 575 scientific articles and I have been recognized by ISI as one of the most highly cited researchers in the field of brain diseases. My wife, Dr. Bonnie Davis, is also researcher and inventor of brain disease therapeutics.

I have had the privilege of serving terms as President of the Society of Biological Psychiatry and the American College of Neuropsychopharmacology, as well as Chairman of the Board for the Greater New York Hospital Association, and the League of Voluntary Hospitals & Homes of New York. In addition to my election to membership in the Institute of Medicine (IOM) of the National Academy of Sciences I was proud to receive the George H.W. Bush Lifetime of Leadership Award—a distinction given to Yale alumni athletes who make significant breakthroughs in their professions, the Rita Hayworth Award from the Alzheimer's Association, the Kempf Fund Award for Research Development in Psychobiological Psychiatry from the American Psychiatric Association, the Gold Medal Award from the Society of Biological Psychiatry for Outstanding Achievement in Psychobiological Research, the American Psychiatric Association Award for Research in Psychiatry, and the Joel Elkes International Award given by ACNP for outstanding research in neuropsycho-pharmacology.

This background hopefully demonstrates my commitment and expertise in the issue before the Committee today. I would like to start by commending the Committee for holding this important hearing to discuss the value of incentivizing drug development. While the solution on how to incentivize drug development may be debated, we all can agree that the problem is pervasive: too many individuals in this country are suffering from chronic conditions without the aid of therapeutics. Not only does this have a harmful impact on families, but we must also remember that the lack of therapeutics for chronic diseases places an enormous strain on our country's finances. Chronic conditions, such as Alzheimer's disease and other dementias, are an enormous part of the cost to our health care system. Without novel therapeutics to prevent or better treat these conditions, costs will only escalate. We must find a better solution than the status quo.

In order to bend the dementia cost curve over the long term, we need laws that are aligned with our nation's priorities and the public good, and those that will encourage the development of orally administered compounds for Alzheimer's disease or other chronic diseases. Specifically, I suggest we offer extended market exclusivity protection for truly innovative compounds that reduce the rate of disease progression. Since the development of cholinesterase inhibitors there has only been one other approved drugs for Alzheimer's (Namenda) and that was over 20 years ago. We need to encourage drug development in order to bring new Alzheimer's drugs to market.

Alzheimer's affects more than five million seniors today and, this year, Medicare and Medicaid are expected to pay $150 billion in health care, long term care and hospice for individuals with

Alzheimer's and other related dementias.[1] By 2050, that number could rise to between 13.8 million and 16 million Americans with Alzheimer's whose care will cost Medicare and Medicaid six times their spending today.[2] According to a recent study, women in their 60s are twice as likely to get the disease as they are to get breast cancer.[3] In 2014, an estimated 700,000 Americans will die with Alzheimer's.[4]

Since the disease kills slowly over a period of 10 years, each individual with Alzheimer's could generate a high cost over the course of his or her illness. This year, the total cost for all individuals with Alzheimer's and other dementias are estimated to be over $200 billion.[5] A 2010 Alzheimer's Association report demonstrated that the cost of caring for individuals with Alzheimer's and other dementias will increase more than 600 percent under Medicare, from $88 billion in 2010 to $627 billion in 2050.[6] In addition, Medicaid costs will increase 400 percent, from $34 billion in 2010 to $178 billion in 2050.[7]

If we are to have any chance of mitigating this epidemic, we must find ways to encourage the development of drugs that slow the progression or delay the onset of the inevitable brain failure that characterizes Alzheimer's. Specifically, we need to find incentives for the development of orally administered compounds that alter the course of the disease. As you well know, Congress has stepped in before to provide market incentives for research (i.e., the Orphan Drug Act and the biologics provision in the Affordable Care Act). We now need a similar exclusivity policy extended narrowly to include orally administered compounds that can slow the Alzheimer's epidemic.

---

[1] Alzheimer's Association, 2014 Alzheimer's Disease Facts and Figures, *Alzheimer's & Dementia,* Volume 10, Issue 2, Pages 16 & 43.
[2] Alzheimer's Association, 2014 Alzheimer's Disease Facts and Figures, *Alzheimer's & Dementia,* Volume 10, Issue 2, Page 21 & 52.
[3] Alzheimer's Association Website, Alzheimer's Facts and Figures, http://www.alz.org/alzheimers_disease_facts_and_figures.asp#women. Accessed June 5, 2014.
[4] Alzheimer's Association, 2014 Alzheimer's Disease Facts and Figures, *Alzheimer's & Dementia,* Volume 10, Issue 2, Page 25.
[5] Alzheimer's Association, 2014 Alzheimer's Disease Facts and Figures, *Alzheimer's & Dementia,* Volume 10, Issue 2, Page 43.
[6] Alzheimer's Association, "Changing the Trajectory of Alzheimer's Disease: A National Imperative," 2010. Page 4.
[7] Alzheimer's Association, "Changing the Trajectory of Alzheimer's Disease: A National Imperative," 2010. Page 4.

With the sequencing of the human genome and other biomedical breakthroughs, drugs to address Alzheimer's disease are more possible than ever. An extraordinary serious of recent studies have found that people who eventually develop Alzheimer's begin accumulating clumps of protein known as beta amyloid as long as 25 years before symptoms begin. Thus, we need to develop a drug that will slow this progress in patients before they are symptomatic. If we were to develop a drug that would be given before individuals were symptomatic, that drug would push back the development of the disease, and as a country we would incur much lower rates of Alzheimer's disease.

Most individuals show signs of Alzheimer's in their 70s, so if we were able to slow the progress of the disease by 50 percent, most of these individuals would not show symptoms until their 90s. However, because toxicity must be assessed and because the FDA requires that efficacy must be demonstrated in two independent trials, developing a drug to address Alzheimer's could easily take as long as the patent life on any compound. For example, such studies could require these pre-symptomatic patients to take the experimental drug for 5 years, take an additional two years to enroll an adequate number of patients, and another year to analyze the data. Since the two trials would rarely be done in parallel, the result of the first trial would be needed to justify the huge expenditure of the second trial. Thus, assuming success (which is far from guaranteed), there would be virtually no patent life left and thus no real incentive for a pharmaceutical company to invest the resources and time in this science. And this is the most optimistic example, where patients begin treatment 5 years before onset of symptoms. Since those protein clumps become visible as long as 15 years before symptoms, we may well be headed toward initiation of therapy to people in their mid-50s in order to prevent a disease that would have developed in their 70s.

Interventions being evaluated today include a class of drug known as biologics. These drugs themselves are proteins which means that they are administered by infusion and require refrigeration. As you know, the Affordable Care Act encourages the development of these drugs by providing 12 years of exclusivity, but these drugs are expensive. Biologics may cost as much as 22 times the cost of ordinary drugs and, at that rate, a biological treatment that alters progression of Alzheimer's would be as or more expensive than the cost of treating patients with the disease, and hence will not help to save Medicare from insolvency.[8]

Alzheimer's science is poised to accelerate but drug development policies and incentives must be realigned in order to provide for the public's best interest. Such realignment will inevitably align with the best interest of our health care economy. The 2010 Alzheimer's Association report also showed that if we could introduce a treatment to delay the onset of Alzheimer's by five years, the total costs to all payers would fall by $447 billion in 2050.[9] These are real savings that will have a substantial impact, not only on families but on our nation's fiscal crisis.

Therefore, in order to bend the dementia cost curve, Congress should develop legislation to provide market exclusivity – independent of patent life – for orally administered compounds that attenuate Alzheimer's pathology and slow dementia progression. This narrow approach would allow innovators to receive a return on the expenditure of resources leading to a discovery of a therapeutic to treat Alzheimer's disease. In exchange, with an affordable treatment, we would bend the dementia cost curve and begin to attenuate the exploding cost of caring for Americans suffering from Alzheimer's disease.

[8] Op-ed by Anthony D. So and Samuel L. Katz, "Biologics Boondoggle," *New York Times*, March 7, 2010.
[9] Alzheimer's Association, "Changing the Trajectory of Alzheimer's Disease: A National Imperative," 2010. Page 8.

In conclusion, I would like to again thank this Committee for shining a spotlight on this important issue.