

SAM GANDY, M.D., PhD.  
DIRECTOR, FARBER INSTITUTE FOR NEUROSCIENCES  
THOMAS JEFFERSON UNIVERSITY  
PHILADELPHIA, PA  
CHAIR, MEDICAL AND SCIENTIFIC ADVISORY COUNCIL  
ALZHEIMER'S ASSOCIATION

## **SUMMARY**

For the first time in history, there is genuine widespread enthusiasm among scientists that effective ways prevent and treat Alzheimer's are within reach. Within three years, it is all but certain we will have disease-modifying drugs that fundamentally change the nature of the disease. Within 25 years, we could save nearly half of projected Medicare and Medicaid costs on Alzheimer's – savings of over \$200 billion a year. We could keep nearly 4 million Americans from getting the disease.

Two of the most promising drugs, which target the brain-destroying amyloid plaques in the brain, are well on their way to market. In controlled clinical trials, we have already proven they are safe, well tolerated, and have significant positive impact in slowing progression of disease. Higher doses or combination drugs might arrest the process completely. One of these drugs could go to FDA for review as early as this fall with possible approval by next year.

Advances in genetics and imaging have brought us near the point when we will be able to identify persons at risk of Alzheimer's, diagnose it before symptoms appear, and begin treatment in time to prevent development of dementia altogether.

There is still a lot of work to be done. Alzheimer's is a complex puzzle and solving it involves multiple strategies. Scientists are pursuing a number of other highly promising theories including the chemical basis of tangles in the brain, the connection to heart and vascular diseases and to diabetes, and the interaction of environment, genetics, and life style. If we can validate these theories through basic research, then every major pharmaceutical company will begin bringing new drugs into chemical trials.

We have reached this stage because of your prior investments in NIH, but we are now at risk of losing momentum. Alzheimer research funding peaked at \$658 million in 2003 and has declined every year since – a 14% decline in constant dollars at the National Institute on Aging alone. This is already having an impact. NIA is funding less than 18% of the best research proposals it receives – down from 30% in 2003. The grants that are approved are funded 18% below recommended levels for the first year, with no inflationary adjustments in the out years.

This means that huge scientific opportunities are being left on the table. Existing projects are taking longer to find results. Some of the most promising clinical trials are being delayed or scrapped altogether. And we are losing a generation of scientists who are either choosing traditional careers or leaving research altogether.

This is killing research, it is killing the minds of millions of Americans, and it is killing your chances of getting health research spending under control.

The scientific community is in a race against time. I urge Congress to provide the funds needed to break through the finish line ahead of the baby boomers who are nipping at our heels.

**STATEMENT OF SAM GANDY, M.D., PhD.**

**DIRECTOR, FARBER INSTITUTE FOR NEUROSCIENCES  
THOMAS JEFFERSON UNIVERSITY  
PHILADELPHIA, PA  
CHAIR, MEDICAL AND SCIENTIFIC ADVISORY COUNCIL  
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to

**AGING SUBCOMMITTEE, SENATE HEALTH, EDUCATION, LABOR & PENSIONS  
COMMITTEE  
MARCH 20, 2007**

Madam Chair, Senator Burr, and Members of the Subcommittee. I am delighted to be here to report on the latest exciting developments in the field of Alzheimer's disease research. Senator Mikulski, you clearly understand the importance and the promise of this research, as evidenced by your Breakthrough Act, which would commit Congress to the \$1 billion goal for Alzheimer research. I'd like to begin my comments by applauding your efforts.

When my colleague John Morris appeared before this Subcommittee three years ago, he was full of cautious optimism. Today, I can report genuine, tangible, quantifiable hope for effective prevention and treatment of Alzheimer's disease. Within the next three years, it is all but certain that we will have disease-modifying drugs that will fundamentally change the nature of Alzheimer's. For millions of Americans, a diagnosis will no longer be a death sentence but the beginning of a manageable chronic illness.

These drugs are very different from the ones now on the market. Current drugs treat the symptoms of Alzheimer's but leave the underlying disease untouched. While they do help some patients temporarily, the predictable progression to death continues along the cruel path we know too well. The new drugs are designed to attack the disease directly. My own laboratory is involved in clinical trials of two drugs that target the brain-destroying amyloid plaques that are one of the two molecular hallmarks of Alzheimer's disease. Results to date are very encouraging. These drugs are safe. Patients tolerate them well. And they appear to show significant positive impact, slowing the progression of the disease. Higher doses or combination drugs might arrest the process completely. This drug could go to the Food and Drug Administration for review as early as this fall with possible approval by next year.

The other exciting news is that we are rapidly gaining knowledge about genetic and other risk factors of Alzheimer's disease, and developing techniques to detect early changes in the brain well before symptoms appear. These discoveries will let us identify persons at risk of Alzheimer's, diagnose presymptomatic disease, and begin treatment in time to prevent development of dementia altogether.

All of this good news is the direct result of your decision to double funding for the National Institutes of Health. The influx of resources moved Alzheimer research from a backwater of obscurity to perhaps the single most visible, most competitive, and most exciting field in the neurosciences. This is the key to drug discovery.

Drug development does not start or end with pharmaceutical companies. It begins at NIH-funded laboratories at academic health centers, where scientists uncover the molecular basis of

disease, identify treatment strategies, and develop the research methods and techniques that make clinical investigation possible. Clinical trials depend on the expertise of NIH-funded investigators, and many require direct NIH funding because the drugs under investigation are not protected by patent.

I emphasize this fundamental role of NIH funding because there is still so much work to be done. We are right to be excited about treatments that attack the amyloid plaques. But they will not likely be the complete answer. Like cancer and heart disease, Alzheimer's is a complex puzzle. Solving it will involve multiple strategies. We already have a number of other potential targets for intervention – including the chemical basis of the tangles in the brain that are the other hallmark of Alzheimer's, the relationship between heart and vascular disease and Alzheimer's, the connection to Type 2 diabetes, the role of nerve growth factors, and the interaction of environment, life style choices, and genetics in the development of disease.

If we can validate the prevailing wisdom about amyloid, and if we can refine these other theories, then every major pharmaceutical company will begin bringing new drugs into human clinical trials. That will not happen, however, unless Congress provides the funds to sustain the Alzheimer research enterprise.

In 2003, annual NIH funding of Alzheimer research peaked at \$658 million. We are living off the results of that investment, but we now risk losing our momentum. Since 2003, we have seen a slow steady decline in funding – down to \$643 million this year and even less if Congress approves the President's fiscal 2008 budget request. In constant dollars, the drop is devastating – a 14% decline in overall funding at the National Institute on Aging (NIA.)

This is happening at a time when the scientific opportunities have never been greater. There are more highly promising avenues of inquiry to explore than ever before. And we now have research tools at our disposal, involving genetics and imaging, that can help us get better, quicker answers. But we cannot use those tools without adding funds to existing projects.

The slow down in funding is already having an impact in the Alzheimer research community. NIA is funding less than 18% of the most highly rated investigator-initiated projects it receives – down from a 30% success rate in 2003. What is more, the first-year grants that are awarded are funded at 18% below the level recommended by NIA's own independent review panels. There are no inflationary adjustments in the out-years or for existing projects. This means that most scientific opportunities are left on the table, and the successful ones are being seriously under-funded. It also means that some of the most promising clinical trials – the way to translate basic research findings into effective treatments – will be delayed or scrapped altogether. And I can say with certainty that we are losing a generation of scientists, who are either choosing less traditional careers or else are leaving research altogether. These brilliant minds are our greatest resource, and we should be applying them to our most difficult problems.

Only money will bring them back.

These budget cuts are not just killing research projects. They are killing the minds of millions of Americans. And they are killing your chances of getting health care spending under control. If we let the disease continue on its current trajectory, in less than 25 years Medicare will be spending almost \$400 billion on 10% of its beneficiaries – those with Alzheimer's. That is

almost as much as we are spending in the entire Medicare program today. Medicaid will be spending another \$50 billion on people with Alzheimer's disease.

We can cut that spending in half – saving over \$200 billion annually -- with treatments to delay the onset of Alzheimer's and slow its progression. And we can also save millions of families from devastation. By 2030, there would be 1 million fewer cases of Alzheimer's in the United States than there are today -- in spite of the rapid aging of the baby boomers. And among those of us who would still get it, most would never progress beyond the mild stages of the disease and could continue to live productively with our families in the community.

Senators, we are in a race against time. With every year that passes, we risk losing that race. We urge Congress to add the funding we need to break through the finish line ahead of the baby boomers who are nipping at our heels. Thank you.