Karen Duff, PhD, a key clinical staffer at the Taub Institute for Research on Alzheimer’s Disease Research at Columbia University Medical Center, is frustrated. National Institutes of Health (NIH) funding for Alzheimer’s disease (AD) research has hit the skids.

She said, “The last few years have been exceedingly bad for Alzheimer’s disease research funding. I have never before seen my research colleagues have to leave their positions, or leave science altogether, because they have not been able to secure NIH funding. The usual casualties are the more junior faculty. But I have seen it happen to senior faculty also, here at Columbia, one of the powerhouses of Alzheimer’s disease research.”

Is help for AD drug research on the way?

In February, the Obama Administration released the Draft National Plan to Address Alzheimer’s Disease.1 The draft laid out a broad strategy, touching on but going beyond drug development, meant to speed the development of effective prevention and treatment modalities by 2025. As an initial down payment, the National Institute of Aging (NIA) at the same time announced that it was increasing its AD research budget by $50 million in fiscal 2012 (the current fiscal year, which ends on September 30, 2012). President Obama has proposed increasing the NIA’s AD budget for fiscal year 2013 by a total of $80 million. Congress will have a say in whether that happens.

Mark Weber, a spokesperson for the Department of Health and Human Services (DHHS), states that the $80 million increase would bring federal AD research funding in fiscal year 2013 to $529 million, up from $498 million (including the extra $50 million) in fiscal year 2012. The NIA is a primary funder of large investigator-initiated clinical trials, including the Alzheimer’s Disease Cooperative Study (ADCS). The DHHS will publish a final plan for AD this spring.

The Alzheimer’s Association says, “As this draft plan is revised, the Alzheimer’s Association urges the administration to specify the level of resource commitment that will be needed to meet the goal to prevent and effectively treat the disease by 2025.”

Some members of the Alzheimer’s Advisory Council say it will take funding at $2 billion each year—similar to what was and is being spent on AIDS research—to achieve the same kind of positive results that occurred with new AIDS therapies.

The draft plan acknowledges what is clearly no secret to the 11 million caregivers responsible for the estimated 5.3 million Americans with the disease. The report states: “While research on AD has made steady progress, there are no pharmacological or other interventions to definitively prevent, treat, or cure the disease.”

The need for pharmaceutical interventions for patients with AD is clear. According to a report by the Alzheimer’s Association, $172 billion is spent annually on AD and on other health care for patients with dementia in the U.S. Medicare’s share is $88 billion, which is 17% of its total budget. Medicare beneficiaries with AD or another form of dementia cost the system three times as much as patients who do not have dementia. For Medicaid, the cost multiplier is nine times for patients with dementia.

The pharmaceuticals that are available today for the treatment of AD are mostly acetylcholine boosters, which basically treat the symptoms, not the cause. Some newer potential treatments in late-state trials have flopped, such as Eli Lilly’s semagacestat, a gamma-secretase inhibitor of the final step in amyloid-beta protein synthesis. Phase 3 trials, which included more than 3,000 patients, were halted after results suggested worsening of cognitive decline and the development of skin cancer, thus indicating little promise for this class of drugs. Eli Lilly is now conducting two phase 3 trials for solanezumab, a monoclonal humanized antibody that binds to beta amyloid. This drug is being studied as a potential therapy to slow the progression of mild-to-moderate AD, according to Lilly spokeswoman Stefanie Prodouz.

In the area of pharmaceutical development, the draft plan includes a strategy to expand research aimed at preventing and treating AD. This appears to include commitments to both basic and applied research (i.e., clinical trials). But there is a big hill to climb here. The draft recognizes that an “incomplete understanding of the disease mechanisms that lead to AD is a major barrier to the discovery of effective therapies.”

On May 14 and 15, the NIA is scheduled to convene the Alzheimer’s Disease Research Summit 2012 in Bethesda. The DHHS will also pursue research partnerships with the private sector.

In the area of basic research, the NIH has committed to undertake an initiative to conduct whole-genome sequencing to identify areas of genetic variation that correspond to increased risk (risk factors) or decreased risk (protective factors) of AD.

The draft also supports an expansion of clinical trials, and enrollment within them, to discover pharmacological and non-pharmacological ways to prevent AD and manage and treat its symptoms.

A lot is riding on the success of the national plan for AD. Representative...
Donna M. Christensen (D-Virgin Islands), addressing the House, said:  

Today, the effects of Alzheimer’s disease are devastating to the estimated 5.3 million Americans with the disease. This disease is on course to be our country’s leading public health crisis of the 21st century and [the] defining disease of the baby-boom generation. If we don’t succeed in changing the trajectory of the disease, by the middle of the century as many as 16 million Americans could have Alzheimer’s.

Ms. Christensen is the sponsor of the National Alzheimer’s Project Act, which President Obama signed on January 4, 2011, as a requirement for development of the AD plan.

REFERENCES