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(Dementia)
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Dr Alison Clegg
Committee Secretary
House of Representatives Standing Committee on Health & Ageing
PO Box 6021
Parliament House
CANBERRA ACT 2600

Dear Dr Clegg,

**HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON HEALTH & AGEING
INQUIRY INTO DEMENTIA: EARLY DIAGNOSIS & INTERVENTION**

The impact of the progress of dementia on a person, their family, their friends and their community is usually devastating. The rising incidence and impact of dementia on Australia and globally is well documented.

The motivation to diagnose and potentially intervene in any of the several underlying causes of dementia is currently affected by the state of understanding of those underlying causes, significant limitations in available treatments, awareness amongst treating clinicians and stigma associated with the condition.

Eli Lilly & Company (Lilly), a research based pharmaceutical company, is strongly focused on investigating the better diagnosis and possible treatments for Alzheimer's disease, the most common type of dementia. Better diagnosis and better treatment options may help remove some of the current barriers.

Alzheimer's disease

Alzheimer's disease is a degenerative condition that destroys brain cells and nerves disrupting the transmitters which carry messages in the brain. The destruction of cells causes the structure of the brain to shrink with gaps developing in the temporal lobe and hippocampus. This has a progressive impact on the sufferer's ability to remember, speak, think, and make decisions and, as a consequence, their behaviour and physical condition.

This progressive decline reaches into every area of a sufferer's life from remembering familiar names and faces, finding the local shops, driving a car, caring for oneself, even recognising a husband or wife. This decline is reflected in the experience of friends, family and partners who slowly lose the person that they knew.

The exact mechanism that causes nerve cells to die remains under close investigation. It is characteristic that 'tangles' and 'plaques' made from protein fragments are observed in damaged areas of brain. A key focus of research has been on one of the main components of the plaque deposits, the peptide Amyloid beta.

Motivation to diagnose and intervene

Lilly strongly endorses the view that, in the absence of better treatments, there are a range of benefits attributed to the early diagnosis and management/treatment of Alzheimer's disease. These include the better allowance for sufferers to plan and organise their affairs; a decrease in the cost impact of the disease through better treatment planning and the opportunity to optimise management of chronic co-morbidities such as diabetes or heart disease in cognitively impaired patients.

In its global work with clinicians, including in Australia, Lilly understands that key barriers to diagnosis or seeking diagnosis for Alzheimer's disease include the current level of understanding of the condition and its several underlying causes; the complexity of the current diagnostic regimes; the associated stigma and the limits of current treatment options. Of key concern for a number of Australian clinicians is a lack of standard treatment guidelines. In relation to intervention it has been said that it is hard to justify subjecting a patient to diagnosis and a positive finding of Alzheimer's disease if there are limited treatment options.

There are a number of organisations investigating the next-generation of potential diagnosis mechanisms and treatments for Alzheimer's disease, including Lilly. If this research is successful, we believe more effective treatments will help motivate clinicians and patients to seek a better understanding of the condition and to pursue treatment. Better treatment will also help address the stigma associated with the condition.

Work on treatments for Alzheimer's disease

There is, currently, no cure for Alzheimer's disease. Nor are there any treatments that can change the rate of functional decline in affected patients. As indicated, Lilly is one of a number of organisations investigating the next-generation of potential treatments for Alzheimer's disease. Lilly is researching a number of treatments on disease modification – that is slowing the progression of the disease, particularly in sufferers with mild to moderate progression. The most advanced of these is currently in Phase III clinical trials. It is currently anticipated that Lilly's results from that trial will be published in the fourth quarter of this year.

Attenuating the progression of the disease would allow people to remain independent for longer. In doing so it would provide both economic benefits, through healthcare cost savings and minimising disruption to the productivity of carers, as well as the much broader benefits of less impaired lives.

Work on the diagnosis of Alzheimer's disease

Lilly is also one of a number of organisations investigating the next-generation of diagnostic mechanisms for Alzheimer's disease. One of these, an imaging agent that allows an estimate of the density of Amyloid beta plaque in the brain, has recently been approved for use in the United States by the Food and Drug Administration. A clearer picture of the presence of Amyloid beta plaque will assist in the assessment of a patient with suspected Alzheimer's and will be a significant advance on the current reliance on autopsy findings to definitively diagnose Alzheimer's disease.

About the development of medicines

The process of discovery, investigation and trial of potential medicines is extremely rigorous and has a very high failure rate. Potential medicines are eliminated at each stage of development

including each of the three phases of clinical trials. In recent years Lilly alone has experienced the failure of five candidate treatments that had progressed as far as phase III. These candidate treatments had offered the possibility of treating conditions ranging from osteoporosis, diabetes, multiple sclerosis and most recently, Alzheimer's disease.

There is no guarantee that Lilly's current candidate treatment for Alzheimer's disease will be successful.

Infrastructure

Several of these next-generation treatments are based on mono-clonal anti-bodies (Mabs). Due to the larger size of the active components of these Mabs, compared to a traditional chemical treatment, the treatments will involve regular infusions (for example, monthly) which will require patients to attend an infusion facility. Given the volume of dementia patients there is not currently sufficient provision for the likely demand for infusion services within the Australian healthcare system. If the current research efforts are successful, awareness and earlier detection will need to be supported by appropriate infusion infrastructure.

Infrastructure issues also extend to diagnosis. The next generation of diagnostic tools are supported by geriatricians and sophisticated diagnostic imaging equipment. In the case of Lilly's imaging agent a Positron Emission Topography (PET) scanner is required. Clinicians and imaging equipment within the Australian healthcare system are currently overstretched.

If, as hoped, the new generation of treatments and diagnoses arrive over the next couple of years we would strongly recommend a coordinated, national approach to these infrastructure issues to ensure there is no inequity created in such a ubiquitous, high social impact disease like Alzheimer's. All parts of the mental health sector will be looking to governments, Federal and State, to jointly lead the debate and action plans on addressing any diagnosis and care delivery gaps.

Early diagnosis of dementia & intervention

Lilly is working, globally and in Australia, to help remove the barriers to early diagnosis of and better intervention for dementia. We look forward to continuing its efforts and working with all parties to support initiatives, including those of this Committee, to provide dementia sufferers longer, healthier, better lives.

If you have any queries concerning this submission, please do not hesitate to contact Stuart Englund on (02) 9325 4669 or at englundst@lilly.com in the first instance.

Sincerely,

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Medical Director
Eli Lilly Australia