

## The search for a dementia cure rests on helping innovators

### Governments must steer private funding towards difficult diseases

DAVID RICKS

Innovation can change the maths of Alzheimer's disease. But to do that, governments need to change the maths for innovators. The estimated annual global cost of care for people with Alzheimer's and other forms of dementia is \$1tn, similar to total global spending on all pharmaceuticals. And Alzheimer's costs are expected to double in 10 years as the number of patients rises from 50m to 82m.

But current intellectual property laws discourage companies from investing in drugs that treat slow-progressing, difficult diseases such as Alzheimer's. It is the only disease among the top 10 global causes of death that lacks a treatment to slow it down. Failure rates have been higher in Alzheimer's drug development than in almost any other disease. In cancer, one in five drugs completes testing successfully; in Alzheimer's, it is one in 200. Pharmaceutical companies are studying more than 20 times as many drugs for cancer than for Alzheimer's, even though the societal costs of each disease are about the same.

One reason is the difficulty of finding clinical trial participants. At least half of dementia patients are not clinically diagnosed — far higher than for other diseases. It has also been difficult to identify patients soon enough for a treatment to be effective. Alzheimer's tell-tale clumps of amyloid beta protein appear in the brain 10 to 20 years before patients experience any change in thinking or memory. Scientists have developed new tests that can diagnose Alzheimer's before

symptoms appear. But these tests are not widely available. And none can yet be the endpoint of a clinical trial, which would shorten the time needed to determine whether potential treatments work.

Shorter clinical trials are key to encouraging private investment, which helps fund more than 70 per cent of Alzheimer's studies. We know this from cancer trials, where private funding tends to flow to cancers with shorter potential survival times. This is because drugs

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that need longer trials — to test earlier interventions or treat slower-progressing cancers — are less productive investments to the company developing them.

While patents disallow copycat versions of a new medicine for 20 years, that clock typically starts before clinical trials begin and years before a medicine is approved for sale. The longer the trials, the less time the company has to sell it. But innovative companies can be encouraged to put more money into diseases with longer development times. Governments can grant periods of "data exclusivity" during which rivals cannot

introduce a copycat medicine without conducting their own clinical studies.

Data exclusivity begins when a new medicine is approved for sale. For drugs developed quickly, the period of data exclusivity overlaps substantially with the patent term, offering little additional benefit. But for drugs that take longer, it offsets the time lost to extended clinical trials. Right now, governments offer a range of data exclusivity protections, from 12 years to none. Making at least 12 years the standard would spur investment into difficult and slow-progressing diseases such as Alzheimer's.

Some people argue the way to cut healthcare costs is to reduce intellectual property protections. But a strong IP system produces breakthroughs today and bargains tomorrow. An effective Alzheimer's medicine would, after a typical post-approval patent life of 13 years, go on delivering value for decades. Nothing in healthcare is more productive.

Governments face a clear choice. Unless we steer private funding to difficult diseases, Alzheimer's will remain an unchecked public crisis. A 65-year-old woman whose brain is accumulating amyloid clumps is still years away from an Alzheimer's diagnosis. Yet a medicine created today is, on average, 14 years away from helping her. Her hope — and ours — is to find a breakthrough now.

*The writer is chief executive of Eli Lilly and president of the International Federation of Pharmaceutical Manufacturers & Associations.*