Business

A Breakthrough For Alzheimer's Patients -- And A Need For More

By Peter J. Pitts
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The FDA just approved a new Alzheimer's medication for the first time in nearly two decades. The drug, aducanumab, could potentially slow patients' cognitive decline. This is a medical innovation of the first order.

And yet, this tremendous breakthrough has led to some ignorant hand wringing. Detractors are questioning the drug's clinical effectiveness and balking at its $56,000 list price.

United States. By greenlighting aducanumab, which is administered via a once-a-month intravenous injection, the FDA has given patients with mild cognitive impairment or early dementia something that yesterday's patient's didn't have: hope.

That is worth plenty in and of itself. But the approval can also help address the economic cost of Alzheimer's disease, which threatens to swamp the U.S. healthcare system. Treating Alzheimer's currently costs more than $305 billion a year. That figure will likely exceed $1 trillion by 2050 unless new treatments or cures are developed, according to a study published in the American Journal of Managed Care. A medicine that slows cognitive decline will significantly help rein in these costs.

Will it work? The FDA granted accelerated approval to aducanumab for its ability to clear amyloid, a form of plaque that develops on patients' brains. By clearing these plaques, the drug may deliver the kind of cognitive benefits that previous treatments have failed to provide. Under the accelerated approval process, aducanumab's maker, Biogen, is required to conduct a new effectiveness trial. If the company can't demonstrate cognitive benefits, the FDA could reverse its decision.

The Accelerate Approval Program, often used for innovative cancer treatments, "can bring therapies to patients faster while spurring more research and innovation," according to the director of the FDA's Center for Drug Evaluation and Research.

Critics of the FDA decision are correct to point out that uncertainties remain. Welcome to science! We have to embrace innovation while also monitoring products in the real world to ensure they maintain a solid benefit/risk profile. That is exactly what's happening. Kudos to the FDA for choosing the course of action with the most potential upside for Alzheimer's patients, their families, and our health system as a whole.

Some pundits and politicians have also criticized the drug's price, with some even using this high list price to drum up support for a drug-pricing bill. That bill, known as H.R. 3, would cap prices on a wide range of new drugs, with limits based on prices paid in other developed countries.

But this is the wrong response to the Alzheimer's crisis. More than anything, patients need sustained progress towards better treatments. Importing foreign price controls, as H.R. 3 does, would slash drug-company revenues and discourage firms from funding new research into Alzheimer's and other serious and life-threatening diseases.

Medical innovation isn't cheap. It costs more than $2.5 billion to create just one new drug, after all. But in the case of Alzheimer's -- a potentially $1 trillion-a-year epidemic -- the cost of inaction far exceeds the cost of progress.

Judging from their decision to move ahead with aducanumab, FDA officials understand this. Given the scope and severity of the Alzheimer's crisis, the agency made the right choice.

Peter Pitts, former associate commissioner of the FDA, is president of the Center for Medicine in the Public Interest.