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Alzheimer's Anxiety

By Ezekiel J. Emanuel

PHILADELPHIA — ALMOST every day I worry about whether my parents have Alzheimer's. My dad is 86 and my mother is about to turn 80. Just because of their age they are at high risk for the disease, and I constantly wonder if their forgetfulness is "normal" or a sign of the worst.

All of us are afraid of Alzheimer's. We worry about having a parent with it or getting it ourselves. Many believe they would rather die.

It is no wonder we fear the disease. Alzheimer's gradually robs its victims of their identities. While many remain happy and unbothered by their forgetfulness, they inevitably become different people, living largely in whatever part of the past they can remember. Eventually, they have to be fed and taken to the bathroom — their existence ever constricting as they drift further and further from their former selves.

The personal effects are devastating, but so are the societal ones. In 1980, nearly three million Americans had dementia caused by Alzheimer's. That number has since doubled. Some estimates show that, in the next 40 years, it will increase almost threefold, to 16 million. This is because the greatest risk factor for developing Alzheimer's dementia is old age, and America is rapidly aging. One in nine Americans over 65 have the disease, and one in three over 85. This adds up to $200 billion a year in health care costs, not counting the tens of billions in unpaid care that families provide.

The costs of the disease, along with the uncertainty over both diagnoses and treatments, is scary, especially for can-do Americans. So it's only natural that, in recent years, people have trumpeted the development of a new test that can measure the presence of beta-amyloid — the protein clumps in the brain that are one of the hallmarks of Alzheimer's dementia. The patient is injected with a radioactive molecule that zeros in on beta-amyloid, and a positron emission tomography, or PET, scanner then detects the radioactivity.

In April 2012, the Food and Drug Administration approved Eli Lilly's radioactive molecule for patients who are being evaluated for Alzheimer's disease and other causes of cognitive decline that result in forgetfulness or disorientation.

In September, Medicare announced that it would pay for the test — which costs between $3,000 and $5,000 and is often not covered by private insurance — but only if the patient was part of a randomized, controlled trial, which is the only way to definitively determine the value of the scan.

Eli Lilly has objected to the ruling, contending that the test should be covered without

restriction. And the Alzheimer's Association, a leading research advocacy and patient support organization, has posted on its website, "Despite the concerns and complications, we believe it is valuable to the Alzheimer field — to the pursuit of better Alzheimer diagnostics, treatments and preventions — to have this product more widely available."

But the Alzheimer's Association isn't entirely unbiased. Since 2008, it has received $1.6 million from Lilly. And in 2012 it received more than $4 million from all drug companies — many of which are selling Alzheimer's drugs.

The question patients and their families should be asking is, what does this test really offer?

Let's be clear: it does not cure the disease or affect symptoms. At best it identifies what might be causing a patient's forgetfulness. But, at worst, it can get that diagnosis wrong. According to the company's own post-mortem study of 59 terminally ill patients, false positives in scans for the presence of amyloid were reported in up to 3 percent of cases, while up to 20 percent of cases resulted in a false negative: patients were diagnosed as not having amyloid and thus Alzheimer's, even when they did.

To make things more confusing, while colloquially called an "Alzheimer's test," the scan doesn't diagnose Alzheimer's dementia — it only determines the presence of amyloid. And our understanding of the connection between the two is shaky. While everyone who has Alzheimer's also has amyloid, not everyone with amyloid has Alzheimer's dementia. Almost a third of cognitively normal elderly people have these protein clusters in their brains. On the scan they would light up. But those patients don't have Alzheimer's dementia and we don't know how likely they are to develop it in the future. Imagine the anguish of that error.

In fact, the only thing the scan can do is confirm that a patient's cognitive problems are not caused by Alzheimer's.

Even if it could diagnose Alzheimer's, it probably wouldn't make much difference to patients. Currently, there are five drugs on the market that treat dementia. None can cure the disease. None can change the downward trajectory of cognition. At best, they can relieve the symptoms of patients with moderate to severe Alzheimer's for about six to 12 months. And let's not forget these drugs all have side effects like fatigue, dizziness and pain.

Even those who advocated the general approval of the scan never argued that it would help patients decide whether or not to use medication: these drugs are not preventive; they are taken only by people who already have advanced Alzheimer's dementia. As one expert who is collaborating with Lilly put it: "Having an amyloid scan is hugely helpful not in determining drug therapy but for other things" — like planning.

But today, individuals 55 or younger are likely to live past 80, which means they stand a good chance of getting Alzheimer's dementia. We don't need an expensive test to tell us that we should all be planning for the possibility of Alzheimer's — investing in long-term care insurance, exercising and staying socially active.

Alzheimer's disease is scary. But that is no reason for society to waste a lot of money on a test that really doesn't help. It is a reason for a lot more research on Alzheimer's,

including Medicare's randomized trial to evaluate the effectiveness of the test. This research will take time, but there is no other path forward.