

# CONTINUED PROGRESS TOWARD NEW TREATMENTS FOR ALZHEIMER'S DISEASE PROVIDES HOPE TO MILLIONS

As America's aging population expands, so does the increasing need to address and conquer Alzheimer's disease. It places significant burden on millions of Americans, their caregivers and our health care system as a whole.

## 6 MILLION AMERICANS

Today, more than **6 million Americans** suffer from Alzheimer's disease.<sup>1</sup>

## 7<sup>TH</sup> LEADING CAUSE OF DEATH

Alzheimer's disease is the **seventh leading cause of death** in the United States.<sup>2</sup>

## \$355 BILLION IN HEALTH CARE COSTS

Caring for individuals with Alzheimer's disease and other types of dementia **cost our nation \$355 billion** last year.

**COMMUNITIES OF COLOR ARE DISPROPORTIONATELY IMPACTED**, with one in three Native Americans impacted by Alzheimer's disease, and Black Americans and Hispanic Americans are at least two times more likely to develop Alzheimer's disease than non-Hispanic white Americans.

**PEOPLE WITH DOWN SYNDROME HAVE A GREATLY INCREASED RISK** of developing a type of dementia that's either the same as or very similar to Alzheimer's disease.

If left unaddressed, the number of patients with Alzheimer's disease is **expected to grow to nearly 13 million people by 2050 and impose more than \$1.1 trillion in annual costs on our nation**, not to mention the immeasurable impact on individuals, families and communities.<sup>3</sup>

Despite challenges and setbacks, biopharmaceutical researchers have pushed forward in the search for lifesaving treatments and cures.

Between 1998 and 2021 alone, there were 198 unsuccessful attempts in clinical trials to develop new medicines for Alzheimer's disease. In that same time frame, only four new medicines were approved to treat symptoms of Alzheimer's disease.<sup>4</sup>

## NEW CLASS OF THERAPIES

Last year, for the first time, research led to an entirely **new class of therapies directed at the underlying cause of the disease**, with one such therapy already FDA-approved.<sup>5</sup>

## 85 MEDICINES IN DEVELOPMENT

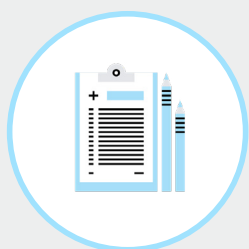
Today, there are also **85 medicines in development** for Alzheimer's disease.<sup>6</sup>

## 82.5% ARE POTENTIALLY DISEASE-MODIFYING

Of the medicines in development, **82.5% have the potential to be disease-modifying treatments**.<sup>7</sup>

## Policies that would limit access to Alzheimer's disease treatments, like the Centers for Medicare & Medicaid Services (CMS) proposed national coverage determination, are devastating for patients.

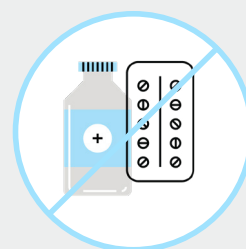
CMS is proposing a highly restrictive coverage policy that would limit coverage only to Medicare patients who are able and willing to participate in a CMS-approved clinical trial and do not have other health conditions that may significantly contribute to cognitive decline. This would worsen existing disparities in access to care, and patients with other conditions, like Down syndrome, could be prevented from accessing this new class of therapies. According to a recent analysis,<sup>8</sup> the proposed coverage policy will discourage continued R&D of treatments for Alzheimer's disease. If the proposed coverage policy was in place:



93% of Alzheimer's disease research projects underway would have negative returns on investment. If the policy had been in place at the outset of these projects, they may never have been undertaken.<sup>9</sup>



It would take three or more years longer for an Alzheimer's disease treatment to see a return on investment, with only three treatments currently in the pipeline seeing any positive return as opposed to the 39 estimated if the policy is not implemented.<sup>9</sup>



Many existing clinical trials for Alzheimer's disease treatments could be halted.<sup>9</sup>

**TREATMENTS FOR THIS DISEASE ARE DESPERATELY NEEDED, AND PATIENTS MUST BE ABLE TO GET THE TREATMENTS AS THEY BECOME AVAILABLE.**

1 2021 Alzheimer's Facts and Figures. <https://www.alz.org/alzheimers-dementia/facts-figures>

2 CDC, Leading Causes of Death. <https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>

3 2021 Alzheimer's Facts and Figures. <https://www.alz.org/alzheimers-dementia/facts-figures>

4 PhRMA Analysis of Adis R&D Insight Database. May 2021.

5 FDA press release, "FDA Grants Accelerated Approval for Alzheimer's Drug" June 2021. <https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-drug>

6 PhRMA Medicines in Development for Neurodegenerative Diseases Report, October 2021.

7 Alzheimer's Association. Alzheimer's disease drug development pipeline: 2021.

8 Vital Transformation, "The Impact on R&D Investment of the CMS Draft National Coverage Determination for Amyloid-directed Monoclonal Antibodies in Alzheimer's Disease," February 2022.