Older Americans

The Leading Chronic Diseases Impacting Older Americans

More Than 400 Medicines in Development for Leading Chronic Diseases Affecting Older Americans

Today, nearly 56 million Americans are 65 and older[i] and this population is projected to reach 80.8 million by 2040 and 94.7 million by 2060.[v] Good health can help people live independently and productively as they age. Yet, many live with chronic diseases–all of which can severely impact quality of life.

Older adults are disproportionately affected by chronic diseases, such as diabetes, arthritis and heart disease. Nearly 95% have at least one chronic disease, and nearly 80% have two or more.[ii] Chronic diseases can often limit an older adult's ability to work, perform daily activities, cause them to lose their independence and lead to the need for long-term care (e.g., in-home, institutional). The combined costs of managing chronic diseases account for two-thirds of all health care costs and 93% of Medicare spending.[vi] Yet, less than 3% of U.S. health care dollars are spent on prevention to improve overall health.[vii]

JUST THE FACTS

Americans 65 years of age and older accounted for

16.8%

of the total U.S. population in 2022.[i]

Nearly

95%

of older adults have at least one chronic disease/condition, such as diabetes, arthritis and heart disease.[ii]

Death rates increased for all age groups in 2021, with increases ranging from

2.4% to 3.8%

for Americans 65 and over.[iii]

Nearly

65 million

people are currently enrolled in Medicare.[iv]

America's biopharmaceutical industry has made notable progress over the past several decades to bring about a robust pipeline of potential new medicines for chronic diseases, including those affecting older adults.[vii] In the last few years, several medicines were approved to treat chronic diseases affecting older Americans, including the first in a new class of medicines to treat chronic kidney disease, a medicine for atherosclerotic cardiovascular disease and a treatment to reduce the risk of serious complications in chronic kidney disease associated with type II diabetes.

Medicines in the pipeline hold the potential to further address unmet needs and improve health outcomes for all Americans with chronic disease, including older adults. These potential medicines target some of the most common chronic diseases affecting older adults. For example:

- Several medicines in development for **Alzheimer's disease** are disease-modifying treatments that may stop or slow disease progression by targeting one or more of the changes in the brain associated with the disease. One monoclonal antibody medicine in development is a Tau protein inhibitor designed to block and reduce the spread of Tau from neuron to neuron and potentially from forming damaging Tau tangles, which is a hallmark of Alzheimer's disease and thought to contribute to Alzheimer's disease progression.

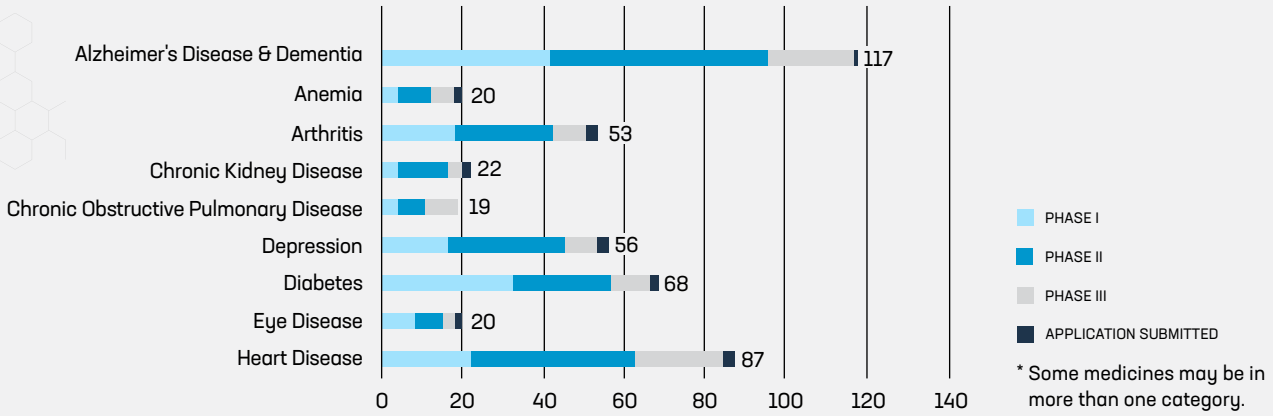
- A once weekly fixed-dose combination medicine in development for **type II diabetes** is comprised of a long-acting basal insulin analog and an approved GLP-1 (glucagon-like peptide-1) agonist. The long-acting basal insulin has the potential to reduce the number of insulin injections from daily to weekly. Research has found that the GLP-1 agonist has the potential to lower blood glucose by stimulating the release of insulin and may also lower body weight.

- A potential first-in class myeloperoxidase (MPO) inhibitor is in clinical trials for the treatment of **heart failure** with preserved ejection fraction – an advanced form of congestive heart failure – caused by microvascular inflammation. The investigational medicine inhibits MPO, which is known to cause the formation of hypochlorous acid and other free radicals that interfere with cardiac microvasculature (the tiny blood vessels in the heart). In preclinical models, MPO inhibitors have been found to reduce inflammation and fibrosis and improve microvascular function.

Medicines in the Pipeline

There are **447** medicines[ix] currently in clinical trials or under review by the U.S. Food and Drug Administration (FDA) for the treatment of conditions that disproportionally affect older populations. The medicines include:

Medicines in Development for Older Americans



Clinical Trials: Unique Challenges in Older Americans

America's biopharmaceutical industry is committed to planning and designing medical product development programs that promote inclusion of diverse populations in clinical trials and aim to understand the needs of those who are affected by the disease or condition being investigated. This can help maximize the generalizability of the trial results and provides the ability to understand the drug's benefit-risk profile across the patient population likely to use the drug once it is approved. In a recent FDA report,[x] 30% of clinical trials participants were 65 years of age and older.

In general, recruiting and retaining participants for clinical trials can often be challenging due to a number of factors. For older adults these may include:

1. Low levels of awareness about clinical trial opportunities
2. Concerns and or distrust of the clinical trial process
3. Not being offered a clinical trial as a potential treatment option
4. Transportation, logistic challenges if the individual can no longer drive themselves
5. Other conditions or medications that may mean the individual does not meet inclusion criteria

America's biopharmaceutical industry is committed to conducting clinical research that recognizes the demographics associated with diseases under study and the importance of ensuring that a wide diversity of patients are included in clinical trials. Enhancing diversity in clinical trial populations will lead to studies better reflecting the patient populations most likely to use the product under study if it achieves regulatory approval. When designing and conducting clinical trials, it is important to strive to create a clinical development strategy representative of the intended population. This includes, inclusion of individuals from a diverse range of backgrounds including, but not limited to race, ethnicity, sex/gender, and age in clinical trials through broad eligibility criteria and novel site placement and recruitment approaches. It is important to encourage inclusion of participants who are more likely to be treated for a disease or condition. For example, certain populations may be at higher risk for certain diseases, such as diabetes or heart disease. The biopharmaceutical industry is committed to working with the FDA, patient advocacy organizations and other stakeholders across the clinical research ecosystem to further collaborate and employ strategies to help increase participation of older adults in clinical trials. For example, the use of telehealth can reduce the number of in-person visits required for the trial and decrease travel burden. Engaging caregivers in the process can also increase patient adherence to clinical trials protocols.

Price Setting Provisions and the Unintended Impact on Biopharmaceutical R&D

Even though the stakes are high, the reported **447** medicines in the pipeline provide potential additional treatment options for Americans with chronic disease, including older adults.

The Inflation Reduction Act (IRA) passed in late 2022 included price setting provisions allowing the government to set the price of medicines covered by Medicare. The provisions ignore the natural R&D process and lay out a predetermined timeline after a medicine is initially approved, at which point the government can select a medicine for price setting. This discourages R&D for medicines impacting the Medicare population because it forces companies to decide whether it is worth investing time and resources into their development and whether they can recoup their costs. This also ignores the additional R&D that continues in the years following approval, the type of R&D which often leads to critical advances in treatment for patients with chronic diseases.

While the IRA will have a chilling effect on biopharmaceutical efforts to meet the unmet needs of patients, biopharmaceutical companies will continue to innovate but will have to make tough choices on which therapeutic areas to invest in. To continue to advance medical discovery for older adults, policymakers should make it a priority to preserve innovation in life-saving treatments and medicines for chronic diseases and the innovation that older Americans depend upon. That means an environment that is supported by a science-based regulatory system, strong intellectual property rights and a recognition that price-setting policies jeopardize both the engine of American innovation and a robust pipeline of novel medicines to address unmet needs.

In a survey, PhRMA member companies[xi] expressed concern with how price setting undermines current incentives for many advances critical to patients, including our nation's seniors. When asked, ***82% or more of companies with pipeline projects in cardiovascular, mental health, neurology and cancers expect "substantial impacts" on R&D decisions in these areas****.*

Sources:

i U.S. Census, www.census.gov/quickfacts/fact/table/US/PST045222
ii National Council on Aging, www.ncoa.org/article/the-inequities-in-the-cost-of-chronic-disease-why-it-matters-for-older-adults
iii Centers for Disease Control and Prevention (CDC), Mortality in the United States, 2021, www.cdc.gov/nchs/data/databriefs/db456.pdf
iv Kaiser Family Foundation, www.kff.org/interactive/medicare-spending/
v Administration for Community Living, 2021 Profile of Older Americans, November 2022
vi Centers for Medicare and Medicaid Services. Multiple Chronic Conditions. www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/MCC_Main
vii Rabah Kamal and Julie Hudman. What do we know about spending related to public health in the U.S. and comparable countries? Peterson-KFF Health System Tracker. Sept. 20, 2020. www.healthsystemtracker.org/chart-collection/what-do-we-know-about-spending-related-to-public-health-in-the-u-s-and-comparable-countries/
viii Medicines in Development 2022 Report: Chronic Diseases. September 29, 2022. https://phrma.org/resource-center/Topics/Medicines-in-Development/Medicines-in-Development-for-Chronic-Diseases-2022-Report
ix Number of medicines obtained through public, government and industry sources, and the Adis "R&D Insight" database; current as of **March 3, 2023**.
x U.S. Food and Drug Administration, www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots
xi Survey commissioned by PhRMA and conducted in November-December 2022 with 25 of 33 PhRMA member company responses.