

SELECTED MEDICINES IN DEVELOPMENT FOR DEBILITATING DISEASES OF AGING

Alzheimer's disease – More than 5 million Americans are living with Alzheimer's disease, with 98 percent of those over age 65, according to the Alzheimer's Association. A potential medicine in development is a humanized monoclonal antibody designed to remove beta amyloid protein from the brain and prevent or reverse progression of Alzheimer's disease. The medicine provides the patient with antibodies directly, rather than the patient having to create their own immune response to beta amyloid. This process – called passive immunization – may provide greater reduction or the elimination of safety concerns due to the lack of stimulation to the patient's immune response to beta amyloid.

Depression – In its many forms, depression affects more than 6.5 million Americans age 65 or older, according to the National Alliance on Mental Illness. One medicine in development is an inhibitor of a brain enzyme that is responsible for decreases of neurotransmitter levels that can cause depression. Depression is associated with decreased levels of three neurotransmitters – serotonin, norepinephrine and dopamine. These transmitters are needed to maintain normal mood, and when decreased, patients can become depressed. Currently available medicines that act against the brain enzyme – and help to maintain healthy levels of the three neurotransmitters – require dietary restrictions to avoid cardiovascular side effects. The potential new medicine is highly selective and allows normal metabolization of food and a diet free of restrictions.

Diabetes – Among Americans age 60 and older, 12.2 million have diabetes, according to the U.S. Centers for Disease Control and Prevention. Uncontrolled diabetes can lead to kidney failure, blindness, amputations and premature death. A new, first-in-class medicine in development addresses insulin resistance, the underlying cause of type 2 diabetes. The medicine selectively modulates genes responsible for insulin sensitization without activating genes responsible for weight gain and edema.

Epilepsy – A seizure disorder affecting more than 3 million Americans of all ages, with the highest incidence in children under the age of 2 and adults over age 65, according to the Epilepsy Foundation. A potential first-in-class medicine in development may treat epilepsy facilitating specific neuronal potassium channels.

Insomnia – The prevalence of insomnia is higher among older adults. According to the National Sleep Foundation’s 2003 *Sleep in America* poll, 44 percent of older persons experience one or more of the nighttime symptoms of insomnia at least a few nights per week or more. One potential medicine binds more selectively than currently marketed products at the specific subtype of GABA-A receptors within the brain believed to be responsible for promoting sleep.

Macular Degeneration – Age-related macular degeneration (AMD) currently affects 1.8 million Americans, but due to the rapidly aging U.S. population, that number is expected to rise to almost 3 million by 2020, according to the National Eye Institute. The potential first-in-class medicine targets vascular endothelial growth factor receptor-1 (VEGFR-1). VEGFR-1 is a key component of the VEGF pathway and is stimulated by both VEGF and PIGF (placental growth factor) resulting in the growth of new blood vessels (angiogenesis). The medicine is designed to reduce angiogenesis mediated by both VEGF and PIGF, a cause of age-related macular degeneration.

Parkinson’s disease – Approximately one million Americans suffer from Parkinson’s disease, and each year 60,000 new cases are diagnosed – one every nine minutes, according to the National Parkinson Foundation. Currently available treatments for Parkinson’s disease can diminish the symptoms of the disease, but do not replace lost nerve cells or halt the progression of the disease. A nervous system growth factor (gene therapy) is being studied. The therapy aims to deliver the growth factor, glial derived neurotrophic factor (GDNF), into the brain to prevent degeneration and the loss of the neurotransmitter dopamine.

* From *Medicines in Development for Older Americans*, PhRMA, 2008

SELECTED FACTS ABOUT DISEASE AND OLDER AMERICANS

10 LEADING CAUSES OF DEATH IN AMERICANS AGE 65 AND OLDER, 2004

1. Heart Disease (533,302)
2. Cancer (385,847)
3. Cerebrovascular Disease (130,538)
4. Chronic Lower Respiratory Diseases (105,197)
5. Alzheimer's Disease (65,313)
6. Diabetes Mellitus (53,956)
7. Influenza and Pneumonia (52,760)
8. Nephritis (35,105)
9. Accidents (unintentional injuries) (35,020)
10. Septicemia (25,644)

Source: *Deaths: Final Data for 2004*, National Vital Statistics Reports, Vol. 56, No. 5, November 20, 2007, National Center for Health Statistics, Centers for Disease Control.

Statistical Profile of Older Americans¹

- The older population (65 and older) numbered 37.3 million in 2006, an increase of 3.4 million, or 10 percent, since 1996. About 1 in 8, or 12.4 percent, of the population is an older American.
- Older women outnumber older men, 21.6 million to 15.7, respectively.
- The 85 and older population numbered 5.3 million in 2006 and is projected to increase to 8.9 million in 2030.
- In 2006, 39 percent of non-institutionalized older people assessed their health as excellent or very good (compared with 65.1 percent for people ages 18-64).
- Most older people have at least one chronic condition and many have multiple conditions. Among the most frequently occurring conditions of the elderly from 2004-2005 were: high blood pressure (48 percent), arthritis (47 percent), heart disease (29 percent), cancer (20 percent), diabetes (16 percent), and sinusitis (14 percent).

Acute Myocardial Infarction (Heart Attack)²

- Coronary heart disease (CHD-heart attack, angina pectoris or both) caused one of every five deaths in 2004. The average age of a person having a first heart attack is 64.5 for men and 70.4 for women. About 82 percent of people who die of CHD are age 65 or older.
- In 2008, the estimated direct and indirect costs of CHD are \$156.4 billion.

Age-Related Macular Degeneration (AMD)³

- The leading cause of blindness among white Americans is AMD, accounting for 54 percent of all blindness. AMD is strongly associated with increasing age, particularly after age 60. AMD rises dramatically in whites over age 80—more than 1 in 10 white Americans in that age group has vision loss from AMD.
- AMD currently affects 1.8 million people in this country. Due to the rapidly aging U.S. population, that number will increase to almost 3 million by 2020.

Alzheimer's Disease (AD)⁴

- Today, more than 5 million people are living with Alzheimer's—every 72 seconds, someone develops the disease. Some 4.9 million people with Alzheimer's are age 65

and older, but at least 500,000 people younger than age 65 either have early-onset Alzheimer's or another dementia.

- Alzheimer's disease is the most common dementia, accounting for 50 percent to 70 percent of cases. Vascular dementia (also called multi-infarct dementia, post-stroke dementia, or vascular cognitive impairment) is widely considered the second most common type after Alzheimer's.
- In 2000, an estimated 411,000 new cases of Alzheimer's were diagnosed. That number is expected to increase to 454,000 new cases a year by 2010; 615,000 annually by 2030; and 959,000 new cases a year by 2050. By that year, the number of people age 65 and older with Alzheimer's could be as high as 16 million unless researchers find a way to prevent or treat the disease.
- In 2004, Alzheimer's was listed as the "underlying cause of death" for 65,829 Americans. From 2000-2004, deaths from Alzheimer's increased by 32.8 percent, while the number one cause of death, heart disease, decreased by 8 percent.
- The direct and indirect costs of Alzheimer's and other dementias amount to more than \$148 billion annually. Costs to businesses for employees who are caregivers for people with Alzheimer's and other dementias amount to \$36.5 billion due to lost productivity, missed work, and costs to replace workers who leave their jobs to meet the demands of caregiving.

Asthma⁵

- Approximately 22.9 million Americans had asthma in 2006, including almost 2.5 million people over the age of 65. That year, more than 1 million people over the age of 65 had an asthma attack or episode.
- The annual direct health care cost of asthma is approximately \$14.7 billion; indirect costs (e.g., lost productivity) add another \$5 billion, for a total of \$19.7 billion dollars. Prescription drugs represented the largest single direct cost, at \$6.2 billion.

Cancer⁶

- The risk of cancer increases with age—about 77 percent of all cancers are diagnosed at age 55 and older.
- The primary risk factor for colorectal cancer is age, with more than 90 percent of cases diagnosed in individuals over age 50.
- The risk for ovarian cancer increases with age and peaks in the late 70s. Women younger than age 65 are about twice as likely to survive five years following diagnosis than women 65 and older, 56 percent and 29 percent, respectively.
- About 64 percent of all prostate cancer cases are diagnosed in men over age 65. African-American men and Jamaican men of African descent have the highest prostate cancer incidence rates in the world.
- In 2007, the estimated overall costs for cancer were \$219.2 billion.

Cardiovascular Diseases (CVD)²

- Since 1900, CVD has been the number one killer in this country every year but 1918. Nearly 2,400 Americans die of CVD each day, an average of one death every 37 seconds. CVD claims about as many lives each year as the next five leading causes of death combined (cancer, chronic lower respiratory diseases, accidents, and diabetes).
- Of the 80.7 million American adults who have one or more types of CVD, 38.2 million are estimated to be age 60 or older. In 1999, 23 percent of nursing home residents in that age group had a primary diagnosis of CVD at admission.
- In 2008, the estimated direct and indirect costs of CVD are \$448.5 billion.

Chronic Obstructive Pulmonary Disease (COPD)⁵

- In 2006, an estimated 12.1 million adults age 18 and older had COPD (an umbrella term for a large group of lung diseases, chiefly chronic bronchitis and emphysema).
- In 2006, an estimated 9.5 million Americans reported a physician diagnosis of chronic bronchitis. The highest prevalence rate was in the over 65 population (60.9 per 1,000 people).
- The emphysema prevalence rate is very low in those under age 45. Of the estimated 4.1 million Americans ever diagnosed with emphysema, 93 percent were 45 or older. In 2006, the emphysema rate in whites over age 65 (60.1 per 1,000 people) was more than 2.3 times greater than that in the population between 45 and 64 (26.3 per 1,000).
- COPD is an important cause of hospitalization in the older U.S. population. Some 65 percent of hospital discharges were in the 65 and older population in 2005. The discharge rate for the population over age 65 (126.9 per 10,000 people) was significantly different than the rate for any other group. For example, the rate in the over age 65 group was four times higher than that in the 45-64 age group (31.4 per 10,000).
- Chronic bronchitis and emphysema take a heavy toll on the U.S. economy—\$42.6 billion in 2007.

Congestive Heart Failure (CHF)²

- Congestive heart failure (CHF) incidence approaches 10 per 1,000 population after age 65. In 2004, CHF total mention mortality was 284,365. CHF was listed as the underlying cause in 57,120 of those deaths.
- In 2003, the estimated direct and indirect costs for CHF are \$34.8 billion.

Crohn's Disease⁷

- While Crohn's disease is often thought of as a disease of the young, about 25 percent of new cases are diagnosed in individuals over age 60.

Depression

- Depression in its many forms affects more than 6.5 million of the 35 million Americans who are age 65 or older. Depression in older people is closely associated with dependency and disability.⁸
- Symptoms of clinical depression can be triggered by other chronic illnesses common in later life, such as Alzheimer's disease, Parkinson's disease, heart disease, cancer, and arthritis. For example, nearly one-fourth of the 600,000 people who experience a stroke in a given year will experience clinical depression.⁹
- Depression is one of the conditions most commonly associated with suicide in older adults. Although they comprise only 12 percent of the U.S. population, people age 65 and older accounted for 16 percent of suicide deaths in 2004. That year, non-Hispanic white men age 85 and older were most likely to die by suicide, with a rate of 49.8 suicide deaths per 100,000 people in that age group.¹⁰

- Older patients with symptoms of depression have roughly 50 percent higher health-care costs than non-depressed seniors.⁹

Diabetes

- Among people age 60 and older, 12.2 million, or 23.1%, have diabetes.¹¹
- The total annual economic cost of diabetes in 2007 was estimated to be \$174 billion.¹²

Dry Eyes³

- Nearly 5 million Americans 50 years of age and older are estimated to have dry eye syndrome. Of these, more than 3 million are women and more than 1.5 million are men.

Epilepsy¹³

- Epilepsy and seizures affect more than 3 million Americans of all ages. Incidence is highest under the age of 2 and over age 65. Some 570,000 people over the age of 65 have epilepsy.
- Epilepsy's estimated annual direct and indirect costs are \$12.5 billion.

Glaucoma

- Open-angle glaucoma, the most common form of the disease, affects more than 2.2 million Americans age 40 and older.¹⁴
- Those at highest risk for glaucoma are African Americans over age 40 and everyone over age 60, especially Mexican Americans. The prevalence of glaucoma rises rapidly in Hispanics over age 65.³
- When comparing African Americans with Caucasians, studies show that glaucoma is five times more likely to occur in blacks than in whites and about four times more likely to cause blindness in blacks.³

High Blood Pressure (HBP)²

- The estimated 2005 prevalence for high blood pressure (HBP) was 73 million people (about 34 million males and 39 million females). Nearly one in three U.S. adults has HBP. A higher percentage of men than women have HBP until age 45. From ages 45-54, the percentage of men and women is similar. After that, a much higher percentage of women have HBP than men do.
- In 2004, HBP mortality was 54,707 (23,099 males, 31,608 females). HBP total mortality was about 300,000.
- In 2008, the estimated direct and indirect costs of HBP are \$69.4 billion.

Incontinence

- Urinary incontinence affects an estimated 38 percent of women and 17 percent of men ages 60 or older.¹⁵
- Of the elderly people living at home or in long-term care facilities, 50 percent or more are incontinent.¹⁶
- The medical and work-related costs of urinary incontinence are estimated to be \$26 billion per year.¹⁵

Influenza and Pneumonia⁵

- Influenza and pneumonia are most likely to require hospitalization in those over age 65. Data from 2005 show that people ages 65 and older accounted for 60 percent of the total number of pneumonia hospital discharges (the diagnosis made upon leaving a hospital stay). The number (36,000) and rate (9.8 per 10,000 people) of influenza discharges were both highest in those ages 65 and older.
- For the 65 and older population, pneumonia and influenza were the sixth leading cause of death in 2005. Nearly 90 percent of deaths due to these diseases occur in that age group.
- Together, pneumonia and influenza cost the economy \$40.2 billion in 2007.

Leukemia⁶

- Although often thought of as primarily a childhood disease, leukemia is diagnosed 10 times more often in adults than in children. In adults, the most common types are acute myeloid leukemia (approximately 13,290 cases in 2008) and chronic lymphocytic leukemia (approximately 15,110 cases).

Osteoarthritis (OA)

- Osteoarthritis, the most common chronic condition of the joints, affects approximately 33 million Americans. Although it occurs in people of all ages, it is most common in people older than age 65, affecting up to 80 percent of the elderly population.¹⁷ It is the leading cause of disability in that age group.¹⁶

Osteoporosis

- Osteoporosis and low bone mass are a major public health threat for an estimated 44 million Americans, or 55 percent of people age 50 and older. An estimated 10 million people have osteoporosis today, 80 percent of whom are women, and 34 million more people are estimated to have low bone mass, placing them at increased risk for osteoporosis.¹⁸
- In 2005, osteoporosis-related fractures were responsible for an estimated \$19 billion in costs. By 2025, experts predict that these costs will rise to approximately \$25.3 billion.¹⁹

Pain²⁰

- Pain is the number one complaint of older Americans. One in five older Americans take a painkiller regularly, although elders are among the most under treated for pain. Of the community-dwelling elder population, 25 percent to 50 percent can expect to suffer pain. Among institutionalized elders, up to 83 percent report at least one pain problem.
- The annual cost of chronic pain in the United States, including health care expenses, lost income, and lost productivity, is estimated to be \$100 billion.

Parkinson's Disease (PD)

- Parkinson's disease affects both men and women in almost equal numbers. Today, 1.5 million Americans have PD, and each year 60,000 new cases are diagnosed. While PD usually develops after age 65, 15 percent of those diagnosed are under age 50.²¹
- It is estimated that PD costs the U.S. over \$26 billion annually in disability costs and lost productivity.²²

Prostate, Enlarged (benign prostatic hyperplasia)¹⁵

- For men over age 50, the most common prostate problem is benign prostatic hyperplasia (BPH). An estimated 9 million men have BPH symptoms, and each year about 400,000 have surgery to remove some of the enlarged gland that impairs the flow of urine through the urethra.
- In 2000, BPH cost \$1.1 billion annually in direct expenditures for medical services provided at hospital inpatient and outpatient settings, emergency departments, and physicians' offices.

Rheumatoid Arthritis (RA)¹⁷

- RA affects some 1.3 million Americans. Seventy percent of people with RA are women, but men tend to be more severely affected when they get it.

Sepsis²³

- Sepsis caused by infection occurs in approximately one in five of all hospital admissions. More than 700,000 cases of severe sepsis occur in the United States annually.
- Death rates from severe sepsis are highly variable, but the overall rate is approximately one-third of all cases. Death rates vary considerably by age, ranging from 5 percent to 35 percent of young people to 37 percent to 50 percent of older people. On average, fewer than one-third of those who suffer an episode of severe sepsis are still alive one year later.
- Every minute of every day, two people die from sepsis in the United States. It is the leading cause of death in hospital intensive care units, taking more lives than breast, colorectal, pancreatic, and prostate cancer combined.
- By one estimate, sepsis is responsible for up to \$10 billion of the annual U.S. health-care budget.

Sexual Dysfunction

- Estimates of the number of men who experience erectile dysfunction (ED) range from 15 million to 30 million. Up to 25 percent of men at age 65 experience impotence. Diseases—such as diabetes, kidney disease, atherosclerosis, vascular disease, and neurologic disease—account for about 70 percent of ED cases.¹⁵
- Female sexual arousal disorder (FASD) affects up to 25 percent of all American women, or an estimated 47 million women. Three-fourths of women with FASD are postmenopausal.²⁴

Sleep Disorders

- Some 60 million Americans a year have insomnia frequently or for extended periods of time. It affects about 40 percent of women and 30 percent of men.²⁵ Insomnia is more common among people over the age of 65 than in those ages 18 to 34.²⁶
- Some researchers estimate that restless legs syndrome (RLS) affects 12 million Americans, but others estimate a much higher prevalence because RLS is thought to be under diagnosed or misdiagnosed. RLS occurs in both genders, although the incidence may be slightly higher in women. While the syndrome may begin at any age, even in infancy, most people who are severely affected are middle-aged or older, and the severity of the disorder appears to increase with age.²⁷

Stroke²

- About 780,000 Americans will have a stroke this year—that's someone every 40 seconds. In adults over age 55, the lifetime risk for stroke is greater than 1 in 6.
- Stroke accounted for about one of every 16 deaths in the United States in 2004. On average, every three to four minutes, someone dies of a stroke. Because women live longer than men, more women than men die of stroke each year. Women accounted for 61 percent of U.S. stroke deaths in 2004.
- The direct and indirect costs of stroke are estimated to be \$65.5 billion in 2008.

Sources:

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23. The Doctor Will See You Now, www.thedoctorwillseeyounow.com
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26. Insomnia 911, www.insomnia911.com
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SELECTED STATE FACTS ABOUT OLDER AMERICANS

State	Number of residents age 65 and older*	Percentage of residents age 65 and older with asthma**	Number of residents age 65 and older diagnosed with diabetes**
California	3,872,680	8.6%	708,000
Connecticut	455,981	5.1%	67,000
Delaware	112,882	6.1%	19,000
Florida	2,931,085	6.0%	489,000
Georgia	834,872	6.5%	171,000
Hawaii	175,331	3.9%	n/a
Illinois	1,403,661	7.1%	250,000

Indiana	737,452	6.9%	149,000
Iowa	393,565	5.3%	68,000
Maine	192,289	9.0%	30,000
Michigan	1,306,745	8.2%	221,000
Missouri	765,919	5.5%	124,000
New Jersey	1,107,485	6.1%	198,000
New York	2,494,425	5.8%	444,000
North Carolina	1,107,041	8.6%	209,000
Ohio	1,388,238	6.4%	261,000
Oklahoma	462,983	6.1%	84,000
Pennsylvania	1,833,398	8.6%	339,000
South Dakota	111,503	8.3%	17,000
Tennessee	829,622	7.7%	131,000
Texas	1,519,126	7.0%	410,000
West Virginia	240,850	8.0%	61,000

Top 10 states by number of residents age 65 and older*	Number of residents age 65 and older*	Top 10 states by percentage of residents age 65 and older*	Percentage of residents age 65 and older*
California	3,872,680	Florida	16%
Florida	2,931,090	Pennsylvania	15%
Texas	2,519,130	Maine	15%
New York	2,494,430	South Dakota	14%
Pennsylvania	1,833,400	Hawaii	14%
Illinois	1,403,660	Tennessee	14%
Ohio	1,388,240	Iowa	13%
Michigan	1,306,750	West Virginia	13%
New Jersey	1,107,490	Missouri	13%
North Carolina	1,107,040	Oklahoma	13%

*Kaiser Family Foundation, State Health Facts, 2006-2007

**Kaiser Family Foundation, State Health Facts, 2005