



Older Americans face new and growing challenges in managing chronic diseases, which are now the leading causes of death among people older than the age of 65.

A New Era In the Science of **AGING**

Every seven seconds someone in the United States is celebrating a 60th birthday.

This trend began Jan. 1, 2006, and will continue for 18 years. The first of the baby boomers will turn 65 in 2011. By 2030, when all of the baby boomers have reached age 65, the number of older Americans is expected to be 20% of the U.S. population, or about 70 million people.

The number of older people could lead to a crisis for the healthcare system.

“Because of the impact aging will have on healthcare and finances, we call it the ‘Silver Tsunami,’” says Daniel Perry, executive director of the Alliance for Aging Research. “The population at high risk will increase as much as four-fold in 25 years.”

He says a crisis could occur because as people live longer they develop chronic conditions, such as hearing and vision loss, bone loss, neurodegenerative conditions, Type 2 diabetes, and cardiovascular diseases.

“Many people are now surviving acute illnesses and are living long enough to develop chronic conditions,” says Patricia A. Grady, Ph.D., RN, director of the National Institute of Nursing Research (NINR), a division of the NIH. “The top 10 diseases in the United States are also among the top Medicare reimbursements.”

The promise of genetics is that it can identify the genes involved in a disease, and then we can prevent progression.

More than 900 new medicines are in development for diseases of aging:

- 399 for cancer
- 373 for debilitating diseases, such as Alzheimer's, diabetes, and osteoporosis
- 146 for heart disease and stroke

Source: PhRMA

TRACKING THE COSTS

More than two-thirds of current healthcare costs are for treating chronic illnesses; among older Americans, almost 95% of healthcare expenditure is for chronic diseases. Alzheimer's disease, for example, costs the nation more than \$50 billion each year in Medicare and Medicaid expenditures. These costs are projected to rise by as much as 54% by 2010. One in 10 Americans older than age 65 and almost half of those older than 85 suffer from Alzheimer's disease.

In fact, Alzheimer's disease has surpassed diabetes, influenza, and pneumonia as the most common cause of deaths for people age 65 and older, according to a July 2006 report from the National Institute on Aging.

Nation's Healthcare Workforce IS IT READY FOR THE GRAYING OF AMERICA?

The aging of America is more than a matter of numbers. The average 75 year old has three chronic conditions and uses five different prescription drugs; older patients also have unique healthcare challenges and different medical needs from younger adults. Unfortunately, America's healthcare workforce lacks the training to provide appropriate care at the present time, and it is wholly unprepared for the coming senior boom. There are far too few healthcare providers specifically trained in geriatrics; moreover, there is a gap between what many primary care providers know, and what they need to know, to optimally treat older patients.

Addressing this problem requires immediate attention and action at the national level and calls for:

- Increasing the funding for geriatric training
- Quickly incorporating new research into practice
- Adopting new practices to achieve change
- Enlisting the support of professional organizations to affect change
- Recruiting new people into geriatrics
- Enhancing the skills of community practitioners
- Developing interest in geriatrics across clinical disciplines
- Increasing geriatric education in healthcare at all levels

Source: CDC and the Merck Institute of Aging and Health

"Alzheimer's is of great concern to all of us," says John Hooper, Ph.D., president and CEO of Genizon BioScience Inc. "There isn't any available treatment that is effective on a long-term basis in terms of preventing the progression of Alzheimer's. The promise of genetics is that it can identify the genes involved, and then we can halt the disease's progression."

The average 75 year old has three chronic conditions and takes five different prescription medications. At least 80% of all older Americans are living with at least one chronic condition and 50% have at least two, according to a report by the Centers for Disease Control and Prevention (CDC) and the Merck Institute of Aging and Health.

According to a report from the National Institute on Aging, average prescription drug costs for noninstitutionalized Medicare enrollees age 65 and older have more than tripled during the decade from 1992 to 2002, increasing from \$542 to \$1,740. Average out-of-pocket costs, the amount that older people

have paid directly, increased over this period from \$326 in 1992 to \$686 in 2002. In 2002, private insurance covered about 36% of prescription costs, public programs covered 24%, and 39% of the costs were paid out of pocket.

"Because 20% of the older population is driving 75% of the costs of Medicare, it's necessary for research efforts to be directed toward chronic conditions," Mr. Perry says. "The race is on for innovative therapies before the elderly population doubles in 25 years and Medicare implodes."

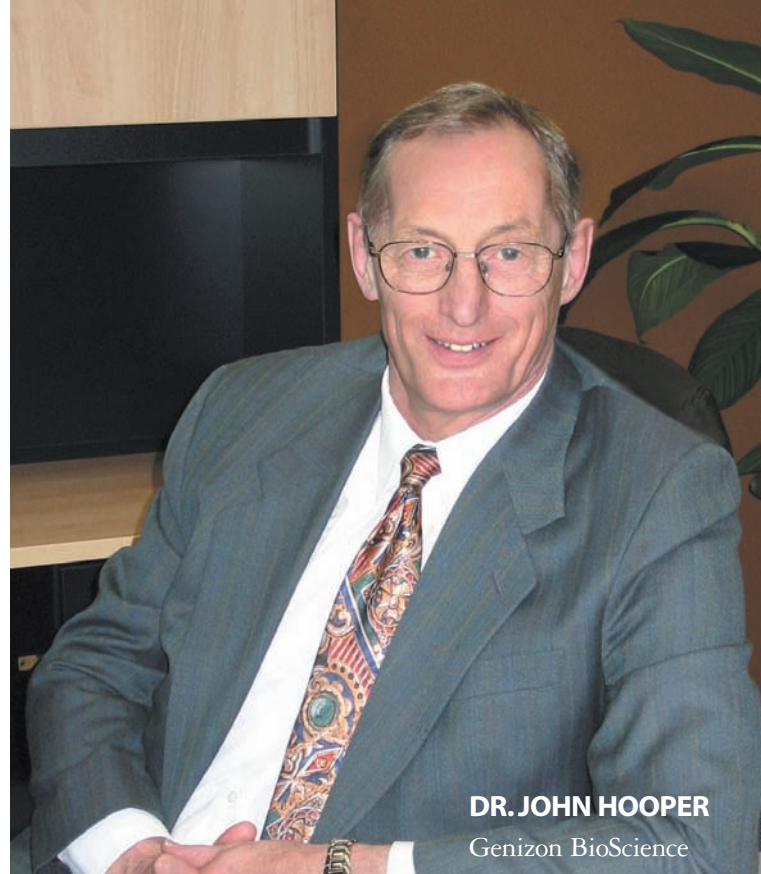
The challenge, he says, is predicting what the breakthrough treatments will be.

"Specific progress has been made in such areas as a shingles vaccine; Lucentis, a treatment for wet acute macular degeneration (AMD); retinal transplant cells for AMD; advances in treatments for heart disease, in particular anti-hyperlipidemia medications; and a rich pipeline for Alzheimer's," Mr. Perry says.

NEW OPPORTUNITIES

The National Institute of Aging, a division of the National Institutes of Health (NIH), is doing extensive research in many aspects of aging, including neurobiology, neuropsychology, and biology. Biological research is identifying opportunities to better understand the mechanisms of aging, facilitating creative approaches to changing needs in the field, and providing service and funding to investigators.

More than 900 new medicines are in development for diseases of aging, including 146 for heart disease and stroke, 399 for cancer, and 373 for debilitating diseases such as Alzheimer's, diabetes, and osteoporosis, according to a report from the Pharmaceutical Research and Manufacturers of America (PhRMA).



DR. JOHN HOOPER
Genizon BioScience

Diseases of AGING

The population of Americans older than 65 is surging, and the pace will only increase in the next couple of years. Indeed, beginning in just five short years, the first of more than 70 million members of the baby-boom generation will begin retiring and further swell the number of Americans older than 65. As life expectancy continues to expand, older Americans face new and growing challenges to their health, productivity, and independence — from geriatric conditions to complications from diseases such as cancer, cardiovascular disease, and diabetes.

The American pharmaceutical industry is working to help Americans live longer, healthier, and more productive lives.

A new survey finds more than 900 medicines are in development for diseases of aging, including 146 for heart disease and stroke, 399 for cancer, and 373 for such debilitating diseases as Alzheimer's, diabetes, and osteoporosis.

Other medicines in development target bladder and kidney diseases, eye disorders, gastrointestinal disorders, osteoarthritis, pain, prostate disease, respiratory and lung disorders, rheumatoid arthritis, skin conditions, and other conditions of aging. All of the medicines are either in human clinical trials or awaiting approval by the Food and Drug Administration. Many of the medicines use cutting-edge knowledge and technology to attack diseases in different ways. These include:

- A potential medicine that blocks the new blood vessel growth that causes one form of macular degeneration, the leading cause of blindness in Americans older than 65.
- A medicine for Alzheimer's that both inhibits plaque formation and blocks the degradation of the neurotransmitter acetylcholine.

Important as these new medicines in development are, the medicines only work if those in need can get them.

Fortunately, the effort to help seniors get the medicines they need at affordable prices has also improved with enactment of the Medicare prescription drug benefit. Beginning in 2006, all Medicare seniors were guaranteed a broad drug benefit for the first time, including 10 million seniors who lacked any drug coverage.

The average 75 year old has three chronic conditions and takes five different prescription medications.

At least 80% of all older Americans are living with at least one chronic condition and 50% have at least two.

Source: CDC and the Merck Institute of Aging and Health

“From the standpoint of fundamental molecular and cellular mechanisms, researchers have been doing a very good job at gaining insights into aging,” says George C. Prendergast, Ph.D., president and CEO of the Lankester Institute for Medical Research. (Dr. Prendergast is also a professor in the Department of Pathology, Anatomy & Cell Biology, at Jefferson Medical School, Thomas Jefferson University, as well as deputy editor for Reviews, Cancer Research.) “My opinion is that understanding the susceptibility of different individuals to inflammatory processes may be a major factor in aging that can be influenced by therapeutics. In any case, translating progress from the laboratory to medical practice continues to be problematic. One thing that is needed is a more realistic appreciation among basic researchers of what medicine needs to achieve in broad societal terms. A second thing that is needed is a better way to facilitate movement of creative new ideas from the laboratory into the commercial and clinical arenas that can appropriately recognize marketplace realities.”

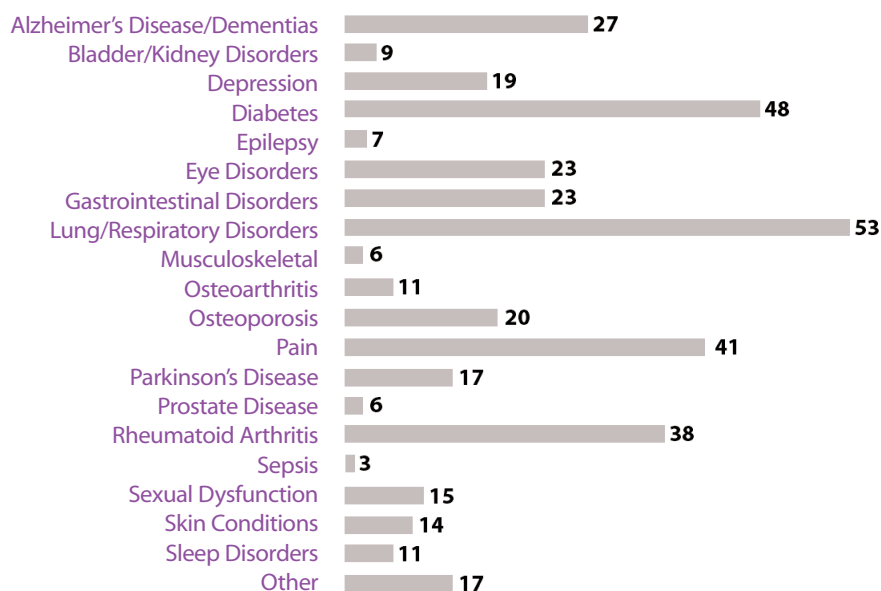
According to Dr. Prendergast, presently, U.S. research is organized into academic guilds that mesh poorly with the modern clinical and commercial arenas.

“One of the ways that my own institution is trying to break down these barriers is by creating an organization that melds together basic researchers, clinical investigators, and commercial start-up companies in a single entity,” he says. “Part of our equation is to change the terms of traditional nonprofit/for-profit partnerships with a ‘philanthropreneur’ philosophy that lies midway between the ‘all-heart’ grants and philanthropy tradition of nonprofits and the ‘all-head’ investment tradition of venture capital. Whatever the answer, it is clear that the traditions in all these spheres must become better integrated to relieve the bottleneck between the laboratory and patient.”

A number of major pharmaceutical and biotechnology companies as well as early-stage companies are trying to relieve that bottleneck through researching diseases related to aging.

For example, Sirtris Pharmaceuticals is a biopharmaceutical company developing novel therapeutics that modulate sirtuins, which are a recently discovered family of enzymes that promote normal cellular function. In particular, sirtuins improve the function of mito-

Medicines in Development FOR OLDER AMERICANS*



*Some medicines are listed in more than one category.

Source: PhRMA, Washington, D.C. For more information, visit phrma.org.



DR. TANNIN FUJA
The National Genecular Institute

Complex diseases in aging require a great deal of genetic data because they are multifactorial.

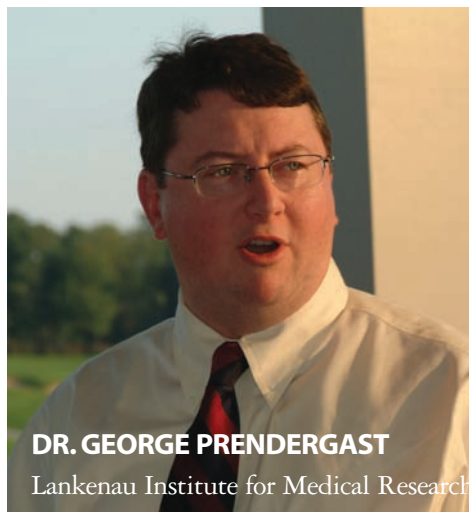
chondria, which generate energy in cells. When organisms face adversity, sirtuins are activated as part of a natural process that maintains healthy function.

In November 2006, Sirtris gained exclusive rights from the Massachusetts Institute of Technology for the discovery, development, and commercialization of assay and gene therapy technologies using the SIRT1 gene, the best characterized of the recently discovered family of sirtuin genes.

Activation of SIRT1 is believed to be a key pathway by which the body regulates such processes as glucose and insulin production, fat metabolism, and cell survival.

Sirtris has applied this scientific discovery to the development of Sirtris' lead product candidate, SRT501, which activates SIRT1, for the treatment of metabolic and mitochondrial disorders. Sirtris is studying SRT501 as a drug candidate for Type 2 diabetes in a Phase Ib clinical study.

Another company doing aging research is National Genecular Institute Inc. (NGI), a biomedical research and development subsidiary of Dermacia Inc. The company was formed in November 2004 with the ideal of extending the quality and length of life. NGI advances biomedical genetic and anti-aging research by identifying and characterizing complex human genetic and environmental factors affecting aging and disease develop-



DR. GEORGE PRENDERGAST
Lankenau Institute for Medical Research

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ment and formulating products and therapies to target issues specific to the individual customer, both for prevention and treatment.

The company has developed a biotrust in conjunction with the University of Iowa, which stores DNA and tissue samples from donors for research on anti-aging and wound-healing products.

"This biotrust is advancing medicine into the 21st century and beyond," says Tannin Fuja, Ph.D., director of research and chief scientific officer with NGI. "Complex diseases in aging require a lot of genetic data since they are multifactorial and co-occurring. The biotrust allows us to collect cell lines that are used repeatedly and are inexhaustible, yet provide for the individuality of the donor. Therefore, the biotrust is a fulcrum to advancing the therapies in personalized medicine."

The goal, he says, is to sell these DNA samples

to third-parties that are doing research on diseases such as Parkinson's disease, Alzheimer's disease, and multiple sclerosis.

"What is exciting about the biotrust is that donors have their clinical data updated every six months, and they can be included in clinical trials pertinent to their diagnosis," Dr. Fuja says.

Another company focused on aging is Auxilium Pharmaceuticals Inc., a specialty biopharmaceutical company that is developing and marketing pharmaceutical products for urology and sexual health.

"We want to help people grow old without suffering from a disabling disease," says Jyrki Mattila, M.D., Ph.D., executive VP of business development, R&D, and technical operations.

Beginning in 2012, almost 10,000 Americans will turn 65 every day, and by 2030 20% of the population will have passed their 65th birthday.

Source: CDC and the Merck Institute of Aging and Health

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DR. PATRICIA GRADY
National Institute of Nursing Research

In osteoporosis, we are studying genotypes to determine those who are more prone to bone loss so that we can target programs for these individuals.

The company markets Testim, which is approved for use in treating men with hypogonadism, a condition characterized by lower than normal levels of testosterone. Hypogonadism is a condition that affects 20% of the U.S. male population older than 50 years of age.

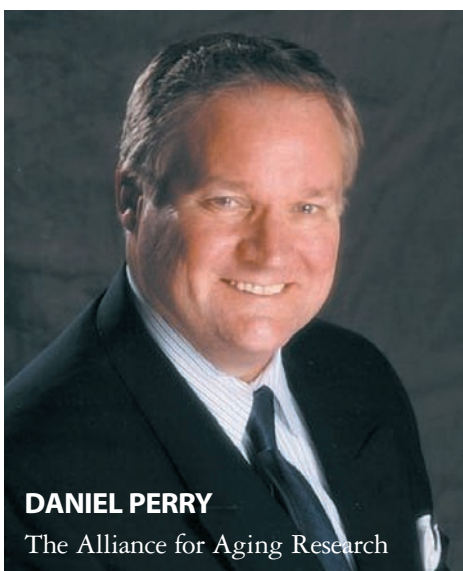
One of the company's development programs for conditions associated with aging is

Health COSTS

The increasing number of Americans age 65 or older has the potential to greatly increase the nation's already high healthcare costs:

- The cost of providing healthcare for one person age 65 or older is three to five times greater than the cost for someone younger than 65
- By 2030, healthcare spending will increase by 25% simply because the population will be older, and this is before inflation or new technologies are taken into account.
- Medicare spending has grown more than seven-fold in the past two decades, from \$33.9 billion in 1980 to \$252.2 billion in 2002, and is projected to double again by 2012.

Source: CDC and the Merck Institute of Aging and Health



DANIEL PERRY
The Alliance for Aging Research

AA4500, an injectable enzyme, which is in Phase III trials for the treatment of Dupuytren's contracture, a condition that

The race is on for innovative therapies before the elderly population doubles in 25 years and Medicare implodes.

affects the connective tissue that lies beneath the skin in the palm of the hand.

AA4500 also is in Phase II development for the treatment of Peyronie's disease, which is characterized by a plaque or hard lump that occurs on the penis, as well as frozen shoulder syndrome (Adhesive Capsulitis), which is characterized by the restriction in both active and passive range of motion of the shoulder joint.

Both Peyronie's disease and Dupuytren's contracture occur most often in men older than 50 years of age, and the incidence of both increases with age. ♦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

Experts on this topic

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Alliance for Aging Research, Washington, D.C.; The Alliance is a nonprofit organization dedicated to improving the health and independence of aging Americans through public and private funding of medical research and geriatric education. For more information, visit agingresearch.org.

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