

**PASSPORT TO INDEPENDENCE: BATTLING THE
LEADING CAUSES OF DISABILITY AMONG SENIORS**

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(II)

CONTENTS

	Page
Opening statement of Senator Charles E. Grassley	1
Statement of Senator John Breaux	2

MODERATOR

Daniel P. Perry, executive director, Alliance for Aging Research, Washington, DC.	4
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PANEL OF WITNESSES

Laurence Branch, research professor, Duke University Center on the Study of Aging and Human Development	8
Terrie Wetle, Deputy Director, National Institute on Aging	13
Marcelle Morrison-Bogorad, Associate Director, Neuroscience and Neuropsychology of Aging Program, National Institute of Health	28
Lindsey Kerr, Green Mountain Urology, and National Spokesperson for the National Association for Continence	38
Joan A. McGowan, Director, Musculoskeletal Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Health	44
Steven Pratt, M.D., senior staff ophthalmologist, Cosmetic Surgery and Eye Center, Scripps Memorial Hospital, La Jolla, CA	55

PASSPORT TO INDEPENDENCE: BATTLING THE LEADING CAUSES OF DISABILITY AMONG SENIORS

THURSDAY, JUNE 10, 1999

**U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.**

The committee met, pursuant to notice, at 9:05 a.m., in room SD-608, Dirksen Senate Office Building, Hon. Charles Grassley, (Chairman of the Committee) presiding.

Present: Senators Grassley and Breaux

OPENING STATEMENT OF SENATOR CHARLES GRASSLEY, CHAIRMAN

The CHAIRMAN. I would like to call the meeting to order. I am Chuck Grassley, Chairman of the Aging Committee, and I am here with my colleague and co-worker, Senator Breaux. The Aging Committee is sponsoring this meeting. We have worked very closely together on the entire agenda in a very bipartisan way.

So we both welcome you, and we will both give some short opening remarks, and then we will go to the rest of our meetings and get the fruits of your labor today through our staff and through the publication.

So I want to welcome all of you to today's forum. I appreciate your being here to discuss the results of a study that will be released today by the Alliance for Aging Research.

I am especially grateful to have a very distinguished panel of speakers that are here at the table already just waiting to go to work. Some of them have traveled a long way. And for those of you that really had to go out of your way to be here, we thank you especially for that. And, of course, we thank Dan Perry and his staff of the Alliance for Aging Research who have been very helpful in organizing the event.

The study being released today identifies the leading causes of disability in the older population. These conditions lead to nursing home care and often result in lost independence. Not surprisingly, they are conditions we are all very familiar with: Alzheimer's disease, vision loss, incontinence, osteoporosis and osteoarthritis. They have affected a lot of people we know, our mothers and fathers, aunts and uncles, grandparents.

There probably isn't a person in this room who has not been touched in some way by one of these conditions. Although they are not exclusively tied to old age, the elderly are the group most com-

monly afflicted. They take a toll not only on the person with the disease, but also on their families and friends who are often left to watch someone they love lose their independence. Families are often faced with caregiving responsibilities that are both financially and emotionally overwhelming.

As we work to prepare for both the aging of the baby boomer generation and increased longevity, there has never been a better time to address these conditions.

In my home State of Iowa, 15 percent of the people are over 65. We have the fifth largest percentage of elderly in the Nation. And though Iowa may have an unusually large percentage of older Americans, we all know that the demographic shift is not unique to our State, and there is going to be the greatest demographic shift in the history of our country, starting with the baby boomers retiring in 2010.

And that is why I am pleased to have this opportunity to highlight these conditions and to look at the positive steps that are being taken in both treatment and research to address these diseases.

Today, we have a great field of experts who will discuss new developments in research and areas of potential for the future. The panelists will also talk about methods to ensure that providers are better trained to assess risk and to intervene to prevent the loss of independence.

Our moderator will be the executive director of the Alliance for Aging Research, Daniel Perry. And in addition, we have many distinguished speakers here today.

My hope is that this forum will serve not only just as a catalogue of the horrors of these conditions, but more importantly as a reminder of new treatments and scientific breakthroughs, that are coming and more importantly, to consider a process that has not gotten us there yet, but that will get us there.

So I hope that we can all learn something today, and once again, I want to say thank you to the panelists for being here.

Senator Breaux.

OPENING STATEMENT OF SENATOR JOHN BREAUX

Senator BREAUX. Thank you, Chairman Grassley, distinguished members of the panel, Dan Perry and members of the audience.

I just want to join with Chairman Chuck Grassley, the Chairman of our Aging Committee—I serve, of course, as the ranking Democrat on the committee—in our enthusiasm for the discussion that you are going to hear and participate in this morning.

We have to go and leave this meeting to go to a Senate Finance Committee meeting. The subject there is Medicare and how we can make sure that that system is doing what it should do in the 21st Century for America's seniors, who make up the fastest growing segment of our population, as all of you know.

The report being released today points out something else that we know, that every day 6,000 more Americans celebrate their sixty-fifth birthday. They constitute about 13 percent of our total population. And those who are 85 and older, represent the fastest growing segment of our population. These are real statistics that have real policy implications for what we do as a society.

And as medical science and research has allowed for people to live longer than they have in the past, we must do more than just adding years to their lives, but we should make sure we also add life to those years. We need to make sure that the quality of their life in their golden years is all that it can be and should be, considering modern science and research.

And it is really particularly important from a research standpoint, which the panelists will address that we, as a Society, do things not to just postpone our birthdays, but to postpone the illnesses and the diseases that too often accompany those birthdays and make those later years void of the quality that they can and should have.

Every year, every day, every month that we can postpone the advent of some serious disease that particular affects the elderly is years that they will have a better quality of life. Not to mention the fact that we, as a society, will have a lot less of financial strain in caring for those people if we can help them to live healthier lives for longer periods of time.

So what we are talking about here with the Alliance for Aging Research is really very, very relevant to what we as a Congress are having to deal with in trying to find out how we can afford to maintain programs and make sure that the money is there. And one way we can do it is by adding quality and life to those extra years that we are all so proud of achieving.

So we congratulate this panel. I look forward to reading the report, and participating with them and implementing their findings into good public policy.

Thank you.

Mr. PERRY. Before Senator Grassley and Senator Breaux need to go to their next appointments, I want to thank them on behalf of the Alliance and on behalf of all of you who are going to participate in this officially sanctioned Special Committee on Aging Forum this morning to look at this issue.

The leadership of you, Chairman Grassley and Senator Breaux, has been outstanding on the issues of aging, aging research and the all-important issues that surround the Medicare program, where we believe that there is a strong forum there to talk about the quality of health care that we are able to deliver to older Americans, and that quality is refreshed constantly by what we are learning in laboratories and the new scientific developments that can keep older people independent, in their homes, in their communities as long as possible, and I want to thank you very, very much.

I want to say a special thanks to the staff. This is one of the great bipartisan committees to work with here in the Senate. And the staff leadership of Ted Totman, and Jill Greenlee and many, many others has been just terrific all along, and I want to thank you for that.

Senator BREAUX. We thought about parachuting in today, but we decided not to. [Laughter.]

The CHAIRMAN. I would not be able to do that. [Laughter.]

Dr. WETLE. We advise against it.

**STATEMENT OF DANIEL P. PERRY, EXECUTIVE DIRECTOR,
ALLIANCE FOR AGING RESEARCH, WASHINGTON, DC**

Mr. PERRY. I would like to just say for the record that my organization, the Alliance for Aging Research, is very pleased to be issuing a report today, "Independence for Older Americans An Investment for our Nation's Future."

The Alliance is a private not-for-profit advocacy organization that seeks to improve the quality of life of older Americans by making sure that the technological and scientific understanding of the aging process and of chronic age-related diseases moves as quickly as possible to the benefit of patients and the elderly of our country.

The report that we issue today does three things:

First, it documents billions of dollars that are drawn out of the health care system every year because older people make transitions from fully abled, fully independent in the community to lesser states of capacity to remain independent and, ultimately, some each year will enter a long-term care facility or a nursing home.

We have tried to sort out from the data of the current Medicare program what it costs because people lose that independence when they begin to make that downward slide toward dependency. We have taken into account what it costs to keep people who are healthy and independent, provide for their health care, as well as the total cost of long-term care.

But those numbers have been taken out of this equation, and we have looked strictly at the additional costs because a fully functional older person begins that slide. And that figure we have determined, through the help of a superb panel of experts, is an additional \$26 billion to the health care system. We identify this now as a flash point, where policies can impact how we can maintain independence for older people a bit longer, delay and postpone the onset of chronic debilitating diseases and improve both the quality of their life and make a major contribution toward equalizing health care delivery and health care costs in this country.

Clearly, we are looking ahead to an age of chronic medicine. Gone are the days when most of medical care in this country was directed at acute, immediate injury and diseases, infectious diseases. We now are looking ahead to a time when it will be the chronic age-related conditions that will drive health care costs and shape health care delivery.

Many of these conditions do not receive the kind of attention and subsequently public support that do the big, scary killer diseases. So we have attempted to shine the light on conditions like immobility, joint disease, osteoporosis, memory loss, mental impairment, urinary incontinence and vision loss, which can be terribly debilitating to one's ability to be independent and to remain living in their own community. These are place keeper conditions. There are many others that we could talk about. But the ones that we focus on in this report, those four: vision, incontinence, mental and memory impairment, and immobility are the ones that we believe stand in place for these diseases that seriously undermine the ability of older people to remain independent.

We also make specific recommendations to policymakers in this report. And let me highlight a few of them, although all six recommendations are listed in the report.

First, we are calling for adequate increases in research funding specifically directed at maintaining the viability of an older person to remain independent. We would like to see increases in the research on these conditions and others and see it directed through the National Institutes of Health toward maintaining functional independence for older persons.

Second, we ask that the debate over Medicare embrace an understanding that the quality of life and the quality of independence that older people will be able to have is dependent upon the investments we make in research and what we are able to translate into effective patient care. It seems that sometimes the Medicare debate is all about holding down costs, and it does not take into account the real functional benefits that are delivered to people because of the innovations that are able to be brought to them through the Medicare program.

We also ask that we have a greater emphasis on the outcomes of care. We need to know what really works, and then we need to put that into medical practice. And here we think that the work of the Agency for Health Care Policy and Research is essential, needs to be supported. We need to have a greater emphasis on identifying what really supports independence and health in older Americans and deliver that.

Last, we believe that there should be a reorientation of medical training in this country. It is appalling that, given that half of the patient population in this country are people over the age of 65, that there are a grand total of two full Departments of Geriatrics in the United States and that less than 3 percent of American medical students each year graduate without having taken a single course in geriatric medicine. We think that that is a misalignment with the real patient needs. So we want to see a greater infusion of geriatric training and leadership in medical education, in nursing education and in pharmacy education as well.

[The prepared statement of Mr. Perry follows:]

**Statement of
Daniel Perry, Executive Director
Alliance for Aging Research
June 10, 1999**

Good morning. I am Dan Perry, executive director of the Alliance for Aging Research. I am pleased to release today the Alliance's newest study, *Independence for Older Americans: An Investment for Our Nation's Future*. This study documents the billions of dollars that are added to the nation's health care costs due to disability among the older population and casts light on underrecognized and undertreated conditions of aging. This report also offers policy recommendations that will help alleviate this potential healthcare crisis.

As our nation experiences the greatest longevity revolution in its history, the ability of our growing population of older Americans to remain living independently is a major challenge - and one which will only continue to grow into the next century. Over the next 50 years, the number of Americans over age 65 is projected to more than double, while those over age 85 will more than quadruple to almost 18 million.

Due to the multitude of debilitating chronic and long-term illnesses that tend to strike later in life, this huge population of older people is at increased risk for mental, mobility, and visual impairment, often leading to loss of independence. Alzheimer's disease, osteoporosis, vision impairment and incontinence are among the most insidious of aging conditions which can trigger nursing home admission or dependent care in the home. And yet, there are few effective treatments, little prevention, and no cures for any of these conditions which afflict millions of Americans.

For this study, the Alliance commissioned a panel of experts to look at the costs of loss of independence for older Americans. They found that the United States currently spends more than \$26 billion annually in additional health care costs for people over 66 who lose their ability to live independently over the course of a year. This number does not even include the total cost of care for persons already disabled or living in nursing homes. This huge expense will only escalate if our nation does not take steps to find better cures, prevention and treatments for the diseases that affect the health and lives of our older citizens.

Action is needed now to ensure that the older Americans who will soon populate society in unprecedented large numbers can continue to lead independent, satisfying lives, and that the United States is in the strongest position to accommodate them. National leaders, researchers, and health care officials must take steps immediately to avert millions more cases of lost independence and the enormous accompanying costs.

In addition, it is imperative that health care professionals practice and promote preventative geriatric medicine, which can head off the looming crisis from loss of independence among older Americans.

Statement of
Daniel Perry
Page 2

The Alliance for Aging Research has developed six recommendations that we believe will stimulate debate and action that could change the way we take care of older people in this country, and enhance their ability to live at home independently. A full listing of them can be found in the report.

1. Research funding at the National Institutes of Health should be increased with a special emphasis on diseases that cause disability in older people.
2. Evaluations of Medicare reform proposals should not solely be based on costs incurred, but also on improvements in the health status of beneficiaries.
3. Research funding should be mobilized to improve outcomes for the chronically ill and elderly, and to identify strategies that improve access and reduce unnecessary health expenditures. In addition, the health community should begin to close the gap between what we know and what we do (i.e. taking what research has found and putting it into practice.)
4. Research should have an increased focus on the impact of preventive measures on postponing the impact of conditions or illnesses that affect loss of independence in the elderly.
5. Better and more reliable population and cost data on the conditions which impact the health and independence of older Americans must be collected, analyzed and put to their best use.
6. Medical providers should be better trained to assess risk of older patients for disability and nursing home admission, and be better equipped to slow that transition if possible.

I would now like to introduce Dr. Larry Branch who served on this report's research panel who will present the report findings in more detail. Dr. Branch is a Professor in Duke University's Center on the Study of Aging and Human Development.

Mr. PERRY. Well, that summarizes the essence of the report, but Dr. Larry Branch of the Duke University Center on the Study of Aging and Human Development is here this morning to give us a much better look at the methodology by which we reached that figure, that \$26 billion figure, and other panelists will talk about specific conditions that stand in for all of the chronic age-related diseases that undermine independence.

Dr. Branch.

**STATEMENT OF LAURENCE BRANCH, RESEARCH PROFESSOR,
DUKE UNIVERSITY CENTER ON THE STUDY OF AGING AND
HUMAN DEVELOPMENT**

Dr. BRANCH. Thank you very much. I am pleased to be here representing a panel of my research colleagues. We developed estimates of the monetary costs to Medicare associated with the loss of independence among Medicare beneficiaries. The Alliance for Aging Research coordinated this study called "Independence for Older Americans." I want to thank the Senate Special Committee on Aging for the opportunity to present the compelling findings of our analyses.

Mr. Perry has presented to you the basic number, 26 billion. Because the findings have such far-reaching implications, please permit me to spend a minute or two to establish the quality of the data and the methods we used. In short, we analyzed comprehensive data from calendar year 1995 on disability, nursing home admissions and the costs of Medical care that were collected as part of the Medicare Current Beneficiary Survey, a study of a representative sample of Medicare beneficiaries over age 66 undertaken by the Health Care Finance Administration.

The Medicare Current Beneficiary Survey is an excellent data source for estimating the costs associated with changes in level of independence for several reasons. It combines information obtained in personal or proxy interviews together with Medicare administrative and claims data.

The Medicare Current Beneficiary Survey includes people living both in the community and in nursing homes. It obtains longitudinal follow-up data on participants, and it can be extrapolated to nearly the entire older population of the United States.

The total estimated financial cost of losing independence was derived by determining the number of people who make transitions across three states of functional independence dependence, and the costs and the additional costs incurred in the year in which they made these transitions.

The three states of independence/dependence that we identified to evaluate these transitions were, first, those people living in the community and independent in performing activities of daily living (ADLs), which include bathing, dressing, eating, toileting and getting in and out of bed. These are called the basic self-care activities.

Second, we looked at people who were living in the community, but receiving assistance from another person to perform one or more of these self-care activities.

Third, we looked at those people who took up residence in a nursing home. So we have the three groups: those who were inde-

pendent in the community and independent in self-care activities, those in the community and receiving assistance from another person with self-care activities, and those who took up residence in a nursing home during the year.

We limited our estimates to only those people who survived the full year of observation. Our total costs, therefore, do not reflect loss of independence that occurs in the year prior to death because we judge that this type of loss of independence prior to death may be less amenable to preventive interventions than disability which occurs earlier. There are the two kinds of disability: the premorbid disability and the long-term disability. We focused on the latter, the long-term, by focusing only on those who survived for the year.

Because people need to be in the Medicare program for at least a year before they qualify for the Medicare Current Beneficiary Survey, these estimates, therefore, are for persons age 66 and older.

The costs of care used in our analysis are only those for formal medical and long-term care paid by Medicare. The costs associated with informal care, such as caregiver's lost time from work, are not included, nor are the human costs of loss of independence to both the older person and family caregivers included. These are just the financial costs to the Medicare program.

Our findings indicate that billions of dollars are spent by Medicare each year on behalf of older persons who lose their independence. Specifically, we want to share four major findings with you this morning.

First, for older Americans who become disabled or enter the nursing home during the course of a year, the increase to Medicare in medical and long-term care costs associated with this loss of independence are \$26 billion greater each year than they would have been if these same people had not had the increase in their level of dependence over that year. If they did not make the transition from a more independent state to a more dependent state, Medicare would not have incurred \$26 billion in additional costs. This means that Medicare spends one-half billion dollars a week on Medicare beneficiaries who lost some degree of independence during the year.

Let me emphasize the \$26 billion estimate does not reflect the total costs for caring for disabled persons in the community or living in nursing homes, but only the additional costs incurred in the year when the older persons actually lose their independence.

Second, total average annual costs of care to Medicare for beneficiaries who remained independent over the year were \$4,800. That figure is the base cost in this analysis. For those who began the year living independently, but ended the year living in the community and receiving help with ADLs, their total cost increased three- to fourfold from the \$4,800 a year to \$18,000 a year. If a previously independent older person entered a nursing home during the year and survived the year, their costs soared to \$36,600, more than seven times that of the person who remained independent in the community—from \$4,800 to \$36,600.

Third, total average annual costs for persons with ADL disability in the community, whose status remained unchanged were \$19,400 to Medicare. That is, for those who had limitations at the begin-

ning of the year and continued to have the same level of limitation without having entered a nursing home, their costs were approximately \$19,400 a year to Medicare. But if an individual who had been dependent in ADL at the beginning of a year further lost function and they entered a nursing home, their costs more than doubled in that year to over \$40,000, to \$40,900.

Fourth and now I'm going to focus just on the long-term care costs—the average annual long-term care costs for those who made the transition from independence in the community to staying in the community with disability for self-care activities incurred additional long-term care costs of \$3,400 a year per person. For those who began the year in the community with an ADL disability and whose status remained stable over the year, \$6,800 were spent on behalf of their long-term care needs. And for those who began the year in the community with disability, but then entered a nursing home sometime during that year, over \$21,000 on the average were incurred by Medicare for their long-term care support.

The findings of this Alliance for Aging Research Study sound an important warning that, in the face of a rapidly aging population, we cannot afford to wait any longer to address the growing crisis of loss of independence in the older population. Billions of dollars could be saved through research advances in prevention and treatment of the diseases that threaten our older population's quality of life and their valued independence. Medicare spends half a billion dollars a week for beneficiaries who lose some independence, but still survive the year. If we spend just one week of these costs on new research to prevent or delay this loss of independence, we would nearly double the total annual National Institute on Aging Budget for all its research combined. Preventing disability demands increased attention.

Thank you very much.

[The prepared statement of Mr. Branch follows:]

Statement of
Laurence G. Branch, Ph.D., Research Professor of Gerontology
Duke University Medical Center
June 10, 1999

I am pleased to be here to represent the panel of researchers who developed the estimates of cost of loss of independence for the Alliance for Aging Research study, Independence for Older Americans. I want to thank you for the opportunity to share the compelling data that was found through our work.

In developing this study we analyzed comprehensive data from 1995 on disability, nursing home admission, and cost of care that was collected as part of the Medicare Current Beneficiary Survey, a study of a representative sample of persons over 66 years of age by the Health Care Financing Administration.

The Medicare Current Beneficiary Survey is an ideal data source for estimating the cost of change in level of independence for several reasons. It combines information obtained in personal or proxy interviews together with Medicare administrative and claims data. It includes people living in both the community and in nursing homes; obtains longitudinal follow-up on participants; and can be extrapolated to nearly the entire older population of the United States.

The total estimated cost of losing independence was derived by determining the number of persons making transitions across three states of functional dependence and the additional costs incurred in the year when they made these transitions. The three states that were used to evaluate the transitions were:

1. Independence in the community in performing activities of daily living, which include bathing, dressing, eating, toileting, and getting in and out of bed
2. Living in the community but needing another person's help to perform activities of daily living, and
3. Taking up residence in a nursing home.

Since estimates are only for those people who survived for the full year of observation, the total cost does not reflect loss of independence occurring in the year prior to death, which may be less amenable to preventive interventions than disability which occurs earlier. Because people need to be in the Medicare program at least a year before they qualify for the Current Beneficiary Survey, these estimates are for persons age 66 and older. The costs of long term care used here are only for formal, paid care. The costs associated with informal care, such as the caregiver's lost time from work, are not included.

Statement of
Laurence G. Branch, Ph.D.
Page 2

The findings of the study show that billions of dollars are spent each year when older people lose their independence. We found:

* For older Americans who become disabled or enter a nursing home each year, the increase in medical and long-term care costs are \$26 billion greater than if they had not had an increase in their level of dependence over that year.

The \$26 billion estimate does not reflect the total costs of caring for disabled persons in the community or living in nursing homes, but only the additional costs incurred in the year when older persons actually lose their independence.

* Total average annual cost for persons with activities of daily living (ADL) disability in the community whose status remains unchanged was \$19,400, but if they entered a nursing home, it rose to \$40,900.

* Average annual long-term care costs were \$3,400 for those who made the transition from independence to staying in the community, but with a disability with self-care activities; \$6,800 for those beginning the year with ADL disability whose status remained stable, and over \$21,000 for all persons who began the year in the community but entered a nursing home at some time during the year.

* Total average annual cost of care for people who remained independent over the year was \$4,800. For those who began the year living independently, but ended it living in the community needing help with ADLs, total costs were \$18,000. If an individual entered a nursing home during the year, costs were \$36,600, more than seven times that of the person who remained independent in the community.

The findings of the Alliance for Aging Research study sound an important warning that, in the face of a rapidly aging population, we cannot afford to wait any longer to address the growing crisis of loss of independence in the older population. Billions of dollars could be saved through research advances in prevention and treatment of the diseases that threaten our older population's quality of life and their valued independence.

Mr. PERRY. Thank you very much, Dr. Laurence Branch of Duke University, and thank you for that honorary doctorate degree, too. I appreciate that. That was just a piece of cake getting that this morning. [Laughter.]

Actually, I had a much rougher education. I was a Senate staffer. So we all know what that means.

Well, now that we have figured out how to double the NIA budget in one year, I would like to now introduce the deputy director of the National Institute on Aging, Dr. Terrie Wetle, for the National Institute on Aging's perspective on this issue.

**STATEMENT OF TERRIE WETLE, DEPUTY DIRECTOR,
NATIONAL INSTITUTE ON AGING**

Ms. WETLE. I am very pleased to see this report from the Alliance for Aging Research coming out, because it provides impetus to what is a very important area in health care research, and in gerontological research.

I bring you a message from the National Institute on Aging of good news, of promise and of hope. The good news is that recent scientific advances show the way for improved health across the life span. The promise is for a healthier and longer life for each of us, as we enter the status of older Americans.

As the baby boomers grow older, the very issues that are being described here are of increasing importance. Also this is of importance with the increasing number of centenarians we currently have 50,000 centenarians; people over the age of 100 in the United States today, and almost all of the centenarians of the next century are alive today. They are not your centenarians and in fact they are our children and grandchildren but they will become 100 during the next century.

So it suddenly is put into perspective that although we talk about the future as if it is a very long time, from now the future is today.

So let me give you my good news message. Until recently, it was generally believed that improvements in health care would save the lives of many people, would prevent them from dying, but we would not cure them. And that the result of this would be a pandemic of disability in old age and an exponentially increasing burden of health care costs and burden on our health service system.

Data are coming in now that challenge this belief. This good news was first reported a couple of years ago by Ken Manton, on the chart (65 and over).

Dr. Manton took data from the long-term care survey in 1982 and applied rates of disability to population projections from the census bureau to project how many disabled people we would expect there to be in 1986 and 1994.

He then compared these projections to the actual numbers of disabled people in subsequent waves of the survey. Dr. Manton discovered that there were 1.4 million fewer disabled older persons in 1994 than had been projected and that the rates of decline of disability was actually accelerating. That was very good news. The rate of decline in disability was about 1.5 percent per year.

As you can see, there still continued to be additional disabled older persons, but that was due to the growth in the population.

But these were fewer disabled older persons than predicted. These data were met with a great deal of skepticism, people who did not believe they were true, who thought they were technical artifacts of the analysis. But now we have new confirmation of these data from Vicki Freedman and Linda Martin at Rand, who used a different data set, a different form of analysis and still found that rates of functional ability were, in fact going down, and that they, in fact, were decreasing fastest in the very oldest and most disabled groups. This continues to be very good news.

There is also new evidence from Tony Vita and colleagues at Stanford that tell us and this is what your mother always told you, but now we have data to prove that she was right—that better health habits help us not only to survive longer, but more importantly, that healthy life habits delay the onset of disease, and that persons with healthy health habits have fewer years of disability before they die. So we actually are compressing the period of disability. In other words, disability once thought inevitable, we now know is preventable. The Alliance for Aging Research Study being reported today shows us that this reduction in disability rates has tremendous potential fiscal consequences for our health care budgets.

At the NIA, two of our most important goals are to increase healthy life span and to prevent disability. I am now going to share with you a few exciting findings demonstrating that we are making progress on both of these goals.

Extending healthy life span requires us to conduct basic research on the biology of aging and on the genetics of aging, to better understand the normal processes of aging, as well as the diseases that rob quality of life from older persons and to help us to develop interventions that delay or prevent the onset of these diseases.

Just a couple of basic science findings to give you a hint as to the excitement of this research. By reducing the caloric content in a rodent's diet by about 30 percent, we are able to expand their life span by 30 percent. We are now doing similar studies in nonhuman primates to see if this finding holds. The important message for people with interests in disability, is not just that these calorically-restricted animals live longer, but that they had fewer malignant tumors and other diseases than control animals, and these tumors appear much later in the life cycles of these mice.

Another relevant discovery is the impact of telomeres, which are entities at the ends of chromosomes that get shorter every time the cell divides. When the telomeres get too short, our cells stop dividing. We call this cellular senescence.

Two kinds of cells do not exhibit telomere shortening germ cells, sperm and eggs and in cancer cells which divide indefinitely. An enzyme, telomerase, appears to prevent telomere shortening. If we were able, through telomerase, to help normal aging cells divide properly, we could keep organs healthier longer. Of course we have to be very careful because telomerase is what helps cancer cells continue to divide indefinitely. More research is required, but these findings contribute to understanding about the molecular clock of aging.

Preventing disability is a second major goal of the NIA. Clinical research in a variety of diseases is showing promise, and we have

experts in preventing disability on the panel who will tell us much more about this. I will point out just a few exciting findings to show you the magnitude of the opportunities that we have.

The SHEP trial, the Systolic Hypertension in Elderly Prevention trial, used an inexpensive diuretic to lower systolic blood pressure in older people. As shown in this chart, this treatment reduced stroke as compared to the control group by 36 percent. They were able to reduce heart failure by 50 percent in the overall group. And for people who had already had a heart attack the treatment prevented the onset of subsequent heart failure in 80 percent of the cases.

The TONE trial shows us that many older people who are currently taking medications to control their blood pressure can safely be withdrawn from that medication and control blood pressure by weight loss by changing diet and exercise, through reduction in dietary salt or a combination of both. Thus, blood pressure control may not require expensive medications: lifestyle changes can make a difference.

A few comments on osteoporosis, and I am sure that Dr. McGowan will have more to say about this. Osteoporosis, or weakening of the bones, afflicts as many as 80 percent of older women. The NIA, in collaboration with the National Institute on Arthritis and Musculoskeletal and Skin Diseases has supported several important studies to look at the prevention of bone loss and to better understand bone strength in women and in men. This is very, very important because falls and resulting fractures, lead to both morbidity and mortality in older people.

We are beginning to understand, for example, the role of estrogen in bone strength. Steve Cummings and his colleagues have shown that very low levels of naturally occurring estrogens, even in postmenopausal women, are associated with reduced occurrence of hip fractures or spinal fractures.

Karen Prestwood at the University of Connecticut has shown that estrogen replacement at very low doses, one-quarter to one-half the usual dose of postmenopausal estrogen replacement, has the desired effects on bone turnover, on strengthening bones, but does not have or has fewer of the negative side effects that discourage many women from taking estrogen after menopause. Scientists are also at UCON studying the effect of estrogen replacement and testosterone replacement on bone strength in men.

Advances have been made in the development of designer estrogens designed to have desired effects without the negative side effects. And, finally, dietary supplementation with calcium and Vitamin D has been shown to cut in half the incidence of debilitating bone fractures.

We can make bones stronger, we also have to prevent the falls. Research conducted by Mary Tinetti and colleagues at Yale University shows that a multifactorial intervention is very effective in falls prevention. This included review of medications, home safety checks, assessment of vision, and balance, and appropriate use of assistive devices. They achieved a 44 percent decrease in falls in the people who had this intervention. And among falls that were so serious that they required hospitalization or medical care, there was a 32 percent decrease. The intervention resulted in a cost sav-

ings of more than \$2,000 for all subjects. And for the highest risk subjects, the cost savings was more than \$3,600 including the cost of the intervention.

Age-related changes to vision also impact on the ability of older people to do many things, important to themselves and to the people they care for. One important function is driving.

One of NIA's Royal Centers has a focused effort on driving abilities. They have developed a test called the Useful Field of View, which measures both the speed of processing visual input, as well as the ability to pay attention to more than a single thing at once. They found that people who have impairment in the useful field of view are twice as likely to incur a crash in their car as persons who do not have such impairments. They are now working on strategies to correct or compensate for this impairment.

Alzheimer's disease is a major cause of disability, and my colleague Dr. Morrison-Bogorad will give you much more information about our Alzheimer's Prevention Initiative.

I have shared with you the good news of scientific advances that show the way for improved life and health. I have shown you the promise of preventing disability and promoting longer and healthier lives. The question next is how we achieve our realistic hopes of capturing some of the \$26 billion which is now being spent each year on people who make the transition from independence to needing services in the community to needing nursing home care.

At NIA we work to provide accurate and timely information on the results of these studies and on making recommendations to health care providers to older persons and their family members, and to the general public. We have books, and other publications and produce material for the electronic media. In fact, this year, the National Institute on Aging won an Emmy, the first Emmy ever given to a Federal agency, for a television spot, called "Madam Eterno." This public service announcement cautions older people, and cautions all of us about some of the anti-aging "therapeutics" that are currently being marketed on the Internet and elsewhere.

We also worked with Astronaut and Senator John Glenn on launching an entire new healthy aging exercise and fitness an Exercise Guide from the National Institute on Aging that will help improve health and well-being.

We have made great strides in reducing disability and improving health of older persons. And I believe that the challenge for the future is to accelerate these trends. As illustrated by the Alliance's report, there is a potential for saving substantial amounts of money.

A recent poll by the AARP of persons 18 through 75 years of age showed that nine out of ten Americans understand that healthy habits at any age will improve the likelihood of good health in old age. And even better, four out of five of these respondents aged 18 through old age had already changed their health habits to ensure healthier later lives. It is never too early for each of us to prepare for a healthy and very long old age.

Thank you.

[The prepared statement of Ms. Wetle follows:]

Reducing Disability and Promoting Longer, Healthier Lives
Terrie Wetle, Ph.D.
Deputy Director
National Institute on Aging

Introduction

The message of today is one of good news and promise. The good news is that scientific advances show the way for improved health across the life span and the promise is for a healthier and longer life for Americans. (Chart 1)

Until recently, it was generally believed that improvements in health care and technology would save people from dying without curing them, producing a pandemic of old age disability and an exponentially increasing burden of health care services and costs. These dire predictions persisted until Kenneth Manton and colleagues at Duke University in Durham, North Carolina published his 1997 finds, based on waves of data from the National Long-Term Care Study, that demonstrated a dramatic and unexpected reduction in rates of disability among older persons. Manton calculated that at least 1.4 million fewer older Americans were disabled in 1994 than there would have been if disability rates had not improved since 1982, and that these reductions accelerated over the 12 years (Chart 2). Manton's conclusions were met with considerable skepticism, and efforts were launched to either disprove or support these findings.

In early 1998, Vicki Freedman and Linda Martin of RAND, using different dataset and different measures of functional ability, found equally large declines from 1984 to 1993 in the prevalence of chronic disability, after controlling for changes in the composition of the population during the study period. They also found that improvements in functioning in absolute terms were greatest among those 80 and older. There is also new evidence, developed by Anthony Vita and colleagues at Stanford University in California, that persons with better health habits not only survive longer, but disability that does occur is postponed and compressed into fewer years at the end of life. These findings and those beginning to be reported by other scientists lend support to the position that physiological changes in capability underlie the trend toward declining disability. NIA focuses much of its efforts on two major goals: 1) increasing healthy life span; and 2) preventing disability.

Expanding Healthy Lifespan

Our understanding of the basic biology of normal aging, including the processes of cellular senescence and the genes that may contribute to increased longevity has increased dramatically in recent years. Caloric restriction is being investigated as an intervention in animals that may not only increase longevity, but also decrease the prevalence of age related malignancies and other diseases. Major advances have recently been made in understanding the role of telomeres and telomerase in aging and cancer.

Genetic influences in longevity and healthy lifespan are being identified. Several genes associated with longevity in lower life forms are being shown to have homologues in human beings, providing new targets for intervention.

Telomeres, repetitive DNA segments found on the ends of chromosomes, help maintain the integrity and function of chromosomes. When cells divide, telomeres normally lose segments and shorten until, at a critical length, cell division ceases and cells become senescent. Telomeres have therefore been regarded as the cell's "molecular clock." The enzyme telomerase compensates for telomere loss by adding DNA segments to the ends of chromosomes in cells such as cancer cells, sperm and eggs. How and why telomerase reactivates to contribute to cell immortalization is not known, but correlation between telomerase activation and cancerous growth has stimulated many scientists to view telomerase inhibition as a potential new approach to cancer therapy. Controlled activation of telomerase, on the other hand, may provide an avenue for healthy cell division by resetting or extending the timing of the molecular clock.

Preventing Disability

On the clinical research front, studies focus on the major causes of disability in the elderly, including cardiovascular disease, osteoporosis, falls and fractures, vision, and Alzheimer's disease.

Cardiovascular disease. For example, collaborative clinical trials funded by the NIA and the National Heart, Lung, and Blood Institute confirmed the efficacy of lowering systolic blood pressure in significantly reducing the risk of major cardiovascular illness and stroke in older people. This includes dramatic reductions (80%) in the occurrence of heart failure in persons with previous myocardial infarctions. (Chart 3)

In another study this year, Paul Whelton of Tulane University and investigators at several other sites completed the Trial of Nonpharmacologic Interventions in the Elderly (TONE), co-funded by the NIA and the National Heart, Lung, and Blood Institute (NHLBI). The trial tested efficacy and safety of withdrawing antihypertensive medication and substituting weight loss, dietary sodium reduction, or both to control blood pressure in a group of 975 men and women ages 60-80 years. Compared to the control group, the risk of recurrence of hypertension and/or cardiovascular complications was lowered in all groups, but most significantly in those assigned to both weight loss and sodium reduction. TONE thus demonstrated the efficacy and safety of nonpharmacologic therapy of hypertension in older persons, and that older patients with hypertension were able to make and sustain the lifestyle changes necessary for these results (Chart 4).

Osteoporosis. The NIA and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) have shared a long collaborative effort in preventing osteoporosis and in the use of hormone replacement toward this end. This year, four studies reported findings on the contribution of sex hormone levels and other factors in minimizing bone loss and osteoporosis in

men and women. A study led by Lawrence Riggs at the Mayo Clinic in Rochester, Minnesota, identified estrogen deficiency as the cause of both the early accelerated and continued slower phases of bone loss in women and as a contributor to bone loss in aging men. Another research team, led by Steven Cummings at the University of California, San Francisco, studied the normally occurring levels of estrogen in nearly 900 women over age 65. These investigators found that women who had measurable blood levels of estrogen — much lower than women currently achieve by taking hormone supplements — had less than half the risk of experiencing a subsequent hip or vertebral fracture than women with undetectable levels of estrogen in the blood. This research team also found that the risk of hip fracture increased with higher blood levels of a protein that reduces the body's access to estrogen in the blood. Women with both high levels of this protein and undetectable levels of estrogen were found to be at a 7-fold higher risk for hip fracture and an 8-fold higher risk for vertebral fracture. These studies suggest that taking very low-dose estrogen supplements or by using new estrogen-like therapeutic agents may prevent bone fractures in women and men without causing adverse effects sometimes associated with estrogen therapies.

Falls and fractures. Dietary supplements have also proved effective in reducing the risk of fracture. A trial of daily supplementation with calcium and vitamin D has shown to halve the risk of debilitating bone fractures in people over age 65. This study performed at Tufts University found that participants taking 500 mg of calcium and 700 IU of vitamin D daily had about half the bone fractures compared with the placebo group. In addition, multiple risk intervention strategies developed by researchers at Yale University have proved effective in reducing the incidence of falls and fractures and resulted in considerable cost savings. (Charts 5&6) Interventions include exercises for strength, balance and endurance, as well as medication adjustment and environmental design.

Vision. In the field of vision research, work is continuing on the age-related changes in visual processing that impact on the ability of older individuals to drive, an activity that profoundly affects an individual's independence. Researchers are trying to determine factors, such as impairments and medical conditions, that place certain older drivers at increased risk for crashes. Previous retrospective research by Cynthia Owsley at the University of Alabama at Birmingham and colleagues indicated that declines in visual processing speed and visual attention skills are strongly associated with a history of driving problems. These investigators developed a measurement of these visual processing skills, which they call Useful Field of View (UFOV). The researchers tested the UFOV of a group of older people and later followed up on their history of vehicular crashes. These researchers also reported that older drivers with a 40 percent or greater impairment in the UFOV were more than twice as likely to incur a crash during the three-year follow-up period than older drivers with a lesser impairment. The inability to divide attention at brief durations was determined to be the main risk factor for future vehicle crashes for older adults. In a separate study, Mary Tinetti and colleagues at the Claude D. Pepper Older Americans Independence Center at Yale University have developed a test battery that could be performed in a clinician's office of visual, cognitive, and physical abilities potentially relevant to driving. The study tracked the occurrence of a crash, moving violation, or being stopped by

police over a period averaging six years. Among the 125 community-living drivers who participated, 50 reported one of these adverse events. Elements of the test that were significantly related to these events included near visual acuity worse than 10/40, limited neck rotation, and poor performance on a test of visual attention. The battery effectively detected disabilities in drivers at risk for adverse driving events, but abnormalities were also found in many who had no adverse events. These findings suggest it may be possible to identify individuals potentially at risk for self-reported driving events using simple tests of functional ability. Further research may help determine interventions to correct or compensate for the impairments.

Alzheimer's disease. A major area of NIA research is Alzheimer's disease. NIA in collaboration with other Federal agencies and private organizations, is launching an Alzheimer's Disease Prevention Initiative with the goal of actually arresting Alzheimer's disease and preventing future cases. Research has indicated that the neuropathologic changes of Alzheimer's disease begin as much as several decades before the clinical symptoms are recognized. The ultimate goal of this initiative is to intervene early in Alzheimer's disease pathology to prevent the disease from ever manifesting itself clinically.

Promoting healthy lifestyles. Health promotion efforts are aimed at the initiation and maintenance of healthy lifestyles, disease prevention, and improved access to health care. Promoting healthy life styles includes proper diet; exercise; cessation of tobacco, alcohol, and medication misuse; adherence to prescribed medical regimens; preventive health care and screening, and early diagnosis and treatment of disease. Particular emphasis is on investigations of factors that may contribute to observed health disparities among older racial and ethnic populations. Efforts to reduce disparities include the development of culturally appropriate screening tools and health care services.

To help ensure that the public benefits from these advances, the NIA provides accurate and timely information on the results of aging research and on related health data to older consumers, patients and family members, health care professionals, the media, and others. In 1998, NIA's publication information program received the first Emmy award given to a Federal agency for a nationally televised public service announcement, "Mme. Eterno, Looking for the Fountain of Youth." This announcement encouraged viewers to seek more information about increasingly popular "anti-aging" therapies, which are often not fully characterized for efficacy or potential danger. Also in 1998, NIA, with astronaut and Senator John Glenn, the National Aeronautics and Space Administration, and other Federal agency partners, launched a national education campaign for keeping fit after 50. The project is tied to release of a new book, free to the public, "Exercise: A Guide from the National Institute on Aging," that shows older Americans how to step up their physical activity to improve health and well-being with age.

Conclusion

The challenge for the future is to maintain the current trend of decline in disability over the next 50 years, which could reduce the growth in or even keep the absolute number of disabled older

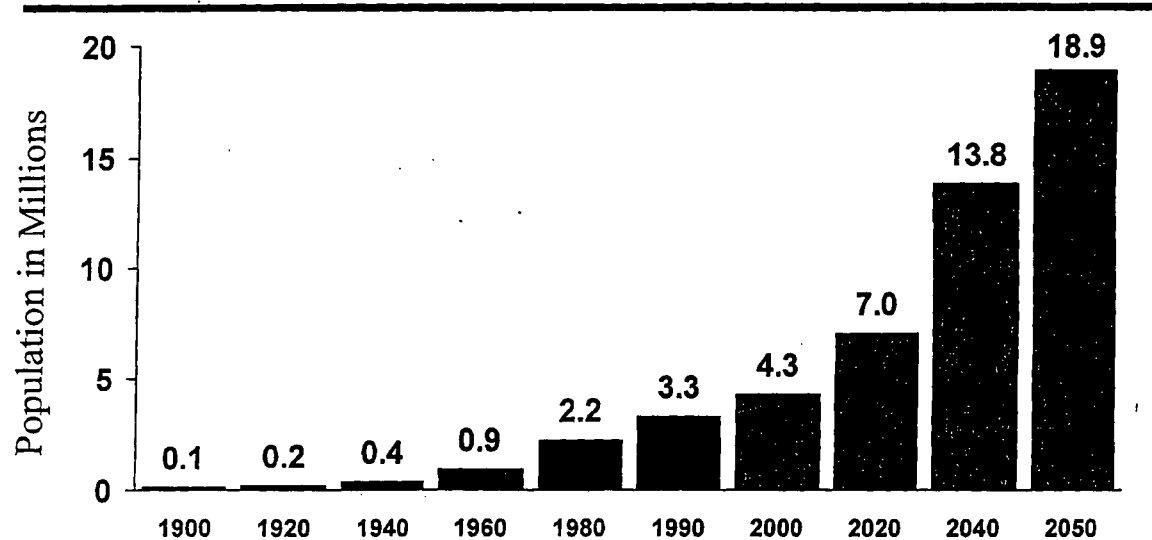
Americans level in the face of the demographic increase in this population expected with the gray of the baby boom generation. Moreover, we must address the increasing number of individuals expected to have Alzheimer's disease, as well as tackling the functional disabilities related to cardiovascular disease, cancer, vision, hearing and musculoskeletal disorders by improving primary and secondary prevention and reducing excess disability.

As illustrated by the Alliance's report, prevention or delay of increasing disability will substantially reduce health care costs. Advances in science as well as innovations in an evolving health care system require redoubled efforts to improve strategies for health promotion and improved service delivery. We must also continue basic and applied research to better understand the etiology, risk factors, and natural history of disease as well as preventive factors and strategies. Research must also focus on strategies to improve quality and efficiency of services to older persons and their families.

A recent poll of persons ages 18 to 75 taken by AARP showed that 9 out of 10 Americans understood that adoption of healthy habits at any point in life, the earlier the better, could improve health in old age. Even better, 4 out of 5 people, across the life span had already changed health habits to ensure a healthier old age. The best news is that millions of Americans are living healthier lives, based, in part, on findings from aging-related research.

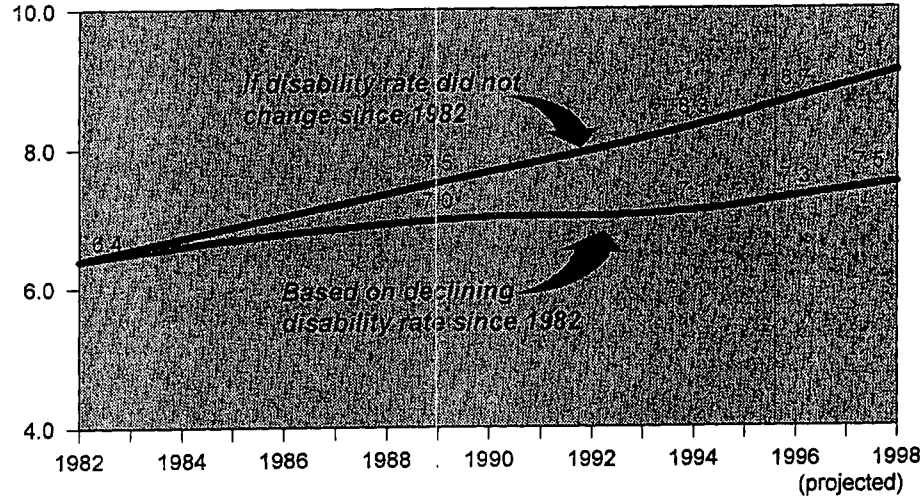
Chart #1

U.S. Population 85 and Older: 1900-2050 Census Data and Middle Series Projections



Source: Bureau of the Census, *Current Population Reports*, P23-178RV (May 1993) and P25-1104 (Nov 1993)

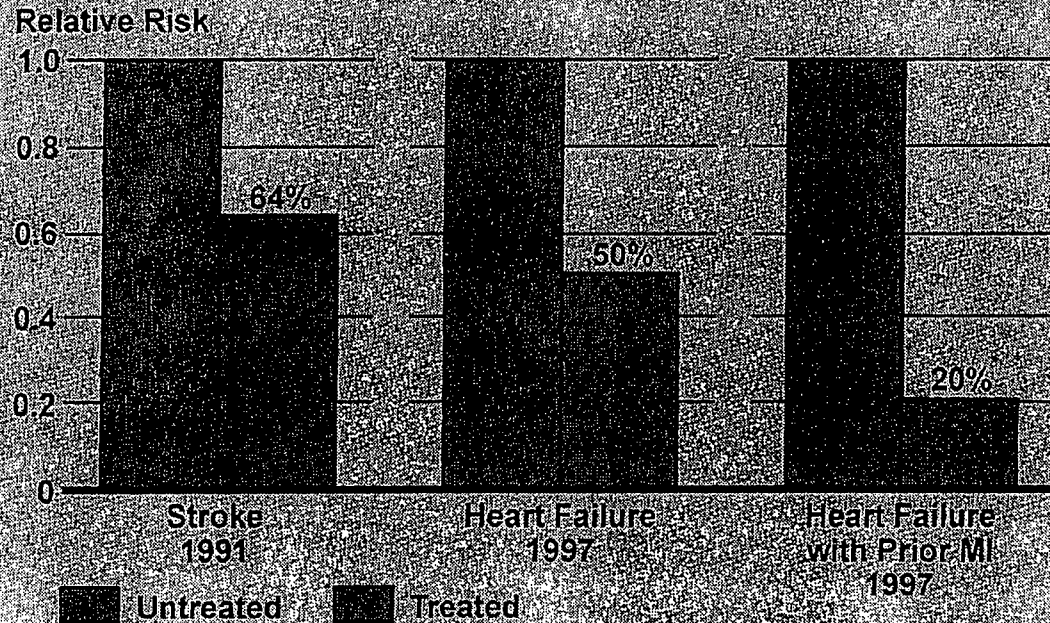
Number of Chronically Disabled Americans Age 65 and Over (In Millions)



Note: The U.S. elderly population (age 65+) totaled 26.9 million in 1982, 30.8 million in 1989, 33.7 million in 1994, 34.1 million in 1996, and 34.8 million in 1998 (1996 and 1998 are projections).

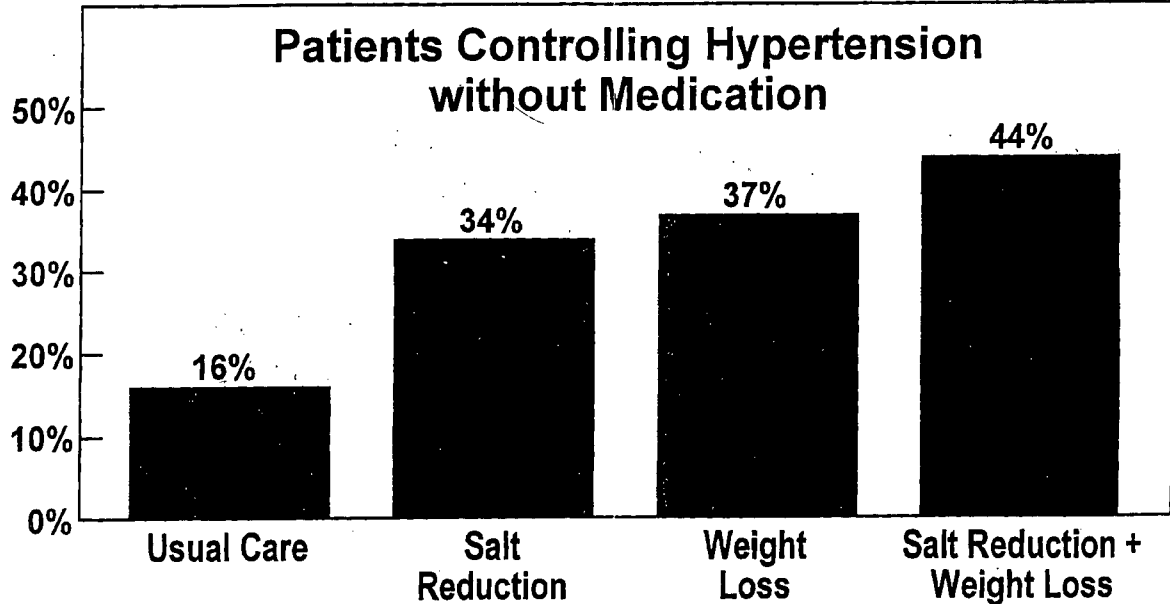
Source: National Long Term Care Survey 1982-1994 (Kenneth Manton, Ph.D.)

Diuretic Treatment of Systolic Hypertension Cuts Cardiovascular Risk



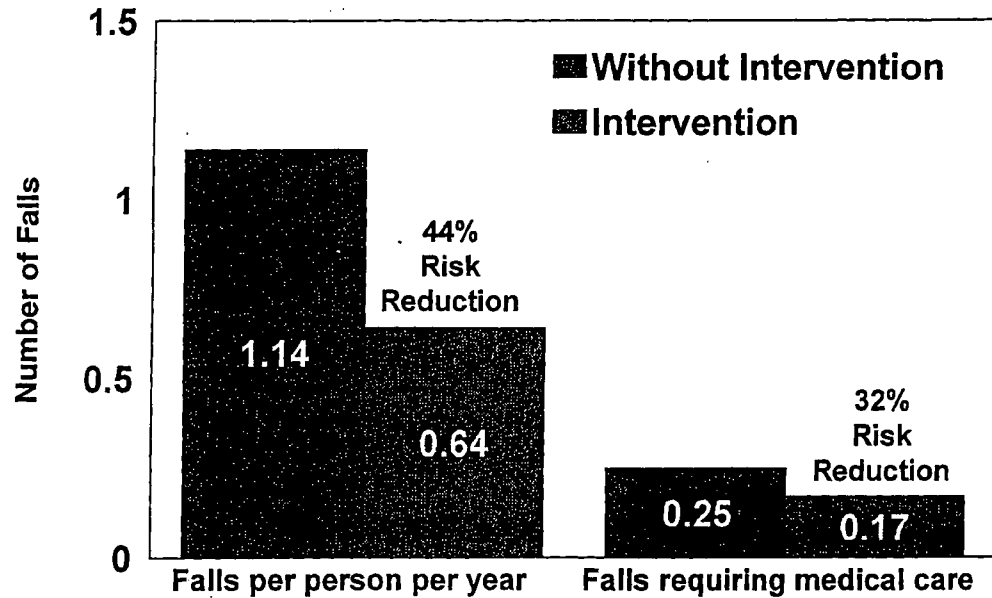
JAMA (265) 1991; JAMA (278) 1997

Lifestyle Changes Can Lower Need for Hypertension Medication in Older Persons



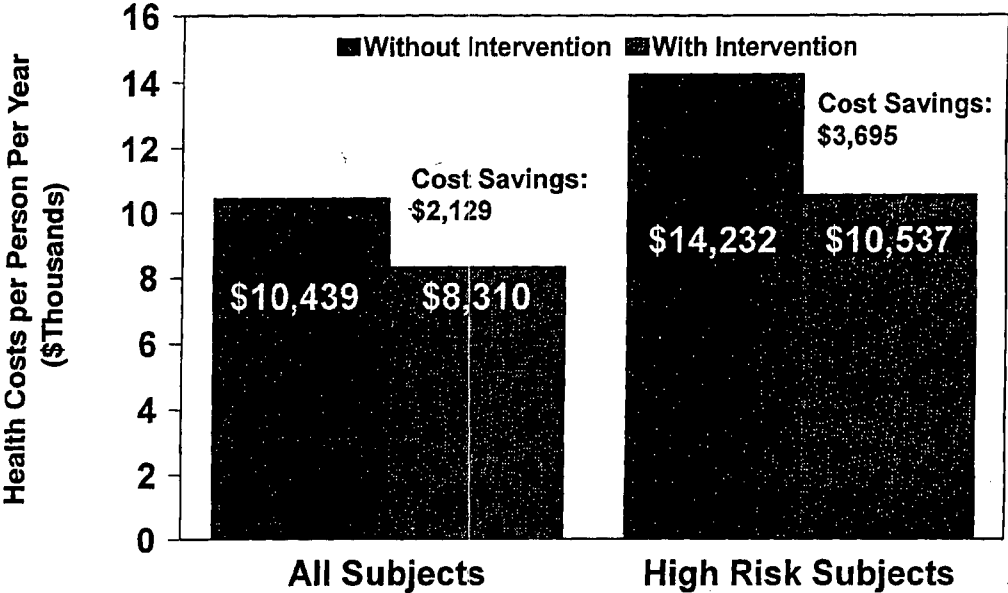
Prevention of Falls

A Clinical Trial of Multiple Risk Factor Reduction



Source: Tinetti *et al*, New England Journal of Medicine, 1994

Prevention of Disability from Falls: Multiple Risk Factor Reduction Cost Savings



Source: Rizzo et al., Medical Care, 1996.

Mr. PERRY. Dr. Wetle gave us a terrific overview of some of the exciting research into these chronic age-related diseases. And if I can summarize that around one real take-home message, is that the old saying about if you want to live a long time, choose your parents wisely, that has gone out the window. We know that you can modify your chances for healthy longevity by lifestyle, and we are certainly going to modify them by what we are learning in laboratories and new therapeutics that will be coming from that research that will help prevent and postpone some of these very disabling conditions.

And moreover, we know that it is working. We know that we can capture longer independence for older people. We can bring those numbers down because it is already happening. She cited the research at Duke University, Dr. Manton's work. There is now an established 12-year decline in disability in the elderly in America. It is very small, but it is significant statistically, and we are not quite sure why older Americans are less disabled now than they were in the 1970's. Can you imagine redesigning the Medicare program without understanding fully what is behind those good trends and how to accelerate those trends and drive down disability rates even further. That is what we are going to learn.

We now are going to focus on four specific areas that are at the heart of lost ability by older people to remain in their homes: memory and mental deterioration, immobility caused by bone and joint deterioration, incontinence and vision loss. And to start with the memory and mental impairment, including cognitive loss in Alzheimer's disease, is Dr. Marcel Morrison-Bogorad. She is the associate director of the National Institute on Aging and heads the Neuroscience and Neuropsychology of Aging Program.

Dr. Morris-Bogorad.

STATEMENT OF DR. MARCELLE MORRISON-BOGORAD, ASSOCIATE DIRECTOR, NEUROSCIENCE AND NEUROPSYCHOLOGY OF AGING PROGRAM, NATIONAL INSTITUTE ON AGING

Ms. BOGORAD. I want to thank the Senate Special Committee on Aging and the Alliance for Aging Research for inviting me to this important forum to talk about a disease of extreme importance to older Americans—Alzheimer's disease.

As the report makes clear, there are tremendously important scientific findings on Alzheimer's disease now, and that is very fortunate. Because if the science does not produce cures we are going to have a real epidemic on our hands.

First, why is Alzheimer's disease indeed such a problem as we look at the demographics of our older and older population? The problem is, that the major risk factor for Alzheimer's disease is age. Below the age of 65, very few people have the disease. But after the age of 65, the number of people with Alzheimer's increases, increasing by at least twofold every 5 years.

One study done about 10 years ago now, suggested that the total number of people with very mild to moderate to severe Alzheimer's was as high as 47 percent, for people over the age of 85. These are truly alarming numbers. In addition, the make-up of the population over 85 will be much more diverse. So we have to think of how to

cure or prevent Alzheimer's disease in all sectors of the population, across all ethnic groups.

The major problem with Alzheimer's disease is that it is such a devastating disease for families and relatives. It starts with a fairly insidious memory loss. It progresses to the point where the person does not know members of his or her own family. And it ends 10 to 20 years later with the patient lying bedridden, usually in a nursing home, completely unable to do anything at all for him or herself. So not only is AD a disease in which economic costs, as much as \$100 billion a year must be considered, but also the impact that it has on the family; the emotional impact and the physical impact must also be addressed.

In response, the National Institute on Aging has developed a Prevention Initiative to spur Alzheimer's research and to develop ways to delay its onset eventually to prevent it altogether.

The Prevention Initiative, first, uses basic research to identify promising targets for drug development, identifies ways in which we can develop new drugs for interventions, starts clinical trials to see what drugs can actually prevent the slow progression of the disease, and aims to reduce suffering by alleviating Alzheimer's symptoms and improving management and caregivers quality of life. Therefore, the initiative has four main thrusts.

I would like to go over with you, as Dr. Wetle did for some of the other conditions, some of the advances we are currently making in Alzheimer's disease research. In our part of the National Institute on Aging, what we really focus on is trying to make sure that most of us age well, with our cognition intact. We would like to even prevent the normal cognitive deficits we see in aging, the sort of problems with memory that we are all faced with: Where are my car keys? Where is my car in the parking lot? We all experience these problems as we age; I certainly do.

But, of course, our first major task is to try to prevent the devastating loss of function that occurs in Alzheimer's. In the last 25 years or so, which is really the amount of time we have had to really focus on this disease, scientists have learned an awful lot about the later stages of the disease. One thing they learned fairly early on was that there was a loss of a chemical called acetylcholine in the brains of people with Alzheimer's, and this chemical is really important for normal memory.

From that discovery, the first two drugs were developed and approved by the FDA a few years ago to treat people who already have the disease. These two drugs boost the levels of this chemical, acetylcholine, give some relief in some patients, for perhaps about 2 years, in slowing the decline which normally occurs in an Alzheimer's disease victim. A study funded by the National Institute on Aging also showed recently that Vitamin E, in high amounts could also slow the development of very practical milestones in people with moderate to severe Alzheimer's disease.

So we have some ways, at the moment, of at least slowing decline. The problem with that though is we are slowing decline in people who have already lost a lot of cognitive ability. One of the major focuses we have right now is to move back in the Alzheimer's curve and try to find ways of preventing development of the disease itself before clinical diagnosis.

Where we are concentrating on right now is this stage, called mild cognitive impairment. Mild cognitive impairment has recently been defined and characterized as a stage of development in some people, where their short-term memory is impaired, severely impaired, but most of their other cognitive functions are relatively intact.

People with this form of mild cognitive impairment sometimes die from other causes, and we know now, from neuropathological research, that people with this major loss in short-term memory have the characteristic plaques and tangles in their brains that are the hallmarks of Alzheimer's disease. These folk have lost a number of important brain cells in the regions of the brain connected with Alzheimer's disease and loss of memory.

Their brains are already compromised, even though there is no diagnosis of Alzheimer's diseases yet. What we are really thinking now is that Alzheimer's, the changes in the brain that take place prior to clinical diagnosis, actually might start occurring two to three decades before hand. And that is good, because it means we might be able to stop these changes occurring before clinical symptoms develop, and bad because changes might start extremely early in life.

This slide is a visual representation of one thing that is happening in the brain of a person as they get older. The red shaded area is the hippocampus, one of the structures important for memory. It is large in a 25-year-old. It gets a bit smaller, even in people who are aging gracefully, like Hugh Downs, however, in older people with mild cognitive impairment, it is much smaller. It has really shrunk, and you see its even smaller size in a person of the same age who has Alzheimer's disease. So there is shrinkage of the brain in mild cognitive impairment.

It should not surprise you, since I am telling you all of these things that are happening in the brain of a person with mild cognitive impairment, that these folk have a much higher risk of developing Alzheimer's disease within a few years than persons of the same age range in the general population who are not memory impaired; 10 percent to 12 percent will develop AD in one year, rising to over 30 percent in 3 years, and this is tenfold the normal increase. These folk are really at risk. One of the exciting things that happened this year is that the National Institute on Aging funded its first clinical trial to try to stop the development of Alzheimer's disease in people who already have mild cognitive impairment.

There are two drugs being tested, along with a placebo, as is the case in most clinical trials. The drugs or compounds are high doses of Vitamin E and Aricept, which was the second drug approved by the FDA to treat people who already have Alzheimer's disease.

So we are tremendously excited about starting this trial. Of course, these trials take several years, and one of the major reasons for them taking so long is that you need to measure cognitive decline over time right now with Alzheimer's disease. We need to develop quicker methods of analyzing whether drugs work, and we need to make the process of enrolling patients in this trial as rapid as possible.

I want to tell you some other things that are going on in the clinical trial world. Several epidemiological studies have shown that

nonsteroidal anti-inflammatory drugs and estrogen might reduce the risk of developing Alzheimer's disease. These are epidemiological studies, and from these we have already almost analyzed a couple of clinical trials, which were really pilot trials to look at anti-inflammatory drugs and estrogen.

At the end of this year, the Alzheimer's Disease Cooperative Study group, which is the major funded NIA grant that does clinical trials for Alzheimer's, will be starting a major trial, looking at one of the major anti-inflammatory drugs which are traditionally used, as well as one of the newer drugs, the so-called Cox2 inhibitors.

Other recently started Alzheimer's clinical trials do not look at Alzheimer's patients, but already are looking at the stage before Alzheimer's, the so-important pre-clinical stage. They are looking at whether certain chemicals can slow development of cognitive impairment over time or development of Alzheimer's disease. There is another trial going on looking at estrogen and women at risk and a couple of add-on studies to ongoing clinical trials looking at antioxidants or aspirin or the Vitamin folate/Vitamin B6/Vitamin B12 combination, which people think might be a risk factor in cardiovascular disease. We are not losing sight of alternative medicines, and the NIH has issued a request for applications for a trial to test Ginkgo biloba in cognitive impairment and Alzheimer's.

The future will come, I think not only from compounds that people can already take, but also from compounds which will have to be developed by researchers, both in the NIH and in industry, which attack specific pathways that we know occur in the Alzheimer's brain.

We will be looking for ways to intervene in the deposition of plaques and tangles, the hallmarks of Alzheimer's disease, to intervene in cell death and dysfunction, and to stop the loss of connections between nerve cells, which is also so characteristic of AD.

We are not forgetting caregivers, of course. We had a clinical trial in Alzheimer's disease which showed that giving caregivers effective ways of dealing with an Alzheimer's patient and giving them constant counseling, was incredibly effective in increasing the quality of life for the caregiver and the patient and for postponing placement in a nursing home.

As a consequence of that study, we funded the REACH study, the Resources for Enhancing Alzheimer's Caregiving Health, using the same sort of methodologies but now in a number of different centers, and importantly, in ethnically diverse populations.

We have really come a long way in the last 20 years. We have got some modest treatments for Alzheimer's. We are starting trials right now to look at a number of compounds to stop people moving from the presymptomatic stages through mild cognitive impairment to Alzheimer's. The future, I think, will be in developing compounds, which stop the development at the very earliest stages and really prevent Alzheimer's disease from becoming the epidemic that we fear in the next 50 years.

Thank you.

[The prepared statement of Ms. Morrison-Bogorad follows:]

Alzheimer's Disease
Marcelle Morrison-Bogorad, Ph.D.
Associate Director
Neuroscience and Neuropsychology of Aging Program
National Institute on Aging

I want to thank the Senate Special Committee on Aging and the Alliance for Aging Research for sponsoring today's forum. It is a pleasure to be here today and to share with you news about the exciting pace of scientific discoveries and strategies we are pursuing at the National Institute on Aging regarding Alzheimer's disease (AD). As the Alliance's report makes clear, the need to prevent or delay the onset of Alzheimer's disease is paramount - particularly as we enter the next century and confront the threat of an Alzheimer's disease epidemic.

According to the Alzheimer's Association, an estimated four million Americans now suffer with Alzheimer's disease and by the time the "baby boom" generation reaches the age of greatest risk, as many as 14 million persons will be afflicted. Projected demographic changes force us to focus on the problem of AD as the risk of developing this disease doubles every five years after the age of 65. Some estimates place as high as 50% the proportion of persons over the age of 85 who have AD - and persons over 85 comprise our very fastest growing age group. As the population changes, not only will there be more persons with AD, but the make-up of this population will be much more diverse, requiring us to consider the special risks and needs of minority groups.

AD is a disease that slowly, steadily, and inevitably robs the patient of all sense of self and of a meaningful relationship with the outer world. The disease progresses through forgetfulness to loss of the ability to function in the home without constant supervision. It often requires a move to a nursing home and eventually results in a bedridden state of total incapacity. Throughout this the process, relatives undergo not only loss but a series of losses as the loved one slips slowly down the AD slope. The financial cost for caring for persons with dementia is estimated at \$100 billion per year. This estimate does not include the toll AD exacts on relatives caring for AD patients and dealing with events that deplete them physically and emotionally, as well as financially, over the course of 10-20 years.

Until recently, memory loss and development of dementia were seen as inevitable consequences of aging, and the related loss of independence the price we had to pay for living into our 70s and beyond. However, with the recent explosion in scientific knowledge, we are beginning to understand the process of aging, the mysterious working of the brain, and how and why the mind falters in aging and completely falls apart after AD strikes. With each advance in knowledge comes insights into ways we might delay "frailty of the mind" and loss of independent function.

The AD Prevention Initiative

To capitalize on recent scientific advances and current opportunities, the NIH has launched an Alzheimer's Disease Prevention Initiative. The AD Prevention Initiative joins the resources of the National Institute on Aging (NIA) with those of other Institutes in the National Institutes of Health (NIH), other government agencies, and voluntary organizations and companies in the

private sector. It aims to slow the progression of and eventually to prevent AD by:

- Using basic research to identify promising targets for preventing disease.
- Identifying new drugs and interventions.
- Starting clinical trials to stop, delay or prevent disease.
- Reducing suffering from AD to alleviating the symptoms, improving management of AD and helping caregivers cope with the disease.

The Prevention Initiative will involve coordination with other Federal agencies, drug companies, and private foundations. Within NIH, several Institutes (NIA, NINDS, NIMH, NINR), which comprise the NIH AD Working Group, are collaborating on the Prevention Initiative. Within the Federal government, ties with HCFA, the CDC, and the VA will be strengthened, as well as those to state and local agencies. The Alzheimer's Association partners with NIH staff and researchers at both local and national levels to sponsor research, workshops, and education and outreach programs. Partnerships with other not-for-profit agencies are also being developed. Finally, the NIH will continue to interact with pharmaceutical companies in basic research, drug development and testing, and, in particular, will continue to encourage small companies to apply for drug development grants. The NIH will also continue to identify partners for collaboration and encourage its grantees to build collaborative research relationships.

Launching this initiative will help ensure that the pipeline of AD research contains an increasing flow of discoveries from basic and clinical research to clinical trials and subsequent implementation of effective prevention and treatment strategies. The goal is to maintain independent life for more people and for much longer than is presently possible.

Treatments already developed to slow rate of decline or disability in AD patients

Once AD was defined clinically, scientists could discover ways in which the brain of a person with AD differed from that of a person with normal cognition. In the 1970s, scientists found that certain brain cells were dying in the brain of a person with AD, depleting levels of a brain chemical essential for memory (acetylcholine). The practical result of these discoveries was development of drugs aimed at temporarily boosting levels of acetylcholine, even though the brain cells continued to die. The two FDA-approved drugs for AD, Cognex (tacrine) and Aricept (donepezil), belong to this class of drugs and more are in development. Aricept has few side effects and recent clinical studies show that for some patients it can effectively slow the slide down the AD slope for up to 2 years. Antioxidants, vitamin E and selegiline (which combat the free radicals generated at high levels in AD brain), have also been shown to delay important milestones in decline (e.g., loss of ability to care for oneself, moving into a nursing home) by up to 6 months. Thus, for persons with AD we can now buy some time for some people.

First steps in prediction lead to the first prevention trials

Most research, until recently, has been aimed at identifying the changes that occur in brains of AD patients who are in later stages of the disease and easily diagnosed. These changes include plaques, tangles, oxidative stress, inflammation, and loss or dysfunction of brain cells and their

connections. Many of these advances were made possible by the funding of the network of Alzheimer's Disease Centers across the country, now augmented by establishment of a common Database Center in 1999. In the last couple of years, researchers have made progress in identifying persons who are at high risk for developing AD, prior to clinical diagnosis. Persons diagnosed with mild cognitive impairment (MCI) have quite severe problems with short-term memory, but are otherwise fully functional. However, they are at least 10 times more likely to develop AD in the next few years than persons who test normally for their age. Clinical and neuropsychological tests are being developed to identify these people. Brain scans of different kinds are showing that persons with MCI have a more rapid rate of shrinkage of important memory regions of brain than controls. These brain scans are potential markers for the disease. The search is on for ways to identify persons at risk ever earlier, before any obvious decline in function. Identifying these persons is important for development of drugs to combat the disease, for persons at risk being able to plan for their future, and for scientists trying to understand the early changes in brain which result in AD.

Using the newly-developed criteria for diagnosing persons with MCI, the NIA-funded Alzheimer's Disease Cooperative Study (ADCS) group, early this year, launched the first NIH trial to try to prevent persons with MCI from going on to develop AD. The agents being tested are the antioxidant vitamin E, and Aricept, one of the FDA-approved drugs for AD. Vital to the success of this trial is rapidly enrolling over 700 persons with MCI at over 70 sites nationwide and Canada.

Pathology of AD may begin long before clinical signs appear

Persons with MCI, who are autopsied after they die of other causes, already show loss of specific brain cells in the most vulnerable part of the brain affected by AD. Their brains already contain a large number of plaques and tangles, the hallmarks of AD. Even persons who have no obvious mental decline sometimes have large numbers of plaques and tangles and many scientists consider that they may be in the very early preclinical stages of AD. It is possible that the first AD changes in brain occur many years prior to the development of clinical symptoms.

Other avenues of research suggest that even prenatal events might affect the brain's ability to withstand the effects of aging. Food supplement studies in animals suggest prenatal levels of choline help maintain brain function in old age. And diets high in antioxidants in later life help maintain brain function in elderly rats. The "brain reserve" hypothesis suggests that the greater the number of healthy brain cells and connections formed during early life, the more reserve there will be in later life against the effects of brain damage such as those seen in AD. Exercise and mental stimulation also build up brain connections and even generate new brain cells from stem cell precursors in rodents, stimulating better blood delivery and production of "growth factors" that help brain cells survive. Investigation of whether these "low tech" interventions might help delay late life cognitive decline or even development of AD is continuing. Other avenues of investigation include whether cardiovascular risk factors, such as high blood pressure in mid-life might increase the risk of developing AD. Recent studies show that small strokes may exacerbate the clinical symptoms of AD in persons who have the disease.

From epidemiology, clinical, and laboratory studies to clinical trials

A number of epidemiology and clinical studies have shown that persons who take anti-inflammatory drugs and postmenopausal women who take estrogen are at lower risk of developing AD than their peers; and recent results link low folate levels in blood to a higher risk of developing AD. The epidemiological studies are supported by laboratory studies. However, the only way to tell whether agents such as estrogen or anti-inflammatory drugs will prevent or slow AD progression is to test them in clinical trials. A number of such trials are now being funded. They test drugs either for their ability to slow the progression of AD or for their ability to slow age-related memory impairment and development of AD.

Slowing progression of AD

The Alzheimer's disease Cooperative Study (ADCS) is:

- Completing the first trial on a steroidal anti-inflammatory drug, prednisone.
- Completing a pilot trial on estrogen.
- Beginning a trial to test a non-steroidal anti-inflammatory drug and one for the new Cox2 inhibitors.

Slowing progression of memory impairment and development of AD

New trials include:

- A trial to test the effect of estrogen in women at risk for AD.
- An add-on to the ongoing Women's Health Study to test the effects of the antioxidant, vitamin E, and the anti-inflammatory, aspirin.
- An add-on to the ongoing Women's Antioxidant Cardiovascular Study to test the effects of antioxidants (vitamins E, C, or beta carotene) or of a folate/vitamin B combination.
- A request for applications to test the dietary supplement Ginkgo biloba.

As the only way at present to test whether a drug is effective is to monitor the slow decline in brain function, these trials take several years. Adding to the time factor are delays in recruiting enough suitable persons to participate. Ways to improve recruitment strategies, as well as to more rapidly chart decline, are being sought.

Genetic and molecular research is beginning to identify targets for future therapies

The clinical trials described above could be started rapidly because the agents they are testing are already approved for human use. The next generation of drugs will be completely new ones developed to combat specific brain pathways that are involved in the disease. These drugs will need to go through the necessary regulatory steps: testing for efficacy in the test tube and for safety and efficacy in animals, then in humans, before being tested for efficacy in AD patients. Clues to how AD can start come from the exciting work identifying mutated genes (amyloid

precursor protein, presenilins) responsible for inherited early onset AD genes and from identification of risk factor genes, such as ApoE4, for late onset disease. Unraveling the pathways leading from these gene changes to disease is providing a wealth of potential sites at which the progression of AD in the brain might be blocked. Transgenic mice carrying the mutated genes show much of the pathology of AD as they age. These mice are being used to study the progression of disease changes, the relationship between abnormal changes in the brain and loss of mental function, and to provide a model in which possible therapies can be directly tested.

Leads for promising avenues of research

Plaques and tangles are the pathophysiological hallmarks of AD. Our goals are to reduce synthesis of precursors, stop aggregation, solubilize deposits, and stop downstream effects. Related to cell death dysfunction, efforts are underway to increase levels of protective growth factors, interfere with cell death pathways and boost ailing cells. In the long term, our goal is to replace dying cells and boost levels of growth factors by employing genetic engineering strategies. Efforts are also focused on stopping the loss of connections between neurons that occurs in AD.

Behavioral and caregiver research

Research has also been focussed on behavioral and medication strategies to manage the most troubling of the behavioral and other consequences of AD - wandering, aggression, agitation, sleep problems, and incontinence. Interventions are being systematically developed and tested to ameliorate these symptoms. Some include the beneficial effects of exercise, sleep hygiene, and strategies for coping with activities of daily living on reducing agitation and other negative behaviors. Better control of these behaviors will improve care and delay institutionalization. Related research focuses on reducing the effects of caregiving on the health and well-being of the caregivers; the stress of caregiving may lead to reduced immune function and increased susceptibility to disease. As another part of this effort, family-relevant measures of patient function are being developed by the Caregiving, Health Services, and Outcomes Research in Dementia (CHORD) project.

The increasing prevalence of AD crosses all ethnic groups. As part of the NIA Alzheimer's Disease Prevention Initiative, the NIA is supporting research aimed at developing caregiving interventions specifically tailored for minority families. Caregiving in minority populations is now being explored in the six sites of the REACH (Resources for Enhancing Alzheimer's Caregiver Health) initiative. This NIH study is designed to test social and behavioral interventions that would enhance family caregiving techniques in these populations.

None of these initiatives will be effective if persons with AD are not efficiently diagnosed and treated by their physician. Practice guidelines for diagnosis have been drawn up by the Agency for Health Care Policy and Research and practice guidelines for treatment by the American Psychiatric Association. Regular physician updates in research and care are carried out at the 28 NIA Alzheimer Disease Centers across the country.

The NIA is also taking steps to make information about AD more accessible to the general public. The NIA's Alzheimer's Disease Education and Referral (ADEAR) Center provides education services to the community through its web site (www.alzheimers.org) and a toll-free number (800-438-4380). In collaboration with the FDA, ADEAR had developed a database of ongoing AD clinical trials. When complete, both government and commercial trials will be represented. The database is accessible through the ADEAR site. Information can also be obtained through trained information specialists on the ADEAR toll-free line. Information on NIA-funded AD trials is now available, and ADEAR is soliciting information about ongoing clinical trials being conducted by drug companies.

Conclusion

The AD Prevention Initiative addresses a major source of disability in older persons, and its success in delaying progression of symptoms will contribute substantially to the projected cost savings described in the Alliance report. The National Institute on Aging, as the lead Federal agency on AD research, is committed to continuing its support of basic, clinical, and behavioral research that will improve our understanding of this devastating disease and help prevent or delay the onset of its symptoms.

Mr. PERRY. Thank you very much, Dr. Morrison-Bogorad.

Our next speaker is Dr. Lindsey Kerr, a physician in private practice with the Green Mountain Urology group.

Dr. Kerr.

Let me also say that because the format for today's forum allows us to have some give-and-take with the members of the media, as well as others in the audience, we will take questions for the entire panel when we are finished, if you will just remember your questions until we get to the end.

Thank you.

STATEMENT OF LINDSEY KERR, M.D., GREEN MOUNTAIN UROLOGY, AND NATIONAL SPOKESPERSON FOR THE NATIONAL ASSOCIATION FOR CONTINENCE

Dr. KERR. Thank you very much. Ladies and gentlemen, I did remember to take my Vitamin E this morning. So I think I can remember what to say.

I am actually the national spokesperson for the National Association for Continence, which is the largest consumer advocacy in the organization solely devoted to people and their families who are struggling with incontinence. We provide information on the diagnosis and treatment of incontinence. We have a referral data base with names of physicians and other care providers for people who are struggling with incontinence and have a special interest in treating the problem. We also publish a resource guide for our clients and advise them on new products available on the market. We also have a newsletter with a circulation of about 128,000.

We do regularly testify before the FDA and Medicare regarding treatment options and coverage of those options, and I will tell you that Medicare has asked us, and the FDA on occasion, to cease and desist because we have a very noisy coalition who like to get on the Internet and do not hesitate to pick up a pen and write to get something that they think they need to have.

Now, I will tell you that incontinence is not very sexy. And by and large, the news media has ignored this. We are willing to talk about sexually transmitted diseases, Alzheimer's, osteoporosis, but, you know, grandma wetting her pants, can we not bring that up, please. And so for those of you writing up there, I would like you to put something in about all of these people who happen to be wet and really struggle with this issue on a daily basis.

NAFC has the best 800 number I know of, back in the days when you actually could get an 800 number. You cannot any more. 1-800-bladder. [Laughter.]

We publish a great resource guide which is available to you, which has quite a bit of data in it that may be worth taking a look at.

I also am in private practice in Vermont. And it is always a pleasure to come to D.C., just so I can know how much fun it is to go back home again. [Laughter.]

I have been working for NAFC for about 4 years, on a volunteer basis, and it is really a privilege to be able to have the opportunity to address you today.

Now, those golden years, that we so fondly call them, may, in fact, be tarnished if one is plagued with incontinence—far from the

freedom and carefree lifestyle that those years are supposed to provide. Incontinence can rob our seniors of their mobility, their autonomy and their feeling of well-being.

Incontinence or even the fear of leakage, if it has not occurred, is debilitating and humiliating. In 1996, the HCPR reported that urinary incontinence affects 15 to 30 percent of community-dwelling adults and at least half of individuals confined to a nursing home. This is about 13 million Americans, and 85 percent of those are women. More recent studies from Kimberly Clark and from Neal Resnick at Brigham and Women's Hospital put those numbers at about 18 to 25 million. That is a lot of wet people out there.

We know the problem is associated with aging, although it should not be considered a natural part of the aging process, and those numbers are just going to increase as our population ages. Twenty-five percent of women, though, ages 30 to 59 complain of being wet.

The people afflicted with incontinence complain that it deprives them of their disposable income, of their time with family and loved ones, of their recreational and social activities and even of their living situations. Those products that you see, for those of you who do go to grocery store, on the shelves that are meant for menstruation, half of those products are used by people to deal with their wetting issues.

In terms of societal costs, incontinence is very expensive. The best studies that we have have come from Dr. Hu out of the University of California at Berkeley. He has developed the most widely quoted economic model on incontinence. And he looked at people I guess now 66 years of age and older—I did not know you had to wait until the sixty-sixth year—he estimated that the direct costs for incontinence were \$16 billion a year—I guess a billion here, a billion there, that does add up to a little pocket change at that point—\$28 billion of indirect costs because of incontinence. The adult diaper industry is a \$1.7 billion industry.

Urinary incontinence is a very valid predictor of rural nursing home use. Because there are fewer community-based services in these settings, older family members may be prematurely institutionalized when their incontinence precludes them from being cared for in their own homes or in extended living situations.

Now, I am not sure of the exact figure of how much it costs to have someone in a nursing home based on the data you gave, but from 1995, that was about \$40,000 to have someone institutionalized. And two-thirds of these people are either Medicare or Medicare-Medicaid dependent, which is an expense that we all bear. We know that doctors are currently undertrained to take care of this problem. Only recently has a diagnosis and treatment of this condition been included in the curriculum and tested for in recertification examinations—recently, that is in the past few years—for internal medicine.

Because incontinence is not life-threatening, it is often overlooked in assessing patients' health, in spite of the far-reaching consequences of its diagnosis. There is a big "don't ask, don't tell" policy when it comes to incontinence. It does not affect people's immediate life. And so the fact that you leak is something you may just have to deal with, or at least your doctor may think so.

Although we can teach residents and train residents on how to diagnose and take care of incontinence, the problem is that we have a huge group of physicians already out there practicing who have never been told to screen or ask their patients about incontinence.

When I go see my own physician, and I fill out that five-page form on every possible problem in my body system, and do I use a bike helmet and wear my seat belt, there is not a single question on that form, and this is from a very, very large health care provider group, there is not a single question that asks me whether or not I wet my pants.

So we need to reach these physicians through post-graduate courses, in-office training and with referral information. Other societies need to make it a priority. My society, American Urological Society, has done a good job in the past few years, but even we were a little bit slow on the uptake.

Patients and physicians need to be proactive in assessing their risk for incontinence and treating the condition when it is present.

We know incontinence is preventable, to a great extent. Work done in European countries supports the notion that pelvic floor exercises, those Kegels that you have heard about, can greatly reduce the degree of incontinence in the long run. There are public health services developed in several nations, which are responsible for these exercise programs.

We know that lung disease, secondary to tobacco abuse, obesity, lack of exercise and even constipation, all of which can be addressed, lead to incontinence, and in those cases, incontinence might very well be preventable if we are proactive. And even institutionalized patients who have reasonable cognitive skills can be helped. Is it possible that we could support a mobile campaign to reach these people and their caregivers?

We have had a very good couple of years in terms of research advances in incontinence, but we do need further research and research dollars spent on treatment methodologies and preventive measures with respect to incontinence. The very first RFA came out this spring, at least to my knowledge, on asking for grants devoted to the pelvic floor, which is the part of the anatomy that is responsible for keeping us all dry. This clearly is not enough.

We should be looking for outcomes-based research on prevention, new devices and drugs, and measure the use of currently available treatments. Money spent here would decrease the cost of taking care of these patients and may prevent the problem from happening at all.

There are a number of minimally invasive, very cost-effective treatments, such as biofeedback and pelvic floor exercise programs, and this is coming from a surgeon—I would rather be in the operating room—which could be implemented in the older population if funding was available. Again, better enjoyment of the senior years, with an increased quality of life. And then, obviously, fewer dollars spent would be the desirable end point.

There have been some promising new developments in the past year. There have been a number of devices which have been approved by the FDA, despite that arduous task of getting them through the FDA. There are several new transurethral devices,

urethral band-aids, home biofeedback units and pelvic stimulation units. There are also many surgical options which are significantly less invasive than what we have had to date, including collagen, which is injected directly into the urethra, and some laparoscopic or vaginal techniques which do not involve an overnight stay in the hospital.

Unfortunately, Medicare has been very slow to act with respect to the devices that have come along. And we have, in fact, lost one prominent company that had four or five devices out in the market because these were not paid for, covered by Medicare or any insurance companies.

For the first time in 17 years we have two new potent drugs for the treatment of urge incontinence; one which is actually a new delivery system for an old drug, and the second is a completely new drug. Both of these drugs have significantly fewer side effects and have been very effective for patients. And it has been wonderful for the people I take care of to finally have something new and useful I can offer them.

There are also several new drugs that are coming to the market for the treatment of stress incontinence, the kind of leakage you get when you cough or sneeze or lift something heavy and lose urine.

There is even an electrical stimulation chair—I will not give you its nickname, but you can just imagine—that has been used to treat people with incontinence that can be placed in a physician's office or another health care provider—this particular technology has also been used to treat refractory depression—and implantable devices that can be put directly into the back and around nerve endings to prevent urinary leakage caused by an overactive nerve system.

We need more options, we need more technology, we need more corporations and individuals who are willing to research these kind of things, and we need to get them covered by insurance companies. Many times these treatments can end up to be about one-tenth the cost of surgery, and in some instances, they are equally efficacious.

So I just want to remind you, again, if you would like to get a copy of our survey, 1-800-bladder is the number to call. There is also some very good information from the American Urological Association on Incontinence. Their number is 877-dry-life, and they have a Web site at www.drylife.org.

Thank you.

[The prepared statement of Dr. Kerr follows:]



NATIONAL ASSOCIATION FOR CONTINENCE
STATEMENT TO THE
SENATE SPECIAL COMMITTEE ON AGING
BY LINDSEY A. KERR, MD
National Spokesperson, NAFC

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"The golden years", as we so fondly call them, may in fact be tarnished if one is plagued with incontinence. Far from the freedom and carefree lifestyle that those years are supposed to provide, incontinence can rob our seniors of their mobility, their autonomy and their feeling of well being.

Incontinence, or fear of urinary leakage, even if it actually has not occurred, is debilitating and humiliating. In 1996 The AHCPR reported that urinary incontinence affects 15 to 30% of community-dwelling adults and at least half of all individuals confined to nursing homes. This represents 13 million Americans, 85% of which are women. Other studies (Kimberly-Clark Inc. and Resnick MD) put those numbers at 18 to 25 million. The problem is associated with aging, although it should not be considered a natural part of that process. It also is not just a problem of the aged, but affects 25% of women between the ages of 30 and 59.

In terms of societal cost, Dr. The-Wei Hu of the University of California at Berkeley has developed the most widely quoted economic model on incontinence. Looking at people 65 years and older, he estimated that the direct costs were 16 billion for this condition, and 28 billion if indirect costs were added to this. Urinary incontinence is a valid predictor of heavy rural nursing home use. Because of fewer community-based services in these settings, older family members may be prematurely institutionalized when their incontinence precludes them being cared for in the home or extended living situation. Based on 1995 figures of the annual cost of long-term care at \$39,000, this is a very expensive proposition. Two-thirds of these residents are covered by Medicare and/or Medicaid, which is an expense the taxpayer bears.

We know that doctors are currently under trained to take care of this problem. Only recently has the diagnosis and treatment of this condition been included in the curriculum and tested for on certification exams in internal medicine. Because incontinence isn't life threatening, it often is overlooked in assessing patient's health, in spite of the far reaching consequences of its diagnosis. Both patients and physicians

need to be proactive in assessing the risk for incontinence and treating the problem when it is present.

We need further research and research dollars spent on treatment methodologies and preventative measures with respect to incontinence. Clearly monies spent here would decrease the cost of taking care of these patients and may prevent the problem from occurring at all. There are a number of minimally invasive, cost effective treatments such as biofeedback and pelvic exercise programs which could be implemented in the older population if funding was available. Again, better enjoyment of the senior years with an increased quality of life and fewer dollars spent overall) would be the desirable endpoint.

The National Association for Continence is the largest consumer advocacy organization devoted solely to improving the lives of those suffering from incontinence. We wish to add life to years for our constituency. The cost of the problem is staggering but solutions are at hand. We hope you will consider budgeting funding and devoting your energies to help us solve this problem.

Mr. PERRY. Thank you, Dr. Kerr, for that statement on behalf of the National Association for Continence.

I would like to point out that the report that we are releasing today is endorsed by over a dozen national organizations that represent advocacy on behalf of Americans with Alzheimer's disease, osteoporosis, incontinence and vision loss. And in the press kits, which I believe many of you have, there is a full list of the endorsing organizations.

The next speaker is Dr. Joan McGowan. Dr. McGowan is the chief of the Musculoskeletal Branch of the National Institute for Arthritis and Musculoskeletal and Skin Research.

Dr. McGowan.

STATEMENT OF JOAN MCGOWAN, CHIEF, MUSCULOSKELETAL DISEASES BRANCH, NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES, NATIONAL INSTITUTES OF HEALTH

Dr. MCGOWAN. Thank you very much. I would like to thank Mr. Perry and the Alliance for Aging Research and also the Senate Special Committee on Aging for inviting me to address some very important topics to the NIH.

Osteoporosis and osteoarthritis are two of the major causes of disability and pain in older people. And while the economic costs of these two conditions are considerable, the psychological and social costs can be devastating to an individual, and we should not forget that aspect, that dimension of these problems.

A hip fracture resulting from osteoporosis often spells the end of independent life for older people. The pain and immobility of osteoarthritis are isolating and can lead to depression. These two diseases can often take the life out of living. Osteoporosis and osteoarthritis are two rather similar sounding names that have very different crippling effects on the musculoskeletal system.

Osteoporosis is a bone disease. It is characterized by low bone mass and also a deterioration of the structure of bone that makes the skeleton fragile and leads to an increased susceptibility to fracture. The most frequent fractures that we see are in the wrist, the hip and the spine. It is the most prevalent bone disease affecting about 28 million Americans, and one out of every two women and one out of every eight men over 50 will have an osteoporosis-related fracture in their lifetime. And although it is the underlying cause of most fractures in people over 50, frequently the condition is silent and it is undetected, in most cases, before a fracture. So identifying individuals at risk and thus preventing fractures is a major goal of our research program.

Let me cite two very important ongoing studies—two of many, in osteoporosis. Dr. Wetle mentioned Dr. Cummings and the study of osteoporotic fractures. This is supported by my institute and the National Institute on Aging and involves over 9,000 women over 65. It has contributed, over the last 10 years to a wealth of information about risk factors for all kinds of fractures. This study and others have demonstrated that a measurement of bone mineral density can be used to predict the risk of hip and other fractures. And once a person is identified to be at high risk, there are several effective interventions to prevent fractures.

Another study, that most will not think of as a study of osteoporosis, is the NIH Women's Health Initiative—one of the largest studies ever conducted involving over 160,000 postmenopausal women in an investigation of the major causes of death and disability in older women. Among its many goals, the Women's Health Initiative will determine the usefulness of calcium and Vitamin D over the long run in preventing hip fractures and also colon cancer in older women, as well as the effect of hormone replacement on hip fractures.

Indeed, there is another part of the Women's Health Initiative that is looking at the effect of estrogen on mental disability, mental decline and Alzheimer's in a group of 28,000 women. So this will provide very important information on a number of the conditions that tend to co-exist in older people.

These two studies, and many others, involve women. Women are more likely to develop osteoporosis than men. However, with the decline in cardiovascular mortality that we see now and hope for in the future, and with the other declining causes of premature death for men, fractures later in life are becoming an increasingly important cause of morbidity and even mortality in older men.

Although 50-year-old white men have a 13-percent lifetime risk of fracture, the causes and mechanisms involved in osteoporosis in men have received little research attention. NIAMS, in collaboration with the National Institute on Aging is about to launch a large epidemiologic study of osteoporosis in men over 65 to study the risk factors for fracture development in men.

Of course, every increment in research progress brings us closer to eliminating the pain and the suffering caused by this disease. Just this past month, one study revealed that women well past menopause can profitably take a lower dose of estrogen, as long as it is in combination with sufficient calcium and Vitamin D. Women can achieve these gains in bone mass and hopefully prevention of fractures without the negative side effects that are often associated with higher doses of estrogen. This is especially significant for older women, as estrogen replacement is now the cornerstone of osteoporosis treatment and prevention for many women.

Another recent study showed that elderly women who have had several spine fractures profit the most from calcium supplementation, both in terms of reducing the future number of spine fractures and in the cessation of bone loss. This finding has clear implications for developing and targeting new preventive strategies. It is never too late for prevention. People who have already had fractures can prevent the next set of fractures. But it is not sufficient for us to conduct and support research. We have to get information out to the public about disease strategies.

The NIH Osteoporosis and Related Bone Diseases National Resource Center was created by NIAMS in 1994 in response to a groundswell of interest, both by voluntary and professional groups, and also by key congressional leaders. Other Federal partners, including the NIA, now support this resource center, and we do this in partnership with the National Osteoporosis Foundation, the Paget Foundation and the Osteogenesis Imperfecta Foundation.

The Center provides an important link to resources and information on bone diseases, and its mission is to expand the awareness

and enhance knowledge and understanding of the prevention, early detection and treatment of these diseases, as well as strategies for coping with disease.

Osteoporosis does not need to be a consequence of aging. It is a highly preventable disease. Remarkable progress has been made in our understanding of the causes, diagnosis, treatment and prevention of osteoporosis. Many new and exciting scientific opportunities exist that enhance our knowledge about how to maintain a healthy skeleton throughout life.

Now to turn again to osteoarthritis, also known as degenerative joint disease. This occurs when the cartilage lining that keeps our bones from rubbing on each other begins to fray, wear, and decay, causing joint pain and reduced joint motion, loss of function and disability.

The frequency of osteoarthritis is expected to rise in the United States because this type of arthritis increases with age, and the population of the United States is aging, as Dr. Wetle has so graphically pointed out. Baby boomers, like us, are now moving into prime osteoarthritis years. Osteoarthritis has a formidable effect on the burden of disability and dependence in older Americans. But scientific opportunities to prevent OA are also increasing, as we recognize more modifiable risk factors. Both sports injuries and obesity put individuals at increased risk, and efforts are underway to reduce their impact.

NIAMS is going to be holding a scientific conference on the prevention of onset, progression, and disability of osteoarthritis in July, and we have brochures outside on "Stepping Away from OA." The overall goals are to stimulate further research in this important area, but also to make available the best information about preventing the disease, about its progression and about slowing the onset of disability. In addition to the scientific sessions, this meeting will also feature a session for the public on what you can do to prevent the onset, progression and disability of OA.

NIH is committed to the goal of reducing the toll of degenerative joint disease and osteoporosis through research on diagnosis, prevention and treatment. Although there has been an explosion of basic and clinical research in osteoporosis and osteoarthritis, more fundamental advances in molecular and cellular biology, immunology, genetics and bioengineering need to be applied to these areas. We are optimistic and really quite excited by the scientific progress and the promise.

The payoff that we expect from this research investment and future research investments will be the increased years of healthy, pain-free, independent life for all older Americans.

Thank you.

[The prepared statement of Dr. McGowan follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

**NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN
DISEASES (NIAMS)**

SENATE SPECIAL COMMITTEE ON AGING

Osteoporosis Research, Prevention, and Treatment

**Joan A. McGowan, Ph.D.
Chief, Musculoskeletal Diseases Branch, NIAMS**

June 10, 1999

About Osteoporosis

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures -- especially of the hip, spine, and wrist. It is the most prevalent of the bone diseases that affect Americans. Although it is the underlying cause of most fractures in older people, the condition is silent and undetected in most cases until a fracture occurs.

Osteoporosis is a major threat for 28 million Americans. In the U.S. today, 10 million individuals already have osteoporosis and 18 million more have low bone mass, placing them at increased risk for this disease. American women are four times as likely to develop osteoporosis as men. One out of every two women and one in eight men over 50 will have an osteoporosis-related fracture in his or her lifetime.

Osteoporosis is responsible for more than 1.5 million fractures annually, including 300,000 hip fractures, approximately 700,000 vertebral fractures, 200,000 wrist fractures, and more than 300,000 fractures at other sites.

Of all these injuries, hip fractures have the greatest morbidity and socioeconomic impact. Following a hip fracture, there is a 10 to 20 percent mortality rate during the next 6 months. This means people can, and do, die as a result of hip fractures. Fifty percent of those people experiencing a hip fracture will be unable to walk without assistance, and 25 percent will require long-term care. The burden of health care costs due to osteoporotic fractures is estimated to be approximately \$14 billion per year.

Osteoporosis, however, does not need to be a consequence of aging. It is largely a preventable disease, and many research opportunities exist to enhance our knowledge about how to maintain a healthy skeleton throughout life.

Remarkable progress has been made in our understanding of the causes, diagnosis, treatment, and prevention of osteoporosis. However, many avenues of scientific opportunity remain. Every increment of research progress brings us closer to eliminating the pain and suffering caused by this disease.

Addressing Osteoporosis: A Collaborative Approach

Significant efforts are underway at the Federal level aimed at addressing this serious public health problem. In particular, several components of the National Institutes of Health (NIH) are currently supporting basic and/or clinical research on osteoporosis and related bone diseases. The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) has taken the lead in initiating the Federal Working Group on Bone Diseases. Launched in 1993, this group provides a forum for the sharing of information between NIH institutes and other Federal agencies

to enhance communication and to coordinate research efforts across all Federal agencies with an interest in bone diseases and bone health.

The Study of Osteoporotic Fractures (SOF), supported by NIAMS and the National Institute on Aging (NIA), and involving more than 9,000 women 65 years or older, described risk factors for hip, wrist, and spine fractures. The study demonstrated that bone mineral density predicts hip and other types of fractures, and also provided evidence that women with low bone density have an increased risk of stroke, as well as evidence of a relationship between bone mineral density and breast cancer incidence. The NIH Women's Health Initiative currently supports the largest study of osteoporosis and fractures ever conducted. This study will determine the usefulness of calcium and vitamin D supplements, and may lead to new public health initiatives to optimize the intake of these nutrients in the U.S. population.

Addressing Osteoporosis: NIAMS' Research Agenda

NIAMS leads the Federal research effort on osteoporosis and related bone diseases, and is responsible for nearly half of the NIH funding for research in this area (which totaled over \$120 million in FY 1998). NIAMS-supported research ranges from very basic studies to clinical and translational research and early intervention and prevention projects, such as "Camp Calcium," a novel program for adolescent girls, which has as its goal the determination of how much calcium growing girls need in their diets so that they can develop the strongest possible bones, and thus help reduce their chance of getting osteoporosis later in life.

Overall, significant advances in prevention and treatment of osteoporosis are available today as the direct result of research focused on determining the causes and consequences of bone loss at cellular and tissue levels, assessing risk factors, developing strategies to maintain and even enhance bone density, and exploring the roles of such factors as hormones, calcium, vitamin D, drugs, and exercise on bone mass.

Selected Scientific Advances

A number of recent advances illustrate the progress being made in understanding osteoporosis and how it might be treated and prevented:

- *The finding that low-dose hormone replacement therapy (HRT) prevents bone loss -- A study published just this month has revealed that women well past menopause can profitably take a lower dose of estrogen than is commonly prescribed, in combination with a sufficient intake of vitamin D and calcium supplements, and achieve gains in bone mass without the negative side effects associated with higher doses of estrogen. This is especially significant as estrogen replacement is now the cornerstone of osteoporosis treatment and prevention.*

- *Findings on steroid-induced bone loss in mice point to preventive possibilities* – Investigators have recently used a mouse model and cell culture techniques to shed light not only on the destructive mechanism of glucocorticoids -- a class of steroidal immunosuppressive medications -- but also on ways to prevent steroid-induced bone loss. Steroid-induced osteoporosis is common among transplant patients, as well as those who suffer from chronic autoimmune diseases, such as lupus and rheumatoid arthritis.
- *The identification of a gene essential for the formation of bone* – Through a convergence of efforts by investigators around the world, research has shown that normal skeletal development -- in both mice and humans -- apparently requires two active copies of the gene *Cbfa1*. This discovery is expected to open a number of exciting new research areas.
- *The finding that estrogen induces "programmed cell death" in the cells that are responsible for the degradation of bone (osteoclasts)* – By paving the way for future assessment of whether other drugs can also affect the programmed cell death of osteoclasts (thereby making them potentially useful as bone-protecting treatments), this discovery represents an exciting link between basic research and tangible patient benefit.
- *The finding that one of a collection of molecules fabricated by researchers (called peptidomimetics) successfully blocks part of the bone resorption process* -- This is the first clear indication that a particular synthetic antagonist may be effective in the prevention of osteoporosis. The finding may hold promise for combating bone loss in women who cannot tolerate estrogen.
- *Patient-based research showing that elderly women who already had several spine fractures at the start of a study experienced the greatest health benefit from calcium supplementation (both in terms of reduction in the rate of new spine fractures and cessation of bone loss)* -- This finding has clear implications for developing and targeting new preventive strategies.

Current and Planned Initiatives

In the past decade, there has been an explosion of basic and clinical research in osteoporosis. Many fundamental advances in molecular and cellular biology, immunology, genetics, and bioengineering could be applicable to skeletal biology. In addition, research on a new class of drugs called Selective Estrogen Receptor Modulators (SERM's) also holds promise in terms of reducing bone loss in postmenopausal women without adverse effects on other organs.

Alendronate, a bisphosphonate, was recently approved by the Food and Drug Administration for treatment of postmenopausal osteoporosis. This class of drugs targets bone specifically, reducing bone breakdown and decreasing fractures in older women. This development, along with other advances, creates vast opportunities to expand the current knowledge base, continuing in a diversified approach to osteoporosis. Initiatives which may serve as a springboard for further

research include:

- *Multi-center clinical intervention studies on combination therapies for osteoporosis* -- Because pharmaceutical companies tend to focus resources on bringing individual drugs to market, Federal support is needed to test combinations of drugs, as well as possible exercise and nutritional modifications to various drug combination regimes. Lower doses and combinations of effective agents may serve to reduce side effects and risks associated with current individual drug treatments, and may improve overall responsiveness. These studies will also generate information on osteoporosis in men, children, adolescents, and others who have diseases and conditions that put them at high risk of osteoporosis, not just on postmenopausal women, the group on whom most private sector research has been concentrated. To this end, the NIAMS recently issued a request for proposals to uncover which combination therapies for osteoporosis optimize improvements in bone mass and bone strength while minimizing deleterious side effects.
- *Large epidemiologic study of osteoporosis in men to study risk factors for fracture development* -- Although 50-year-old white men have about a 13 percent lifetime risk of fractures of the hip, spine, or wrist, the causes of and mechanisms involved in osteoporosis in men have received little research attention. Men develop osteoporosis and osteoporotic fractures about a decade later than women do. This has been attributed to a higher peak bone mass at maturity and a more gradual diminution in sex steroid influence in aging men. At each age the rate of hip fracture in men is about 50 percent that in women. With the decline in premature cardiovascular mortality in men, fractures later in life are becoming an increasingly important cause of morbidity and mortality in older men. NIAMS solicited research on the basic biology, epidemiology, prevention, and treatment of osteoporosis and osteoporosis-related fractures in men in order to reduce the incidence. In response to this solicitation, a large epidemiologic study will be launched to study the risk factors for fractures in men over age 65.
- *Development of new technologies to measure bone quality as well as bone mineral density* -- The need to evaluate the contribution of bone architecture -- in addition to bone mass -- in determining resistance of bone to fracture in vivo is spurring interest in new methods, which may include variations of micro-computed tomography or magnetic resonance imaging (MRI) techniques. Ultrasound technology is emerging as an alternative to bone densitometry for some clinical applications, and studies are also underway to develop blood and urine tests that may one day be used to screen for osteoporosis.
- *The Bone Density, Biomarkers and Physical Activity component of the National Health and Nutrition Examination Survey (NHANES) IV* -- National Health and Nutrition Examination Surveys have been conducted periodically since the 1960's, via household interviews and physical examinations provided in specially designed mobile examination centers, and with data collections periods ranging from 3 to 6 years. NHANES IV is planned as a continuous survey with data collection beginning this year. NIAMS is

specifically interested in information from three tests to be included in the exam: dual energy x-ray absorptiometry (DXA), measurements of markers of bone resorption in urine and blood samples, and assessment of musculoskeletal strength in participants aged 50 and over (one of two levels of physical fitness included for the first time in the Survey).

- *Research on bone and hematopoiesis (a process in which blood cells are produced, including the many different cells of the immune system)* -- Following an August 1997 workshop, a program announcement has been developed which focuses on the interactions between two cellular systems which develop in close proximity in the bone marrow: the cells of the skeletal system (the cells that form and break down bone) and the cellular components of the immune system. The initiative will encourage collaboration between investigators with expertise in one area, such as bone biology or immunology, with other investigators having complementary expertise.
- *Research on risk factors for bone fragility fractures in children and adolescents* -- Current research is underway which will examine bone mineral density and measure dietary calcium intake in children and adolescents with distal forearm fractures and in normal controls. It is expected that this research will provide significant evidence that calcium may immediately reduce the number of fractures in children, and that it may serve to provide an incentive to families and their adolescent children to increase calcium intakes.
- *Consensus Development Conference on Osteoporosis Prevention, Diagnosis, and Therapy* -- The last Consensus Development Conference on Osteoporosis (1984) marked a turning point in the view of the public and the research community about osteoporosis. Because there has been an explosion of information about diagnosis, treatment, and prevention since that time, an assessment of recent developments and research directions is warranted, aimed at ensuring that all physicians who see people at risk of osteoporosis -- not just expert bone endocrinologists -- have the latest information. Accordingly, the NIAMS is sponsoring another osteoporosis consensus conference in March of 2000.

Information Dissemination and Education Efforts

The NIH Osteoporosis and Related Bone Diseases--National Resource Center was created by NIAMS in 1994 in response to a groundswell of interest by several voluntary and professional groups and key congressional leaders. Other Federal partners now support the Resource Center in addition to NIAMS, including NIA, as well as the National Institute of Child Health and Human Development, the National Institute of Dental and Craniofacial Research, the National Institute of Environmental Health Sciences, the NIH Office of Research on Women's Health and the HHS Office of Women's Health -- in cooperation with the National Osteoporosis Foundation, the Paget Foundation, and the Osteogenesis Imperfecta Foundation. This Center provides an important link to resources and information on metabolic bone diseases, and its mission is to expand awareness and enhance knowledge and understanding of the prevention, early detection, and treatment of

these diseases, as well as strategies for coping with them.

Through the Resource Center, collaborative efforts to enhance the strategies to promote bone health for women are being instigated through the National Osteoporosis Education Campaign. The initial focus of the campaign will be to encourage teenage women to develop positive health behaviors (for example, diet, exercise, calcium intake) that can have effects on bone strength that last a lifetime.

FEDERAL WORKING GROUP ON BONE DISEASES

Federal Member Organizations

National Institutes of Health:

- National Institute of Arthritis and Musculoskeletal and Skin Diseases
- National Institute of Child Health and Human Development
- National Institute of Environmental Health Sciences
- National Institute of Diabetes and Digestive and Kidney Diseases
- National Cancer Institute
- National Institute of Dental and Craniofacial Research
- National Institute on Aging
- National Institute of Nursing Research
- National Institute on Alcohol Abuse and Alcoholism
- National Center for Research Resources
- Office of Research on Women's Health

Other Federal Agencies:

- Agency for Health Care Policy and Research/Forum for Quality and Effectiveness of Health Care
- Health Care Financing Administration/Office of Research and Demonstration
- Department of Agriculture/Human Nutrition Research Center
- Department of Defense/Army Operational Research Program
- Centers for Disease Control and Prevention
 - National Center for Chronic Disease Prevention and Health Promotion
 - National Center for Health Statistics
- Food and Drug Administration/Division of Metabolism and Endocrine Drug Products
- Department of Education/National Institute on Disability and Rehabilitation Research
- National Aeronautics and Space Administration/Life and Biomedical Sciences Applications Division

Liaison Organizations/Federal and Non-Federal

NIH Office of Disease Prevention
NIH Clinical Center Nursing Department
NIH Nutrition Coordinating Committee
Department of Health and Human Services
 Office on Women's Health
 Administration on Aging
 NIH Osteoporosis and Related Bone Diseases-National Resource Center
National Osteoporosis Foundation
The Paget Foundation
American Society for Bone and Mineral Research

Mr. PERRY. Thank you, Dr. McGowan.

Our wrap-up speaker on the panel, and before we open the forum to questions, is Dr. Steven Pratt. Dr. Pratt is in private practice. He is the chief staff ophthalmologist at the Scripps Memorial Hospital in La Jolla, CA. And he will be talking to us about age-related blindness, certainly a much-feared and devastating condition which would destroy independent living for many older Americans.

Dr. Pratt.

STATEMENT OF STEVEN PRATT, M.D., SENIOR STAFF OPHTHALMOLOGIST, COSMETIC SURGERY AND EYE CENTER, SCRIPPS MEMORIAL HOSPITAL, LA JOLLA, CA

Dr. PRATT. Thank you very much. It is certainly a pleasure and an honor to be here today. I am Dr. Steven Pratt, and I am a senior staff ophthalmologist at Scripps Memorial Hospital in La Jolla, CA. I am also assistant medical professor of ophthalmology at the University of California, San Diego, School of Medicine.

Over the last 22 years, I have diagnosed vision loss in thousands of seniors, people for whom their eyesight suddenly becomes the center of their existence. I have seen them struggle with remaining independent, and I have seen them lose that independence when nothing more can be done. I have seen devastation when an older person loses the ability to drive, in a country where driving really equates with independence.

There are four main causes of vision loss in senior citizens in this country today: cataracts, glaucoma, diabetic retinopathy and age-related macular degeneration or AMD. As a physician, it is my job to diagnose and treat these conditions whenever possible, and in many cases, I can do my job. I can remove cataracts, I can treat glaucoma with medications, and or with surgery, I can use lasers for diabetic retinopathy. In these cases, I can cure and I can give hope to my patients.

However, every day across this country, ophthalmologists and optometrists diagnose patients with age-related macular degeneration. In many cases, these eye-care specialists must send their patients home without hope, without a cure, and there is really little that we can do about giving them hope for their future.

Because of AMD, I have watched my own mother and grandfather become legally blind from macular degeneration, a truly unpleasant and very helpless situation.

AMD is the leading cause of irreversible blindness in persons over the age of 65. The Beaver Dam Eye Study estimates that 25 percent—that is one-quarter of the population—over age 65 has clinical evidence of this disease. The numbers worsen as age increases. For persons 75 and older, fully 33 percent have clinical findings of AMD. Another 23 percent will have signs of AMD by the time they turn 80 years of age. The prevalence of AMD is highest in the fastest growing age group of this country, and that is 85 and older. By the year 2050, there will be upwards of one million Americans 100 and over.

Combine these facts, and we have a vision loss epidemic not only in the U.S., but also in industrialized countries around the world. As we increase life span, we must do much more to increase our health span.

Unfortunately, AMD is an invisible disease. Awareness is extremely low. Because treatment options are limited and a cure does not exist, it seems that very few health care dollars are spent on AMD. The fact is, however, that AMD and other diseases that cause vision impairment in the elderly do cost money—primarily from an increased need for nursing home care and assisted living.

In addition, AMD has a disabling ripple effect in seniors. With vision loss, falls and fractures increase, exercise then decreases, leaving persons at increased risk for diabetes, obesity, heart disease, depression and a variety of cancers. In my opinion, changes in diet and other lifestyle habits should be our priority as we combat this disease and hopefully keep our health care costs under control.

Numerous studies are underway to find a cure. Some forms of AMD can be treated with lasers but, at best, we can only halt progressive loss of vision. Promising phototherapy techniques are under development, but can only be used in a small number of cases. Tissue transplants are being investigated, an expensive solution to disease that affects millions of people in a health care system with limited resources.

By the time a person is diagnosed with AMD in their sixties or seventies, the disease has been developing for decades. This leads me to conclude that prevention is the only realistic hope for halting the increasing prevalence of AMD, prevention that ideally must start at an early age. And remember that prevention is always going to be less expensive than is treatment.

Prevention of AMD must involve synergy between changes in both dietary habits and lifestyle. Increased risk of AMD has been linked to a multitude of risk factors, including cigarette smoking, excess alcohol intake, lifetime sun exposure, genetics, gender and light-colored irises. But the most intriguing risk factor is low dietary intake of fruits and vegetables.

Several dietary factors may contribute to AMD prevention, including Vitamin E, polyphenolic flavonoids, carotenoids and the mineral zinc. Most promising are two nutrients, lutein and zeaxanthin, found in fruits and vegetables, but particularly in dark green, leafy vegetables. Lutein and other essential anti-oxidants can also be well absorbed from vitamin supplements, raising blood and tissue levels.

Research provides conclusive evidence that lutein functions as an anti-oxidant in the human macula and in other parts of the body subject to damaging free radicals. Investigators at Schepens Eye Research Institute in Boston have found that high levels of lutein and zeaxanthin in the macula may protect against retinal disease. In one study, persons with high levels of lutein in their diets had a 43-percent decreased risk of developing wet AMD, the most visually disabling form of this disease.

Equally important, research indicates that lutein may help in the prevention of cataracts and even perhaps glaucoma.

Indications are that Americans do not consume enough of this beneficial nutrient. Recent studies indicate that only 1 percent of Americans eat a green, leafy vegetable each day, and less than 15 percent eat the USDA-recommended five servings of fruits and vegetables. Lutein consumption in women actually decreased by 18

percent between 1987 and 1992, despite higher AMD risk in women.

Recently, I attended the annual meeting of the Alliance for Research in Vision and Ophthalmology and met researchers from across the world who are focusing their studies on Lutein and its link to AMD prevention. They shared with me their triumphs, the growing scientific evidence that lutein and zeaxanthin are two of the essential nutrients in prevention of AMD. They also shared with me their frustration, their repeated, and for the most part, unsuccessful efforts to obtain funding from the National Institutes of Health to further lutein research.

I respectfully submit that we must focus our attention on research and education that will help prevent age-related macular degeneration and other eye diseases. Clinical trials must be done to determine lutein's role in treatment and prevention. Americans must learn to eat more carotenoid- and lutein-rich foods or at least take a well-balanced supplement containing a wide variety of nutrients, including lutein. We owe it to ourselves and our rapidly aging population.

I hope, the golden years hopefully will arrive for all of us. If we want to keep the golden years truly golden, then there are things we need to start doing throughout our entire life to prevent vision loss.

Thank you very much.

[The prepared statement of Dr. Pratt follows:]

My name is Dr. Steven Pratt. I am a senior staff ophthalmologist at Scripps Memorial Hospital in La Jolla, California.

Over the last 22 years, I have diagnosed vision loss in thousands of seniors, people for whom their eyesight suddenly becomes the center of their existence. I have seen them struggle with remaining independent and I have seen them lose that independence when nothing more can be done. I have seen devastation when an older person loses the ability to drive, in a country where driving equals independence.

There are four main causes of vision loss in elderly Americans: cataracts, glaucoma, diabetic retinopathy and age-related macular degeneration or AMD. As a physician, it is my job to diagnose and treat these conditions whenever possible. And in many cases, I can do my job. I can remove cataracts. I can treat glaucoma with medications or surgery. I can reduce vision loss from retinopathy through photocoagulation therapy. I can cure and I can give hope.

But every day across this country, ophthalmologists diagnose patients with age-related macular degeneration. And then, in many cases, those doctors must send the patients home without a cure, without hope.

Because of this, I have watched my own mother and grandfather become legally blind from macular degeneration — a truly unpleasant, helpless experience.

AMD is the leading cause of irreversible blindness in persons over the age of 65. The Beaver Dam Eye Study estimates that 25 percent – one-quarter of the population – over 65 has clinical evidence of the disease. The numbers worsen as age increases. In persons 75 and older, fully 33 percent have symptoms of AMD. Another 23 percent will have signs of AMD by the time they turn 80 years of age. Prevalence of AMD is highest in the fastest growing age group—85 and older. By the year 2050, there will be upwards of a million Americans 100 and over.

Combine these facts and we have a vision loss epidemic, not only in the U.S. but also in industrialized countries across the world. As we increase lifespan, we must do more to increase health span.

Yet, AMD is an invisible disease. Awareness is extremely low. And because treatment options are limited and a cure does not exist, it seems that very few health care dollars are spent on AMD.

The fact is, however, that AMD and other diseases that cause vision impairment in the elderly do cost money, primarily from increased need for nursing home care and assisted living. In addition, AMD has a disabling ripple effect in seniors. With vision loss, falls and fractures increase, exercise decreases, leaving the person at risk for diabetes, obesity and heart disease.

The position I will present today is that changes in diet and other lifestyle habits should be a priority as we combat this disease and attempt to keep our health care costs under control.

Numerous studies are under way to find a cure. Some forms of AMD can be treated with lasers but, at best, we can only halt progressive loss of vision. Promising phototherapy techniques are under development but can only be used in a small number of cases.

Tissue transplants are being investigated -- an expensive solution to a disease that affects millions of people in a health care system with limited resources.

By the time a person is diagnosed with AMD in their 60s or 70s, the disease has been developing for decades. This leads me to conclude that prevention is the only realistic hope for halting the increasing prevalence of AMD — prevention that must start at an early age.

Prevention of AMD must involve synergy between changes in both dietary intake and lifestyle. Increased risk of AMD has been linked to cigarette smoking, excess alcohol intake and lifetime sun exposure, in addition to genetics, gender and light colored irises. But the most intriguing risk factor is low dietary intake of fruits and vegetables.

Several dietary factors may contribute to AMD prevention, including Vitamin E, polyphenols, carotenoids, and the mineral zinc. Most promising are two related nutrients -- lutein and zeaxanthin -- found in all fruits and vegetables but particularly in dark green

leafy vegetables. Lutein can also be well absorbed from vitamin supplements, raising blood and tissue levels.

Research provides conclusive evidence that lutein functions as an antioxidant in the human macula and in other parts of the body subject to damaging radicals. Investigators at Schepens Eye Research Institute found that high levels of lutein and zeaxanthin in the macula may protect against retinal disease. Persons with high levels of lutein in their diets have a 43 percent reduced risk of developing wet AMD, the most visually disabling form of the disease.

Equally important, research indicates that lutein may help in the prevention of cataracts, and perhaps glaucoma.

But indications are that Americans do not consume enough of this beneficial nutrient. Recent U.S. Department of Agriculture studies indicate that only 1 percent of Americans eat a green, leafy vegetable each day. Lutein consumption in women actually decreased by 18 percent between 1987 and 1992, despite higher AMD risk in women.

Recently I attended the annual meeting of the Alliance for Research in Vision and Ophthalmology and met researchers from across the world who are focusing their studies on lutein and its link to AMD prevention. They shared with me their triumphs -- the growing preponderance of evidence that lutein and zeaxanthin are essential nutrients in the prevention of AMD. But they also shared with me their frustration. Their repeated

efforts to obtain funding from the National Institutes of Health for further lutein research. And their repeated failure to obtain the dollars they need.

I respectfully submit that we must focus our attention on research and education that will help prevent age-related macular degeneration and other eye diseases. Clinical trials must be done to determine lutein's role in treatment and prevention. Americans must learn to eat more carotenoid- and lutein-rich foods or take lutein supplements. We owe it to ourselves and our rapidly aging population.

Thank you.

Mr. PERRY. Thank you, Dr. Pratt.

The panel is resuming their original seats at the dais, and now is the time when we can open up this forum and have some interchange with those of you, both those who are from the media and from various organizations.

This is all being taped and will be made part of the official record of the Senate Special Committee on Aging. Therefore, I ask that each of you, when you ask your question, to please come forward and ask your question into the microphone so that we can record it.

And just to kick off the discussion, I will ask you to be reminded once again of three figures: \$4,800 a year that we spend for Medicare beneficiaries who are healthy and independent; for those that lose some ability to care for themselves and their daily activities, it goes from \$4,800 to \$18,000; and for those that further deteriorate to the point where they need to enter a nursing home for at least some time during the year, that figure goes to \$36,000.

It is a tremendous economic outflow from health care delivery system because people lose that ability to stay on their own, and you have heard from the specific diseases that are the major causes behind that. And we have superb experts that can speak to each of those diseases, as well as Dr. Wetle and Dr. Branch that can talk about the health of the elderly in the macro sense.

So do we have a question? [No response.]

We have answered all of your questions. Does anyone at all want to take an opportunity to ask of one of our experts?

Ms. WETLE. I would like to ask a question.

Mr. PERRY. Please.

Ms. WETLE. Is that all right? Is that allowable, Dan?

Mr. PERRY. It is absolutely.

I had a question about incontinence. I have been very interested in this problem professionally for a long time. In fact, Dr. Branch and I had the opportunity many years ago to do research in the area with Dr. Resnick.

One of the problems that we have struggled with, is getting people to report symptoms of incontinence to their physicians. As you said, there is a "don't ask, don't tell attitude." But even when people report to their physicians concerns about their continence, the physicians, in half the cases, just say, well, use pads. The educational problem that we face is so broad regarding this issue because it cuts across family members, the individuals who are suffering, and the professional community. I wondered if you had a sense of what might be done.

Dr. KERR. It is an interesting issue on a number of fronts. One is that since the problem predominantly affects females and since women have menstruated up to about the time that they start to leak urine, which is around the time of menopause, that switch from using one product, using a product for one thing versus the same product for something else is not often a difficult transition for these people. It is also a source of great embarrassment and shame on the part of the patients to even bring it up with their doctors, and to a great degree, doctors are willing to say that it is not an issue. Although we know it is closely linked to sexual dysfunction, it is very closely linked to depression, it is very closely

linked to sleep deprivation. So it has some very significant impacts on patients' lives that menstruating did not have at all on their lives.

The most interesting thing that I have noticed over the past year actually came because of a pharmaceutical drug campaign over the summer. And this was a nonlabeled campaign for—it was addressed to people who suffer from frequency and urgency or the new coined term “overactive bladder.” And the ads started to appear in August. It was not until October that it was labeled or tagged to the drug. And we saw this huge surge in patients coming in to their primary care doctor's office with this ad torn out of the magazine and saying, “Look. They say it is a problem. Why is it when I tell you, it is not a problem? They say this is not normal. What can I do about it?” So it came from an outside source that patients acknowledged, and then when the ads appeared on television, well, once it appears on television, then it is OK to talk about. But we are still lagging behind having it discussed in the lay press, having it brought up and written about in magazines. I have done a number of interviews for *More Magazine*, *Glamour*, *Cosmopolitan*. And when they have gotten around to actually writing the article, it is a hard sell for the writers to their editors because their editors say we do not really want to put this in the magazine.

Even *Modern Maturity* refused for years to include anything in their magazine regarding incontinence, because incontinence in their population was a sign of debilitation, and they wanted to portray their seniors of having this active lifestyle and being able to enjoy their senior years and not deal with something which, for a lot of them, was keeping them from enjoying their senior years.

So I think there has been great societal pressure, to put it all together, great societal pressure not to even discuss it. And then there has not been an emphasis in medical schools and residency training to do anything about it. And part of that has to do, I quite frankly believe, with the segment of population which was affected, and that was it was women. Now that the Internal Medicine Board has taken a close look at it and made priorities for women's health and the teaching of women's health, and we have done the same thing in my specialty, I think it is going to be addressed much more thoroughly.

Mr. PERRY. Others on the panel that would like to comment on that? [No response.]

I would actually add my own comment, that past generations of older people have come to accept the notion that with old age there are all of these problems. And past generations have been rather stoical about that—sort of accept, get on with your life, do whatever you can to muddle through. But there is a new generation of people now moving from middle age into the age when they are eligible to join AARP and other seniors groups, and there is a very different mind set, and that is one of take care of yourself, be in charge of your own health, get as much information as possible and demand that your physician and that your health care provider give you the latest means to maintain your life and the quality of your life.

I think that is going to be a good thing for health care of the elderly. I think that we will find a lot more consumer demand that insists that we have the means to forestall memory loss, and osteoporosis, and vision loss and incontinence. So I think that day is probably changing. And we will be overcoming some of the ageism that has filtered down in our health care delivery where we sort of assume, you know, "What do you expect? You are 75 years old."

Well, increasingly, those 75-year-olds are going to say, "I expect to be able to walk around. I expect to be able to live independently."

Ms. WETLE. To jump out of airplanes.

Mr. PERRY. And jump out of airplanes, particularly if you are former President or go into space if you are a former Senator.

Other questions for this panel to stimulate discussion?

Yes, sir? If you would come to the microphone, please.

Mr. GOLD. Just a very general question. My impression is that, at least among certain segments of the population of baby boomers, there has been an increased emphasis on fitness, lifestyles, primarily in exercise and diet. And I am wondering what the impact of that is likely to be, and then is there a downside in terms of the joint diseases that I believe Dr. McGowan was speaking to?

Thank you.

Mr. PERRY. Thank you.

Dr. MCGOWAN. You are right. The emphasis on health certainly should promote a decrease in some of these diseases, but there is a down side. I think that the last 20 years has seen a great increase in eating disorders in particularly young people that does not portend well for their bone health.

On the joint disease side, there has been a great revolution and increase in women's participation not only in exercise and fitness, but in elite sports. And the down side of that is that we are seeing more sports injuries in women. The number of women participating in elite collegiate sports has increased enormously since Title IX was passed 25 years ago, and there is a great need to address the issue of women's sports injuries because this is a precursor to osteoarthritic changes later in life. So we still have issues we need to focus on.

Ms. WETLE. I would like to make a follow-up comment. There is a greater awareness, and we are certainly getting many more calls from people, who are what we call middle-aged, interested in things that they can do for a healthy older age. And one of the important things in encouraging exercise, is to help people to identify exercises that are healthy for them and that are in keeping with their own body's abilities, and that are less likely to exacerbate damage to joints or muscles.

The Exercise Guide from the National Institute on Aging, provides information with illustrations on how to do the exercise. And if you are a "Webnik," you can get the book on the Web. NASA has as one of our collaborators with the Office of Women's Health, has put up on the Web site little moving figures doing the exercises. These are exercises that are for endurance training or aerobic training, for balance, for strength and for flexibility.

The other comment I will make involves a "good news/bad news"—although people are very interested in healthier lifestyles and related interventions, they are particularly interested in pills they can take, as opposed to things they themselves have to do. Despite understanding that healthy diet and exercise are good for us we still see that America's prevalence of obesity continues to increase. Although there are some indicators that Americans are adopting healthier diets there are certainly subpopulations that still are eating diets that are very high in fat, and low in the vegetables that Dr. Pratt indicated were so important. So we have a health education message that needs to get out there, and I think all of you can help us.

Dr. PRATT: I would just like to make a comment. I think, at this time and in the future when you are seeking a health care professional for eye disease, it is beneficial to find somebody that has some understanding and knowledge about prevention. I would contend that in this day and age, if you are given the right tools for prevention of cataracts, and prevention of macular degeneration, your risk for acquiring these two problems as you get older is going to be significantly less. There are really hundreds of scientific articles to substantiate prevention as a major tool in lessening our chance of acquiring these diseases.

As you mentioned earlier, studies show that we have a pretty good idea that people are eating less fat than they did 10 years ago. Unfortunately, we are still very obese. We have not really increased our intake of fruits and vegetables. We need to do a better job on that. You know, nobody ever died prematurely of eating fruits and vegetables. Though it may not sound so appealing, we really have to find a way to get the public to buy into the fact that we must eat these foods if we want to stay healthy.

Think about it, if you were 20 and someone could sit you down and say, "OK. Listen, if you eat five to nine servings of fruits and veggies every day and do exercise and a few other things, your chance of getting all of these chronic diseases is going to be much less when you get older," you would probably buy into it. Even though you cannot imagine being sick when you are 20, take a look at the older folks, and visit a nursing home and say, "Gee, I do not want to be like that." It really gets quite simple.

So we have to find a better way to get the message out there about diet and preventive measures.

Mr. PERRY. Another question?

Ms. BOGORAD. Could I make a comment about exercise and diet, as well?

Mr. PERRY. Please.

Ms. BOGORAD. And that is that studies we have been supporting amazingly suggest that exercise of the body might also be good for the mind because exercise, certainly in rats and mice, increase the level of growth factors in the brain, and growth factors are some of the things that keep brain cells healthy.

There are also other studies, still only in rats and mice, that suggest if you give them certain extra constituents in their diet, things like choline, even when the mice and rats are babies or prenatally, and if you feed them diets high in anti-oxidants, spinach, strawberries, blueberries, then the rats when they get older have much

better cognitive abilities than the rats who did not get these supplements.

So I am not saying that these necessarily apply to human cognition, because they are still animal studies, but I think they sort of tie in with all of the rest of the stuff, don't they.

Dr. PRATT. Yes, I would certainly agree with that. In fact, the USDA did sort of a food showdown for anti-oxidant capabilities of foods, and interestingly enough, the best anti-oxidant food was blueberry, followed by kale, followed by strawberry, followed by spinach. So two of the four best—and this was 25 fruits and vegetables—two of the four top ones were berries, the other two were green, leafy vegetables. I have never known anybody who did not like berries—spinach maybe. I have learned to like spinach. There is always a way to like it. If you want to avoid vision loss, then it becomes quite easy.

Dr. BRANCH. Thank you Popeye. [Laughter.]

I wanted to weigh in on this discussion as well. I think the original question posed invites us to think about the issue in the following way: One can lose functional independence because of overuse, as well as underuse, and this can occur both in physical function, as we have been discussing, and cognitive functions perhaps, as is being investigated.

I think it is important for us to always be mindful that as things stand in this country at this time, underuse seems to be a much more serious problem than overuse for both physical and cognitive functions.

Mr. PERRY. I think what comes through here is that we do not have to accept our visions of old age that we have from remembering our grandparents and those that came before, but that all of these conditions can be modified, the risk factors can be modified, and our ability to live independently is largely in the hands not only of ourselves and our own lifestyle, but of those that will make the applications of research in the next few years that will vastly improve the therapeutic maintenance and therapeutic benefits for the diseases that we have talked about.

We still are in an era when we are trying to reduce the outward manifestations of bone disease, and joint disease, and cognitive loss. But I think those that are looking just a bit ahead on the horizon see that we may be entering an era, particularly with what we are learning from the human genome project, where we may be able to prevent, postpone and delay the onset of age-related diseases in a very profound way, at a very basic level of human biology.

So if we can keep ourselves and our older citizens functioning, living independently a bit longer, still more dramatic ways to manage and postpone the onset of diseases like Alzheimer's, and osteoporosis, vision loss and incontinence are in the cards, if we get lucky. And part of that is the policies that are developed here in Washington that will have so much to say about the rate of speed of medical discovery.

Do we have another question from the audience? [No response.]

Do we have another comment from the panel? [No response.]

Superb panel. I want to thank each and every one of you.

I also want to give my thanks again to the Senate Special Committee on Aging for creating this forum and to the staff for helping make this possible.

Thank you all very much for coming.

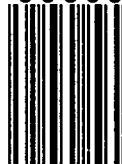
[Whereupon, at 11:41 a.m., the forum was adjourned.]



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