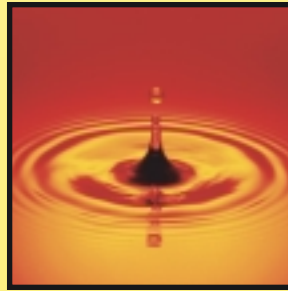
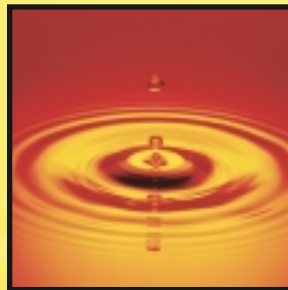


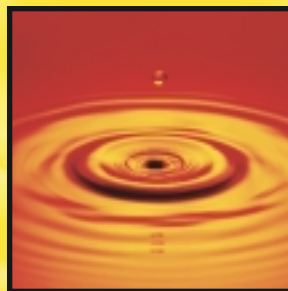
[MEDICAL INNOVATION & THE AGING OF AMERICA]




COUNCIL OF STATE GOVERNMENTS HEALTH POLICY FORUM



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[MEDICAL INNOVATION & THE AGING OF AMERICA]

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INTRODUCTION

On October 18 - 20, 2001, a Council of State Governments Health Policy Forum was held to analyze the impact of new medical technologies on individuals' longevity and quality of life, examine the unique health care needs of America's seniors and assess the short and long-term benefits and costs of providing access to new technologies as America's population ages.

Health care has often been described as a three-legged stool that rests on access, cost and quality. If one of these three elements is out of balance, the whole stool will wobble and threaten to topple over.

In this triad, health care costs traditionally have been given the most emphasis. With health care costs rising faster than the rate of inflation over the past 30 years, it's not surprising that costs have received the greatest share of policymakers' attention. In the 1990s, however, health care cost increases remained relatively low—in the range of 5 to 6 percent. When government budget surpluses were growing, the decision to devote more resources, energy, and attention to the quality of health care was easier.

States enacted patient protection measures, and some employers made quality a factor in their health care spending decisions.

Recently, however, the financial picture has changed again. Overall, health care spending for

the privately insured person increased 7.2 percent in 2000, the largest increase since 1990. Publicly funded programs have experienced even larger increases, with some state Medicaid programs seeing double-digit increases last year.

As concerns about costs mount, the concern is that quality will fall by the wayside. In tight budget times, the accepted thinking is often that we cannot afford quality. Yet, as the metaphor of the three-legged stool suggests, when quality suffers it is not long before we pay the price in other ways.

As we look to the future and at the trends in health care, we see new challenges. First, our population is aging rapidly. In 2000 there were an estimated 35 million people age 65 or over in the United States, accounting for almost 13 percent of our total population. The size of the older population is projected to double over the next 30 years, growing to 70 million by 2030. Because the older population uses health care services more intensively, health care costs are expected to increase significantly.

Another trend is the surge of medical research and technology. The Human Genome Project, the growth of medical research and the budget of the National Institutes of Health, and the health care information revolution all promise to produce

unprecedented leaps in medical innovation in the coming years. Americans expect new medical discoveries and technologies to help them live better and longer, but this will come at a higher price than current medications and treatments.

The trends in cost, in aging, and in the development of new technologies raise difficult questions:

- *How do we protect quality and innovation while keeping costs at reasonable levels?*
- *How do we decide as a society, which innovations are worth the added costs?*
- *How can we maintain and even improve health care quality as our population ages?*

The Council of State Governments, the Alliance for Aging Research, the National Health Council, and Pfizer believe it is critical for policymakers and health care leaders to have a dialogue about these issues and how we should deal with them. This report, based on the transcript of the sessions of the meeting, was produced to expand the reach of information from this meeting with the hopes that it will add to the development of good public policy.



LAWRENCE BROWN

Professor, Department of Health Policy and Management
Mailman School of Public Health,
Columbia University

Innovation and the aged are central parts of a perceived crisis that is at the heart of health care deliberation in this nation and many other Western countries. We have an irresistible force of medical progress coming up against the immovable object of limited resources. We hear that health care spending is bankrupting the economy. Budget-makers in the United States and Europe say, “We can no longer afford the system we have.”

I hear these arguments all the time. Then I do research in the real world and I find tremendous variance between the academic theories and the actual practice. I want to argue that the academic view is, in many respects, simplistic, and I want to make three arguments:

- *This image of epic clashes between innovation and resources requiring hard choices and priorities is in many ways overstated and misleading.*

KEYNOTE ADDRESS: HEALTH CARE FOR THE ELDERLY AND MEDICAL INNOVATION

- *The main recipes for affecting the resolution offer a lot less to policymakers and to citizens of our democracy than their proponents think.*

Most of these challenges have elicited remarkably little interest among medical researchers, health services researchers, and health policy analysts. That needs to change, because unless the clinical component is situated amidst the complex points on the continuum of caring for the elderly, we'll have trouble figuring out what the appropriate costs or the likely forecasted costs of caring for people really are.

- *Instead of explicit hard choices and prioritization, what we're likely to see is more of what we already have and what works pretty well - namely, a wide variety of incremental coping and constraining mechanisms that don't do such a bad job of balancing innovation and resources.*

The litany that health care is destroying the private economy is rhetoric. I'm not an economist, but the success of individual firms in the private sector depends on much more than just health care. Health care is one factor in the cost of production; one part of a compensation package, and it's easy to overemphasize the extent to which it drives the success of private firms. It is not an insignificant problem, but it's easy to let the rhetoric get inflated about the rapidly rising costs of health care as if everything depended on it.

Finally, on the affordability issue, much depends on whether you choose to raise the money and how you choose to raise it. If you want to do something like the British and have a single-payer system with public financing for most medical services, you may have what the British have - a crisis about how much more should we be spending. Theirs isn't a crisis of affordability - it's a crisis of alleged underinvestment.

It's easy to say that what we need is prioritization and it must be explicit, but this notion of making hard choices explicitly contains a contradiction at its core: it's very hard to make these decisions be analytically coherent and broadly participatory.

Innovation can be steered in several different ways. We control innovation through controls on its introduction. The Food and Drug Administration and other evaluative bodies take a look on the front end of these innovations, and decide whether they should be passed through to assist the public. Second, we can impose controls on the diffusion of technology. Further down the line, we can have controls on the application of technology: one is the ratio of generalists to specialists. Practice guidelines are another control. Then there are controls at the end of the line, such as possible withholding of technologies. We see this with transplants, which are naturally scarce, and there are protocols about who gets priority when organs are available.

Is it easy to steer innovation this way? Of course not. Is it possible to reach socially acceptable accommodations through these approaches? I think it is. And that's why I think we'll see the refinement of these various approaches rather than some sort of analytical revelation as to how you make hard choices. Hard choices are actually in many respects political choices, not philosophically trying to find out The Right Answer.

The aging of the population will make these mechanisms break down. We simply can't afford to supply all the medical benefits that the population wants; the population is living longer and has more needs; and the working population, which is contributing the cost of these systems, is smaller and more overburdened.

The implications of aging for the health system go far beyond the use of clinical services. Older people are where they are today because of medical innovation, but there are other issues such as availability of home health care workers, problems of managing the transitions among hospitals, home health care, and nursing homes, and the affordability of it all—the roles of Medicare, Medicaid, pension, Social Security, and so on.

Most of these challenges have elicited remarkably little interest among medical researchers, health services researchers, and health policy analysts. That needs to change, because unless the clinical component is situated amidst the complex points on the continuum of caring for the elderly, we'll have trouble figuring out what the appropriate costs or the likely forecasted costs of caring for people really are.

Policymakers are looking for bright ideas to cut through the complexity, explain the dynamics of the rising costs and want strategies to control them. Academicians and others respond with models that purport to tell us how to make the hard choices.

While these analytical constructs hold center stage among academicians, in my view they remain sideshows in the world of policymaking. Policymakers see the problems with the arguments that we can't go on as we are—actually, it's easy to go on as we are. Second, policymakers don't necessarily buy the crisis view, though they may use it for matters of rhetoric. Third, most policymakers understand that health care policy is made not by formula or recipe, but by managing and balancing among conflicts of values and interests held by multiple and increasingly activated players. That cannot be solved; those conflicts are the heart and soul of health care policy. We cannot make them go away; we can only manage them.



DR. DAVID CUTLER
*Professor of Economics
 Harvard University*

I. OFF THE CHARTS: TRENDS IN AMERICAN HEALTH CARE

We are aging in a way that is more healthy, rather than less healthy. I think that's an extremely important thing that will drive public policy.

The elderly are living longer than they used to. The expectation of life at age 65 over the course of the 20th century has increased by about 5 years, and most of that has happened during the last half of the century. During the first half of the century, overall life expectancy was increasing rapidly because most of the improvements in health were at very young ages and infants were not dying as frequently. Much more recently, the health of seniors has been improving, and the single biggest contributor has been a decrease in mortality from cardiovascular disease. About 80-90 percent of the lower mortality rate is due to reduced deaths from heart disease, stroke, and other conditions.

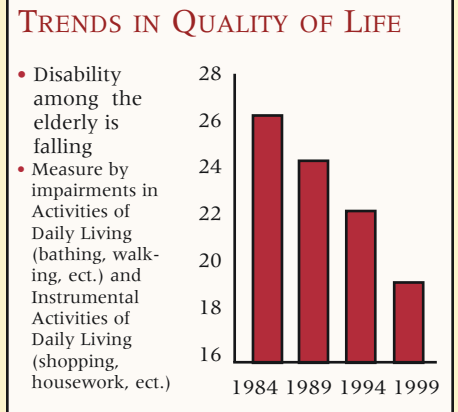
What to make of this? The good news is that everyone wants to live longer, and that people can be active at later ages if they can stay healthy until those ages. However, are people really healthier or are they just spending more years in a disabled state, and what will this do to public budgets?

Has living longer been accompanied by better health or by worse health? The arguments go both ways. In the case of cardiovascular disease, one reason why people are living longer is that we are getting better at treating people with these conditions. But many of those people will have fairly severe disabilities—people who have had stroke may be in nursing homes, and those with heart disease may require home health care or other long-term care.

By preventing some diseases in the first place, we prevent some of the adverse consequences. By treating them better after the fact, we allow people to recover more completely. So it's not entirely clear whether living longer ought to be associated with better health or declines in health. That has been a major research issue over the past few decades.

Most people measure health of the elderly using various measures having to do with the ability to perform basic tasks of daily living. About one-quarter of the elderly have some kind of impairment in basic measures of living.

About 10 percent of people between ages 65-74 have an impairment, compared with about 60 percent of people above 85. The share of the elderly that have those impairments is declining; the overall health of the population is improving by about 1 percent per year over the past two decades. So we are aging in a way that is more healthy, rather than less healthy. I think that's an extremely important thing that will drive public policy.



Across a variety of groups, people are in better health. Why is this?

FIVE EXPLANATIONS:

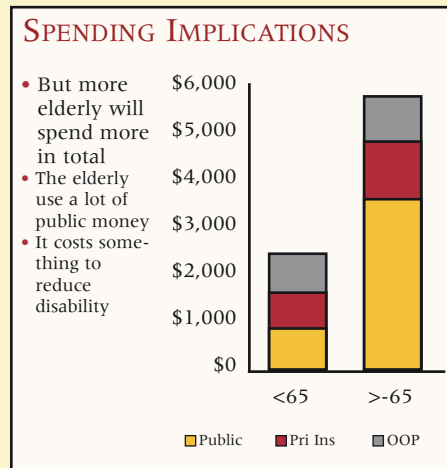
- 1 Some people are in better health because of medical advances, both high-tech interventions and low-tech medical changes.
- 2 There have been changes in behaviors. The single most important one is the decline in smoking. Since 1960, smoking has dropped by 50 percent.
- 3 We are using what we have in a better way. Twenty to 25

years ago, it was accepted that elderly people had arthritis and they just had to get used to it. We still can't cure it, but the idea that you wouldn't treat it is a thing of the past, and disability associated with arthritis has dropped.

- ④ People are more educated now. Better-educated people have about half the disability rate of less-educated ones. The reason is not clear. More educated people may have less physically demanding jobs, more mental and cognitive stimulation, know more about how to care for themselves, or be better at interacting with the medical system.
- ⑤ Less disease exposure over the course of one's life: in utero, as a young child, and on the job. These exposures have long-term implications. Public health measures that were taken decades ago have reduced these exposures and this can translate into long-term benefit.

Because some of the improvements in health come about because of better medical care, it is going to cost the nation something to have a healthier population. There may be lower nursing home spending, but we can't have that without the invest-

ments of treating people with medications or surgeries.



On net, we will surely spend more. The cost increases for medicine and technological changes will be greater than the cost reductions for people in better health. This will be true at the federal level, state level, for private insurance companies and out of pocket spending.

Currently we spend about 14 percent of our gross domestic product (GDP) on medical care. If that increases, what does that imply for society and the economy?

Incomes go up by about 2 percent per year. Medical increases will eat up some of that increase, but will they take all of it? Accommodating increased health care spending will not mean cutbacks on other spending. If health care spending increases to 28 percent of GDP, we won't give up anything: we

will just have less rapid increases in some other areas. It is easier to adapt to something that you're getting more of, but not as much more of, than it is to cut back on something.

In the public sector, there would have to be a tax increase to get more money for health care spending. It will be a more difficult adjustment than in the private sector, but even when spending more money on health care, spending on non-health-care items will still increase—the increase will just be less rapid than it would have been.

The real question is not, "Could we afford it?" We could. The real question is, "Do we want to afford it?" Is it worth spending that extra money on health care?

Because people value their health so highly, the money spent on medical care has been quite worthwhile. If you couple that with the sense that there will not be cutbacks in other areas to finance health care spending, but rather less rapid growth, I am much less worried about the increase in health care costs than the typical analyst is. People value it and it's doing something that people want; it's just getting the money to the right place.



DAVID LIPSCHITZ

Director, Center on Aging, University of Arkansas for Medical Sciences

Despite the fact that we have a graying society, there are very few geriatricians to meet the need. One of the goals of the Donald W. Reynolds Foundation is to develop models of addressing the geriatric shortage in the United States. We have received \$30 million dollars to establish a center to do this. We now have more geriatricians per capita in the state of Arkansas than anywhere in the world.

There is nothing elderly about a 65-year-old. The idea of older people, the stereotypic view of them as being functionally dependent, frail, and unable to do anything is just not true for 65-year-olds these days.

We can divide the older population into the young-old (65-80 years) and the old-old (over the age of 80). The old-old are more likely to become functionally dependent. They have multiple co-morbid conditions, and one of the cardinal features about growing old is the so-called diminished reserve capacity- an

II. THE UNIQUE HEALTHCARE NEEDS OF SENIORS

impaired ability to respond to a maximum stimulation. There is, however, a wide range of highly variable individual responses to aging, environment, and diseases.

Our goal must be in the future to promote independence. Can we do it? Can we promote a message of lifelong health? Clearly, the solution is prevention.

Aging is accompanied by a dramatic increase in the prevalence of dependency. By age 85, 50 percent are dependent; by age 90, 65 percent are. We as a society are getting older; we also appear to be healthier. But if we invariably achieve the ages of 85 and 90, the risks of dependency are going to go up dramatically. We may be able to extend the time at which dependency occurs, but the longer we live, the greater our risk of becoming dependent.

There are some serious concerns in our health care system. We are an acute care high-tech system but we pay little attention to chronic care. There's little support or reimbursement for programs meeting chronic care needs. There are no incentives

for physicians to become geriatricians.

The resources to meet these needs are adequate, provided we rethink our priorities. If we continue spending a significant percentage of our health care dollars in the last few months of life, we must find ways to assure that we also pay attention to those aspects of health that will prevent high-tech needs.

What about medications? Dental care? Prevention programs? Hearing aids? Eyeglasses? All of which are critical to the lives of older people but are not reimbursed, and many individuals do not get them because they can't afford them.

I think nursing home care is a national crisis. The needs of people in nursing homes have become more complex in an environment where reimbursement has not gone up much and where manpower is a major concern. We pay minimum wage, there is 300 percent turnover a year, and we provide virtually no training.

Physicians cannot deliver the kind of care that's needed for the amount of money that's paid to a nursing home, but at the same time nursing home owners are taking money and diverting it to profit rather than improving conditions.

One of the major problems facing our society is that the doctors who work in nursing homes have no interest in, or understanding of, the people who reside in those facilities. The care is crisis care, and often crisis is missed.

Fifty percent of those over 85 are dependent; that means 50 percent are independent. Our goal must be in the future to promote independence. Can we do it? Can we promote a message of lifelong health? Clearly, the solution is prevention.

We have to follow a prescription for successful aging that includes diet, exercise, stress management, regular medical check-ups, and the idea that the more you do, the healthier you'll be.



SUSAN DAVIDSON

Consultant to the National Osteoporosis Foundation

Osteoporosis has been dubbed a pediatric disease with geriatric consequences. The roots of this disease are in the nutritional habits learned early in life. It's a silent disease without symptoms that progresses until bones become so porous that they fracture.

Osteoporosis is largely preventable. It is not an inevitable

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part of aging, but right now it's a public health threat for more than 28 million Americans. In 2015, about 42 million Americans will be affected. How do we decrease the proportion of people with this disease?

Calcium intakes in this country are abysmally low. Ninety percent of teen girls do not get the recommended intakes of calcium. This is particularly disturbing when you realize that 90 percent of a young woman's bone density is attained by age 13 and 98 percent by age 19. In the late 20s, early 30s, bone density starts decreasing. By 5-7 years after menopause, up to 20 percent of bone mass can be lost.

This country spends \$13.8 billion (in 1995 dollars) on direct expenditures related to this disease. The cost of a hip fracture is about \$40,000 a year. Productivity loss and quality of life are not included in these figures.

A bone density test is the only way to tell whether you have low bone mass and are at risk. The test can also predict your chances of fracture in the future and how you are responding to medications for osteoporosis. The test takes about 10 minutes and is done fully clothed.

Access to the test machines is a problem. I did a survey with

Medicare populations around the country and found that in one state, people had to travel 50 miles to get to a machine.

There are many approved medications to help prevent additional or initial fractures. At some point in a person's life, you may need a medication even if you are doing all the other things right like getting enough calcium or not smoking.

Currently, Medicare covers five groups of qualified individuals when it comes to bone density tests:

- ❶ Estrogen-deficient woman at clinical risk for osteoporosis
- ❷ Individuals with vertebral abnormalities that show up on X-rays
- ❸ People on glucocorticoid (steroid) therapy
- ❹ People with primary hypoparathyroidism
- ❺ People on medication for osteoporosis who are being monitored to gauge response

Reimbursement rates run about \$135 for the test that measures density in the hip and spine; the one that measures wrist and heel density is reim-

bursed at about \$40. The cost of the wrist and heel runs about \$100 on the private side; the hip and spine test costs about \$250. There is no federal law to standardize charges or reimbursement, so they vary.

Osteoporosis is largely preventable. It is not an inevitable part of aging, but right now it's a public health threat for more than 28 million Americans.

However, there are things being done. The Office on Women's Health has a funded program to educate 9-12 year old girls; the next phase will educate them in their teen years.

About 28 states have passed education legislation. Massachusetts was a groundbreaking state-it allocated \$500,000 to its education program and has done wonders educating people about osteoporosis. The efforts are not high tech, but they are very effective.

The National Osteoporosis Foundation has developed model legislation that encourages or mandates that health insurance

companies cover bone density tests for certain qualified groups.

The Medicare Wellness Act has been introduced by Sen. Bob Graham (D-FL) on the Senate side and Rep. Sandy Levin (D-MI) on the House side. We are strongly behind this act, which expands the benefit of the five qualified groups and looks at expanding the coverage of the bone density test.

This act also increases counseling for post-menopausal women about the risks of osteoporosis and includes a national fall and prevention education and awareness campaign. Nine out of 10 fractures are the result of a fall, and people suffer fractures because they have low bone mass. Ninety-nine percent of fractures are due to osteoporosis because you have to have low bone mass in order to fracture.

The National Osteoporosis Foundation is also helping develop measures to require health plans to report information on the quality of care they're giving people pre- and post- fracture. And we are very interested in seeing how to decrease the number of fractures and improve quality of care in nursing home settings.

II. THE UNIQUE HEALTHCARE NEEDS OF SENIORS



DEBORAH THOMSON

Director of Public Policy, the Alzheimer's Association

Alzheimer's disease is a terminal, progressive, degenerative brain disease. It is one of a group of dementias that includes Parkinson's disease, multi-infarct disease, and Creutzfeldt-Jakob disease. Alzheimer's affects about 4 million people in the United States right now; we expect 14 million to be affected by the year 2050. The cost per patient is about \$175,000. Currently, the United States spends about \$100 billion on Alzheimer's care. It is an expensive disease.

Several drugs are available to treat the symptoms of Alzheimer's disease and slow its progression, but there is no cure. It is terrifying to people, in the

way that cancer used to be. At the Alzheimer's Association, the number-one problem we deal with is people not wanting to get a diagnosis. People say "Oh, that's just normal aging, she's got memory loss; it's just one of those things." Well it's not; it's Alzheimer's, and a good neurodiagnostic evaluation is important to treatment.

Once it is diagnosed and recognized, there are things family members and patients can do to make it less unpleasant. The interventions required for Alzheimer's tend to be low tech. They include services that make it possible for the person to stay at home, preferably in the care of a family member, and that family member gets support that makes the caregiving bearable. Family and friends provide about 75 percent of home-based care, and it's a burden. One in 10 caregivers becomes ill because of their responsibilities, and almost half are depressed. It is worse than having a small child in terms of constant responsibility.

People who have dementia often are placed in nursing homes not because they necessarily need that level of skilled care, but because the family can no longer provide support. It becomes important to provide support services to delay institutional care as long as possible. If we could delay nursing-home placement of every Alzheimer's patient by one month, we could save \$1.2 billion annually.

People can have Alzheimer's and be incredibly dependent, yet they're physically healthy. This creates a lot of problems for public payer programs. We tend to assess the need for public services based on medical and nursing need, which does not always fit the profile of Alzheimer's patients. There is often a care gap- people whose non-medical care needs are so great that they can't be maintained in the community do not qualify for their state nursing home Medicaid eligibility because criteria are based on medical care needs. Many states have home and communi-

ty-based waiver programs, which is a way to garner federal funds through Medicaid to pay for services that aren't normally covered.

Other issues in Medicaid and Medicare make it difficult to provide good dementia care. Dementia care requires increased levels of staffing, specific training in behavioral interventions, and increased physical plant standards for safety. Most Medicaid and all Medicare programs do not recognize the additional cost factors. This results in people not being welcomed by providers. Patients with behavioral issues in nursing homes may be sent to a hospital for evaluation and then the nursing home will not take them back because they are too need-intensive.

As long-term care becomes increasingly a state-based responsibility, states are looking at what is needed for dementia care. Most studies conclude that states rely too heavily on nursing home care. Nursing homes are very expensive and if you can keep

people in the community, you are going to be more cost-efficient.

We have to be more flexible. We tend to define health care as a series of boxes, and if you don't fit in a box you don't qualify.

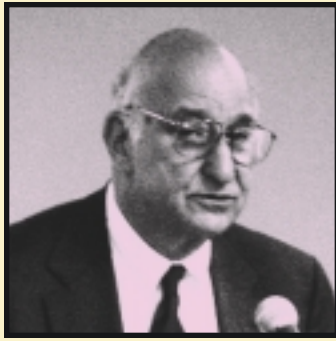
States are now grappling with the applications of the Olmstead decision, which says that people with disabilities have the right to be cared for in the most integrated setting. States have been encouraged to undergo a planning process to figure out how to do this. All plans emphasize increased community care.

On the federal side, there is the Family Caregivers Support Program, a new program that is part of the Older Americans Act. Money is used for classic caregiving support services- things that patients and caregivers need to stay at home longer. These include

support groups, in-home assessments, enhanced case management, and respite care programs.

To meet the future needs of people with Alzheimer's and their caregivers, we have to be more flexible. We tend to define health care as a series of boxes, and if you don't fit in a box you don't qualify. The result is that people end up in institutional care, which could have been prevented through a provision of good community-based care.

Rather than have a progression of care- which is how most of us think about long-term care- we could focus on a case manager encouraging the family to reach out for what they need when they need it. All state budgets have the same issues. We have a huge investment in institutional care, but elders now don't want it and we don't think it's a great idea.



SAMUEL SILVERSTEIN

John C. Dalton Professor of Physiology and Cellular Biophysics, Columbia University

Every baby born in the United States today has a life expectancy of 77 years. Babies born in 1900 had a life expectancy of 46 to 49 years. It's an extraordinary achievement. How did we do it? We invested in clean air and clean water, we drained the swamps to eliminate malaria, we pasteurized milk, regulated the preparation and distribution of food, and we created the worlds best system for ensuring the safety and efficacy of drugs, the Food and Drug Administration.

In the last 50 years we've invested more generously and effectively in health research than has any other nation in the world. The point of medical and health research is to allow us to enjoy our lives as healthfully and for as long a period as our genetic endowment will allow. It's been called rectangularizing the life expectancy curve: we want as few children to die soon after birth, and ensure that those of us

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who emerge from childhood live healthy, vigorous lives until it all just falls apart.

There are still great disparities in neonatal mortality in this country. In New York City, on the East Side of Manhattan the neonatal mortality rate is 7 per 100,000; in Harlem it's 13 per 100,000. We need to eliminate that.

Nothing trumps the human quality of health, but health is also of great economic value. Consider these three examples:

- The United States leads the world in development, discovery and export of pharmaceuticals and medical devices.
- The decline in the incidence of morbidity and disability is key in keeping Medicare solvent.
- Studies show that 34 percent of the increase in the U.S. standard of living between 1975 and 1995 was due to decreased deaths from cardiovascular disease and stroke.

Mary Lasker had it right: if you think research is expensive, try disease.

Who are the major performers of medical and health research in the United States?

- 1 The pharmaceutical and biotech industries: total economic activity is \$38 billion and these industries employ more than 400,000 people.
- 2 Universities, medical schools and research institutes: \$20 billion in economic activity and more than 100,000 people employed in research.
- 3 Federal research facilities: \$10 billion in economic activity and 26,000 employed.

This is a total investment of \$68 billion and 526,000 people employed.

In the university setting, the federal grant system is as competitive an activity as any other in the United States. That's why it works, and why conservative Congressmen have come to understand that this is not a government welfare program for scientists. What do these monies do?

- 1 They help improve the knowledge and technical competence of the health professionals already in your community.

- ② They attract new highly skilled professionals to the community.
- ③ They make available new research to your community.
- ④ Medical research attracts enormous private philanthropy.
- ⑤ Medical research is a major stimulus to economic development.

Universities and medical schools attract investments in biotech, information technology and pharmaceuticals. These are clean industries with low environmental impact; they are expected to grow over the next 20 years. They also create stable high-paying jobs, with a median salary of \$55,000.

The second measure of the economic impact of universities and medical schools is patents and licenses. Data from the Association of University Technology Managers survey, done in 1999, shows that patents and licenses from 98 universities generated 417 new products, \$40 billion in economic activity, 270,000 jobs and \$5 billion in taxes. Based on licenses from academia that year, 344 new companies were formed. That's going on in your cities; it's an

important engine of economic growth.

How much did states invest in research in 2000? They spent \$5.5 billion for higher education and around \$3.2 billion for research, give or take \$1 billion. There isn't any comprehensive survey for state spending on medical and health research and development (R&D). States use many different mechanisms, including tobacco settlement funds, R&D tax credits and state lotteries.

States are spending a comparatively small amount on medical and health research compared to the federal government. The NIH budget is expected to double, from about \$13 billion in 98 to \$27 billion in 2003. About two-thirds of that money goes to researchers in universities, medical schools and small biotech companies throughout the United States.

In contrast to state spending, NIH spending is reliable, continuous and shows a steady upward progression. One can't run a research establishment without a steady source of support. You can't keep high-quality people; you can't train students. The variability in state support makes it unreliable for direct support for

research, but it's extremely valuable as a source of support for infrastructure and for start-up and pilot projects.

States would be in a stronger position to understand the value of their investments in medical and health research if there were standard mechanisms for reporting these state investments. Scientists seeking to start companies and companies seeking to expand or relocate would find it easier to determine the types of state support available if data was reported in a uniform manner to a national repository. Governor's should ask the President to assign the National Science Foundation responsibility for collecting and reporting these data on an annual or biannual basis as it does for other indicators of our nation's investments in research.

There's no doubt that investments in medical and health research pay big dividends. To paraphrase Nobel Laureate Leon Lederman: Support for research offers a double whammy: the advantage of a solid payback of between 30 and 60 percent per year and an array of new knowledge, technology, and products that create wealth, add to human health and longevity, and help fulfill human potential.



KENNETH KAITIN
Director, Tufts Center for Drug Development

III. SEARCHING FOR CURES: MEDICAL RESEARCH & INNOVATION FOR AMERICA'S AGING POPULATION

biotech industry is not coming up with some exciting new leads.

A typical elderly person in a clinical trial is in their mid-60s and in good health, whereas the people who will actually use the drugs are well over 60 and are taking multiple drugs.

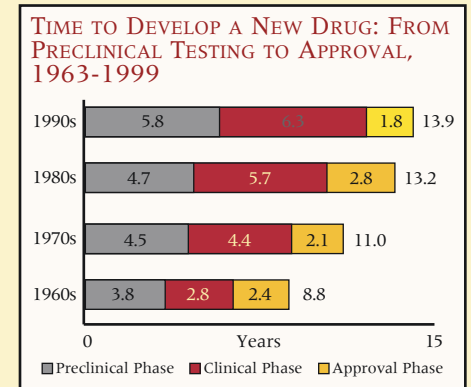
Voltaire said the art of medicine consists of amusing the patient while nature cures the disease. As funny as that sounds now, you could paraphrase that and say that in many diseases, the art of medicine consists of comforting the patient while nature takes its toll. Many of the diseases we're talking about today reflect that sentiment- there isn't a lot that medicine has to offer except for some comfort as people go through an arduous disease process.

Some research occurs in the public sector, academic institutions and the NIH; that research is used by the pharmaceutical industry to bring products to market. This is not to say that the

Once a product is isolated or synthesized, it begins the development process. That includes the preclinical phase- everything that happens before it gets to humans, including animal pharmacology, safety issues, and chronic toxicity testing.

When enough information is gathered, an Investigational New Drug Application has to be filed with the Food and Drug Administration (FDA). The FDA evaluates it, and if it decides to let the research go on, the clinical

part of the process can begin. The clinical phase includes three phases as well as pharmacoeconomic studies or market-oriented studies that allow the manufacturer to create a niche for the product.



Once clinical information has been obtained, a New Drug Application is filed with the FDA and the FDA has to approve that before the manufacturer can market the product. That occurs during the regulatory review phase. After the product is on the market, research continues- looking for new uses of the product, new ways of administering it, and post-marketing surveillance,

as well as looking at the long-term use of it in large populations to make sure it's as safe and effective as they thought it would be.

From the 1960s to the 1990s, the time to get through the pre-clinical phase has increased from 3.6 to 5.8 years- about 60 percent. The clinical phase has seen a 122 percent increase, from 2.8 years to over 6 years. The FDA has taken less time in recent years to approve products, but that's not enough to offset the preclinical and clinical time increases. It's a challenging and time-consuming process.

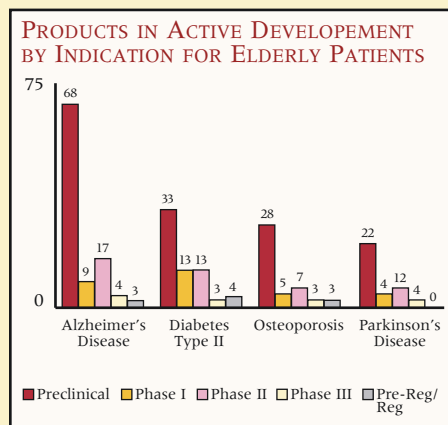
The diseases of the elderly include Alzheimer's disease, Parkinson's disease, coronary artery disease, stroke, chronic renal failure, diabetes, and osteoporosis. Drugs for chronic and complex diseases take a long time to get through the process- 8 or 9 years through the clinical phase alone. That's a significant challenge.

There are special considerations for the elderly in clinical trials:

- It's difficult to find older people that have only one disease.
- It's difficult to find people who are not on multiple medications.
- It is more difficult for older people to comply with trial instructions because they tend to have memory loss.
- Attrition is always a factor- people drop out. Younger people drop out because they lose interest; older people die.
- Elderly people metabolize and excrete drugs differently than younger ones do.

The bottom line: a typical elderly person in a clinical trial is in their mid-60s and in good health, whereas the people who will actually use the drugs are well over 60 and are taking multiple drugs. The trials done don't often represent who is going to use the product once it reaches the marketplace.

This is not to suggest that the industry isn't interested in developing drugs for the elderly. It's a large population and for the most part, the extended lifespan doesn't mean people stay young longer, it means they stay old longer. You end up with a large market, which is attractive.



There are significant challenges to developing drugs for the elderly. They include long development times and significant risks and costs. The government should play a greater role in encouraging manufacturers to develop drugs for older people.

IV. NEW TREATMENTS, NEW CHALLENGES



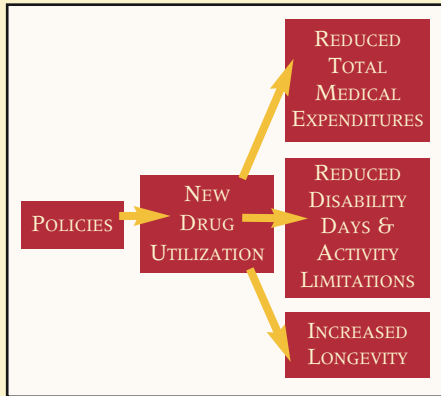
FRANK LICHTENBERG

*Courtney C. Brown Professor of Business,
Columbia University
Graduate School of Business*

I've been engaged for the last few years in studying the contribution of new drugs to health and economic growth in the United States. I've been trying to determine whether the benefits to society of new drugs exceed their costs. Many people do studies of individual drugs, but what I'm after is the big-picture question.

There are three types of potential benefits:

- Reduction in non-drug expenditures, especially hospital expenditures
- Improved quality of life, measured in terms of reduced disability and activity limitations
- Increased longevity



To the extent that drugs do provide these benefits, policies that reduce the number and availability of new drugs deprive society of these benefits.

Product innovation is of fundamental importance to economic progress. It's been argued that innovative goods are better than older products because they provide more services related to their costs of production. A new computer may cost more than an old one, but the benefits of the new one outweigh the higher cost.

A key hypothesis of some of my research is that holding other things equal, a person's health is an increasing function of the vintage of the drugs he or she consumes. In general, newer drugs are better than older drugs.

I've tried to quantify the dollars saved by replacing old drugs with new ones for a given disease. The general findings are that newer drugs are associated with lower total medical costs and fewer lost work days. The reduction in total medical expenditures is about four times the higher cost of the newer drug.

On average, upgrading to a 5-year-old drug from a 15-year-old drug raises the cost of the prescription by about \$18, but it reduces the cost of other medical services. The cost savings from that would more than offset the increase in price.

Most of the reduction in medical costs comes from reduced hospital admissions. Not only are the numbers of admissions smaller, but the length of stay is shorter and there are fewer emergency-room events. People consuming newer drugs are also less likely to die or miss work days.

I'm doing some research right now on the quality of life issue—that's probably the hardest one to nail down. In a recent study I found results relevant to a 10-

year increase in drug vintage (switching from drugs that were approved in 1980 to ones that were approved in 1990). The new drugs increased expenditures by about \$71, or 27 percent. However, workdays lost per person declined by about a day a year. Since the average compensation of workers is about \$140 per day, that's worth more than twice as much as the increase in drug cost. I also estimated there would be a reduction in the number of restricted activity days of about 9 percent.

A third potential benefit of newer drugs is increased longevity. A compelling way to study this is to provide some case study evidence. In 1983, Congress passed the Orphan Drug Act to encourage the development of drugs for rare diseases. The rate of introduction of drugs for rare diseases increased by a factor of 12 after the act was passed. I found significant and important effects of the act on mortality from rare diseases.

On average, upgrading to a 5-year-old drug from a 15-year-old drug raises the cost of the prescription by about \$18, but it reduces the cost of other medical services. The cost savings from that would more than offset the increase in price.

Of course, drug development is expensive; it's estimated it costs about \$500 million to bring a drug to market. But if we have an estimate of what the economic value of (or willingness of people to pay for it) a life-year is, we can estimate the "bang per buck," and the "social rate of return." My estimates indicate that the rate of return is in fact very high. I have a paper that will be published in a few months on this topic. I chose a conservative figure of \$25,000 for a life-year. Some of my colleagues suggest

that the number might be four to six times as high. Based on my figure, the rate of return was 40 percent.

I've performed several studies that demonstrate that the benefits of new drugs greatly exceed their costs. The costs are very visible- we can all see a pharmacy bill. The benefits are a little bit harder to identify. Policymakers and insurers should be cautious about policies that reduce the availability of new drugs.

IV. NEW TREATMENTS, NEW CHALLENGES



J.D. KLEINKE

President, Health Strategies Network

Managed care's central premise has always been proactive management of disease, which translates into finding creative ways to get more people on more and better drugs.

If I can leave you with a message, it's that all drugs are not created equal, and even the same drug is not created equal for every patient. Expensive drugs in many cases are a bargain, but it depends on the disease, how long a time frame you're looking at, and the patient. It's a lot more complicated than the techniques pharmacy benefit managers (PBMs) have been using, which are based on price. There are a lot of drugs that we ought to pay patients to stay on because they keep them out of the emergency room and out of surgery. Conversely, certain expensive drugs are not a bargain, although they may make life better or make pharmaceutical companies' bottom lines better.

If I can leave you with a message, it's that all drugs are not created equal, and even the same drug is not created equal for every patient.

We're in the midst of a profound rotation in health care; we are rotating away from service-based, labor-intensive services (hands-on, palliative care, hospitals, doctors, nurses) and toward more technology-based care. Just as offices have gone from three secretaries per executive to one, we are moving away from many doctors and nurses per sick patient to lots of drugs per sick patient. That's why drug budgets and expenses are going up, hospital costs are going down (adjusted for inflation), and physician budgets are relatively the same.

The end result of managed care is more drugs, more people, more prescriptions, less time in the emergency room, less time with doctors, less time in the hospital. That's why the drug benefit has always been liberal. How did the plot thicken?

If health plans say they want to invest in people's health status and wellness, but they have problems with drugs that cost more money, what's the issue? The issue is one of investment horizon. The typical managed care organization has quarterly and annual financial targets that it has to hit. The treatment for the typical person's cholesterol or depression- which is what the HMO is investing in- may improve that person's health in five years. But that person may join another HMO before those five years are over. Twenty percent of the average health plan's population switches plans every year. So why should I invest in their healthy heart or a drug that prevents osteoporosis? So I can make my competitor's risk pool healthier five years from now?

This is a significant problem; it's why managed care has broken down in terms of what it promises versus what it actually delivers. It's something to be aware of as you look to try to manage something like COX-2 inhibitors versus non-steroidal anti-inflammatory drugs (NSAIDs) in a formulary decision.

The fact that life expectancy increased by nine-tenths of a year last year is tremendous. Where it really comes from are pickups on heart disease, cancer, AIDS and infant mortality, and all four of those are probably, after depression, the most heavily medicated conditions. It's a huge social return, but it's not free.

I don't have a homogenous answer like "expensive new drugs are bad and cheap old drugs are good." That simple-mindedness is one thing that has given managed care such a bad name. Sometimes expensive is cheap, and vice versa.

How can we manage the drug budget in an enlightened way? First, with creative contracting. One of the best examples I've seen to deal with these issues has been between Pfizer and the state of Florida. On a fairly large num-

ber of diseases, Pfizer is saying to Florida, "Let's not play the price game, let's not do the rebate game, let's keep the prices where they are. But, we will guarantee reduced budgets for hospitals and for other health services." Pfizer is mobilizing people to manage the medicine and related care for these diseases. Pfizer gets to price drugs the way it wants to and is at risk for the drugs potentially not being used and managed well. If the theories are correct, then this experiment will probably work.

Second, formularies shouldn't be based on price, but rather on value. We ought to be doing everything we can to encourage rather than discourage diabetics and asthmatics to be on the best drugs. It keeps them out of the hospital.

Third, drug utilization review (DUR) ought to be consistent with these concepts. State Medicaid programs have provided huge fodder for researchers to prove that when you are penny-wise and pound foolish in terms of managing the drug benefit, you end up paying more later. When we end up putting a meaningless constraint on a drug budget, we end up paying for it over and over.



ROBERT FRIEDLAND
Director, Center on an Aging Society

V. HEALTH CARE CHOICES: ENSURING QUALITY CARE FOR AN AGING SOCIETY

With longevity comes the risk of chronic illness, long-term care and outliving one's assets.

For most of recorded history, people lived a relatively short and brutal life; life expectancy was less than 30 years. About 300 years ago, life expectancy began to increase, and there have been dramatic increases over the last 100 years. Advances in technology and the synergy between technology and human physiology have brought fantastic improvements. These changes have changed our expectations and decisions concerning education, work, retirement, and family. They have also affected the economy and society.

More food, better nutrition, clean running water, better sanitation, vaccinations, plastics, microcomputers and miniaturization have brought us into the information age and we are now at the cusp of a revolution of molecular medicine. In a time frame too short to be biologically evolutionary, we witnessed a 100 percent increase in longevity and a dramatic expansion in population and quality of life.

I view longevity as a gift that we have used to expand the intellectual, cultural, and financial wealth of the world. Despite the fact that the world is older than it's ever been, it's also richer. Despite a doubling in the population over age 65 since 1962, real gross domestic product (GDP) per person has more than doubled. We have grown wealthy just as fast as we've aged.

Productivity growth in the 1970s was dismal and there was a pessimistic outlook. The growth in the early 1990s was remarkable - far in excess of what was expected. Economists are now wondering how to speculate about future economic growth. It's my hypothesis that part of the story rests on the expansion and contraction of the labor market. The growth of the labor market slowed and the market responded; investments were made in technological advances and ensuring workers knew how to use them. In the 1960s and '70s, the labor force grew dramatically.

With so many people in the labor force, employers had a relatively inexpensive source of labor. This tended to delay investments in labor-saving production, which would delay advances in productivity. When the growth slowed in the early 1980s, employers were forced to produce goods in less labor-intensive ways.

With longevity comes the risk of chronic illness, long-term care and outliving one's assets. Even with financial security, no one who lives to a very old age can escape the risk that they will suffer from discomfort, disability and perhaps dependence.

The absolute number and the proportion of people who need long-term care, as well as the duration of long-term care, have been increasing, in part because of advances we have made in acute care.

The standards of health care will change; payers will be pushed into paying for new technologies while still financing the technologies that became obsolete. While the tax base for public health programs will increase, it will not increase as fast as prices and the population. From a budgetary perspective, expenditures will increase as both quantity and prices increase.

How productive are workers in the future? The size of the population demanding goods and services will grow faster than the population producing them. My bet is that ingenuity and market forces will push for productivity improvements and we will continue to experience economic growth. If we achieve economic growth similar to that of the past 35 years, then health care expenditures could be about what they are today in 2030, as a proportion of national income.

But I do not expect that we will be able to simply grow our way out of the challenges we face. We will have to divert more of our nation's income toward health care. Not all individuals and not all states share equally in economic growth. The states that will be aging the most are the ones with the smallest proportions of older people now. The ones with the largest proportions of older people will not age as fast, and they have already made adjustments in their infrastructure to serve older people. Younger states may not have those infrastructures, so they will have to catch up.

I fully expect that the price and quantity of health care will increase, and so too will expenditures, but what we fail to recognize is that in health care, what we buy today is not likely to be the same as what we buy in the future.

I fully expect that the price and quantity of health care will increase, and so too will expenditures, but what we fail to recognize is that in health care, what we buy today is not likely to be the same as what we buy in the future. We spend more on health care today than we did 50 years ago, but we are buying a different product.

There's little evidence to suggest that taxpayers do not think it's worth it. People believe there's too much waste, fraud and mismanagement in government health care programs, but the vast majority of workers are willing to pay more for Medicare, if necessary, to maintain the health care of their families. There's much more public confusion about Medicaid.

Those in charge of health care programs must be vigilant- seek out fraud, question costs and the values of new procedures- but they must also recognize that many advances, though expensive, have the potential to add more value back to society than their costs. Public expenditures will be relatively less, the greater our economic growth. Economic growth is directly related to education, the funding of basic research and the cost of capital for development. More health care resources will be demanded, but it will be worth it and taxpayers will support it.

We will continue to struggle with access and always will struggle with costs. The glaring discrepancy and the interdependence between medical care and supportive services, along with cost concerns, will push us toward experimenting with new ways to expand and deliver care. This push is likely to be stymied by a relative shortage in personnel. The growth of demand in long-term care relative to the supply of providers will affect prices even more. This is a critical issue that requires looking not only at the specific labor markets involved, but also at key junctures at which people make educational and career choices.



LAURENCE BRANCH

Professor, Duke University Center for the Study of Aging and Human Development

We have heard that there are innovations happening at all levels and in a wide variety of areas. How will states pay for these innovations and monitor their quality? I want to consider four levels of traditional care: the primary care of older people, acute care (hospital care), institutional long-term care, and community long-term care. Let us consider how states can pay for innovations and monitor quality in these four settings.

In order to start this discussion, though, we need to consider a few background issues. The first background question is how much of the health care dollar is spent on acute-care hospitals? The answer is about 37 cents of every dollar. So when we talk about outcomes that might avoid inpatient stay, there is a lot of health care dollars that can be redirected.

V. HEALTH CARE CHOICES: ENSURING QUALITY CARE FOR AN AGING SOCIETY

I also want to spend a moment identifying some philosophical issues that help frame the issues. One of them is paternalism versus autonomy. If you are the state long-term care czar and you are regulating the nursing home industry or the home care industry, to what degree are you going to emphasize patient safety (paternalism) or allow individuals to make their own choices even though that might increase the likelihood of falls and hip fractures (autonomy).

What is good for the individual is sometimes not good for the total population, and the total population is not always simply the sum of the individuals.

Another philosophical issue to consider is individual good versus common good. For example, prescribing an antibiotic before the physician is sure a person has a bacterial infection - that may be conservatively useful (at least not harmful) for the individual but what is the impact

of that on the common good? What is good for the individual is sometimes not good for the total population, and the total population is not always simply the sum of the individuals.

In 1999, an estimated \$33.1 billion was spent on community long-term care. This is a growth industry. It is likely that there was unmet need of dramatic proportion in the nursing home industry and those home and community-based programs that have been allowed to develop were meeting a part of the unmet long-term care need. However, to access Medicare home care funds, a physician had to certify that the older person who needed to receive home care was homebound, and the older person had to have had an inpatient stay of at least 3 days during the previous 90 days.

Medicare has gone back and forth on the requirement of a three-day prior hospitalization, but if you are a physician caring for a frail older person who would benefit from home care, what qualms do you have in checking the box that they are homebound- whether they really are or not- so they can receive

the clinically appropriate services? It has been suggested that many physicians have very few such qualms. What is the long-term effect of asking clinicians to commit fraud on forms in order to meet the responsibilities they have to their patients? In the long term I think it creates extreme divisiveness between regulators, providers and patients. Unfortunately, I think we have a 25-year history of that kind of divisiveness right now. Most people, physicians, older people, taxpayers, elected officials, and bureaucrats do not care that the scope of Medicare Part A has not been enlarged to cover anything beyond hospital related care. They all want appropriate health care for seniors, not just hospital care.

I want to make three suggestions for improving health care service delivery for older Americans:

① When you consider an innovation, make sure you do the outcome evaluation. And here is the important point: do not consider only your own budget. Consider the taxpayers' burden, regardless of which budget the service dollar comes from. The Department of Health and Human Services started this flawed strategy about 25 years ago of only focusing on their own health budget, and if it reduced costs in their health budget it was okay, regardless of whether it increased costs elsewhere. Right now in home and community-based care, we are doing that again. Many community programs emphasize reductions in the Medicaid part of the health care budget but increase federal Housing and Urban Development budgets by providing housing service for the community-dwelling

frail older person.

② Focus on the person, not the service. The discussion I have heard is still focusing on the service.

③ I think that we have not brought the consumer into their care as well as we can and should. If you are in charge of state Medicaid programs, is it not possible to allow individuals who are up to date on all their prevention services to receive free copayments for medications? You can, but if you do that, make sure you do the outcomes research and do it with a long enough follow-up interval. Those people who are fully compliant probably will not show the cost decrease for several years. Do the intervention and monitor the outcome, and you are bringing the consumer back to the point where they can control their health care, know what they need and get a benefit from it.

CONCLUSION

This meeting has given us a look at some of the real challenges, and ideas about better ways to do things. By and large, we are dealing with the problems of our success. Our issues are based on the tremendous advances we have made in longevity, health status, and better quality of life.

The Baby Boomers are turning 50 at a rate of 10,000 a day. In less than 10 years, these people are going to start filling the Medicare rolls. Are they going to be healthier, or sicker? We have learned that there is tremendous variability in terms of older people's health and capacities, more than any other age group. One 75-year old may be in a nursing home on Medicaid, and another 75-year old can be a CEO who plays squash three times a week.

It is not aging that is going to get us- it is diseases; not the dis-

eases we worry about at 35, but Alzheimer's disease, diabetes, osteoarthritis, Parkinson's disease, depression, cancer, osteoporosis, and congestive heart failure. After age 50, your risk for some of these diseases doubles about every five years; and by the time a person is 85, the risk is as high as 50 percent. The annual national expenditures for these eight diseases of aging is \$700 billion nationwide- the biggest part of our health care budget. The single biggest health concern for the next century is going to be keeping older people functional, independent, and in their communities, and the biggest obstacle we must overcome is the presence of these continuing diseases.

In terms of national policy, a prescription drug benefit for Medicare is probably not going to happen in this session of Congress, but it will return to

national attention. Such a benefit will be of tremendous help to you and your constituents; people will have better access to the medicines they need to keep them independent and functioning.

Technologies that have helped make the difference between a life expectancy of 49 (at the turn of the 20th century) and one of 79 (at the turn of the 21st century for women; 75 for men) are going to cost more, but by and large they are worth it. We must use new drugs and technologies wisely, prioritizing them based on value, and not cost. A drug that costs a few dollars more may save hundreds in reduced hospitalization rates.

We must consider all aspects of health and health care before we make decisions that affect the lives of the elderly, their families and their neighbors.



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