

A WORLD WITHOUT INNOVATION

A World Without Innovation
Prologue Series



Michael O. Leavitt

Secretary
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Prologue Series

I have come to understand that public service is a generational relay. Many of the most profound problems are not ours to solve in finality, but rather to incrementally improve during our temporary stewardship.

Three foundation goals thus form the basis for my public service: to leave things better than I found them; to plant seeds for the next generation; and to conclude my work knowing I have given my all.

For nearly sixteen years, my life has evolved in four year terms. I was elected three times as Governor of Utah. Some of what I consider our accomplishments were initiated in my first term, but fully matured in my third. Likewise, some seeds planted in my third term are only now beginning to flower.

Living in four year cycles has taught me the importance of choosing priorities and impressed the need for urgency. Time passes quickly.

I am currently in my fifth year as a member of President George W. Bush's Cabinet. I served first as the Administrator of the Environmental Protection Agency and now as Secretary of Health and Human Services. The constitutional constraints on the President's service imposed limits on what initiatives I might see to completion. However, I view it as my obligation to lead with a longer horizon in mind.

Over time, I have developed a set of tools useful in keeping a long-term vision in mind while managing the day-to-day problems. One such tool is establishing a 5,000 Day Vision, with a 500 Day Plan.

The 5,000 Day Vision is our aspiration for various long-term outcomes. The 500 day plan is more granular, listing what needs to be done now to bring about the larger vision. Both are recalibrated periodically.

As my stewardship comes to a close, it is time to plant seeds for the next generation. I intend to write and deliver a series of formal speeches to convey some of the 5,000 Day Vision and share what I see on our approaching horizon.

I call these speeches *The Prologue Series*. There is a statue behind the National Archives that I look at nearly every day as I drive between HHS and the White House. The statue, the work of Robert Aitken, is called "The Future." It depicts a woman looking up to the horizon from a book as if to ponder what she has just read. At the base of the statue are the words from Shakespeare's *The Tempest* "What is past is prologue."

I have titled this speech in *The Prologue Series*: "A World Without Innovation."

Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
Speech given on September 10, 2008
in Paris, France

These are complex times in health care. We've seen historic advances in technology, but we're also facing unsustainable costs.

It is that complexity I wish to address. It is the subject of debate in the United States as we approach our presidential election. It is certain to be a part of the congressional agenda during the next year. It is reflected in similar debates in presidential cabinets across the world.

The health care debate worldwide is framed by two competing but rather divergent philosophies about the role of government. One philosophy holds that governments should own the health care system. This philosophy proffers that government should decide who gets care, how much care is given, and the price of care.

A competing philosophy is that government should organize the health care system. This philosophy holds that governments should set rules under which the market will operate, resolve inequities and subsidize those who are in hardship.

My own view is that governments should assume responsibility to assure that citizens have access to an affordable insurance policy. Governments should organize markets to produce that result; and if a person is in hardship, governments should help them pay for it.

The reality is that both of these philosophies are currently present within the health care system of the United States. Sixty percent of our insurance market is a private market and some 40 percent is currently a government system.

Governments should assume responsibility to assure that citizens have access to an affordable insurance policy.

Health care on its current course is not sustainable in most nations.

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Neither of these works to perfection, and that is at the heart of our dilemma. Our government system lacks consumer sensitivity. Our private market has gaps in availability. Both are flawed in their current form.

What is not widely understood is the broad impact that Medicare—our system of health for the elderly—has on other segments of our private health care system. Medicare's systems are used as a model for virtually every other part of our delivery system.

Insurance companies, hospitals, and clinics all organize their financial systems around Medicare because it is by far the largest single player in our marketplace. No other part of our system has the capacity to shape the marketplace like Medicare.

Medicare is a government-run, price-fixing system of health care finance. The government decides who gets care, the government decides how the care is given, and—make no mistake about it—the government sets the prices.

It is very similar to systems that are deployed throughout Europe, with this exception: It lacks the discipline of a global budget or the constraint that comes with it.

In fact, nothing constrains Medicare. Medicare and its partner, Medicaid—which is our health care system for those with a financial disadvantage—are unrestricted entitlements, and these entitlement systems have problems.

Our system suffers from the “silo syndrome.” That is to say, there is little coordination among the caregivers.

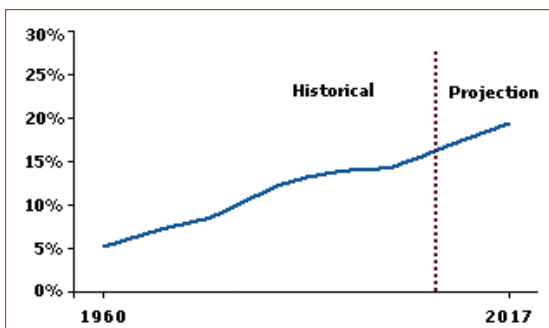
The system lacks the proper incentives. I refer to this as the “chronic more,” incentives that encourage more care, not better care.

And the system is quality-indifferent. That is to say, we pay the same for poor quality as we do for excellent quality.

Medicare's silo syndrome, chronic more and quality indifference have driven health care costs in a direction that will, left on autopilot, produce disaster.

I am 57 years old; I was born in 1951. When I was born, overall health care costs were 4 percent of our gross domestic product.

National Health Expenditures as Percentage of GDP



Source: Office of the Actuary National Health Expenditure Data

When my first son was born 25 years later, they had doubled from 4 percent to 8 percent. When my first grandson was born a generation later, they had doubled again, this time to 16 percent.

And while overall U.S. health care costs have doubled, Medicare and Medicaid costs haven't just doubled; they have tripled as a percentage of our gross domestic product.

That is not sustainable.

My grandson will face a world where demographic trends are working against us even more. When the Medicare system in our country was originated, it was assumed that there would be a steady supply of workers per beneficiary, with each worker having a responsibility to provide health care for their parents' generation.

Today, there are almost four workers for every one Medicare recipient in our country. Within 20 years that number will drop to just two and a half. A smaller and smaller percentage of our population will bear a heavier and heavier burden.

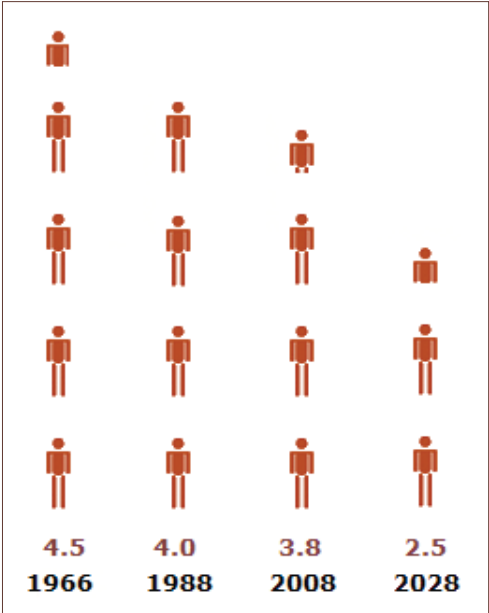
Twenty years from now, our costs per beneficiary will have doubled, but we will have fewer than two-thirds as many workers per beneficiary to cover those costs. So for every \$3 in costs now shared by three workers, we will soon have \$6 in costs shared by only two workers. Our costs per worker will triple in the next 20 years.

When you boil all of that down, what it means is this: the financial burden my grandson carries to pay for my generation's health care will be ten times as great as mine was at his age. My grandson will have to spend ten times as much to subsidize the health care of his parents and others as I did when I was in his shoes. And that's even after adjusting for inflation, in actual dollar figures, he'll have to spend a lot more.

That is not sustainable.

There are systems all over our planet that face the same dilemma. Unless the current course is altered, Medicare and systems like it around the globe will be insolvent within a decade. And in our case it could potentially drag our nation into a financial crisis that makes our major sub-prime mortgage crisis look like a warm summer rain.

Workers Per Medicare Beneficiary



Source: Office of the Actuary, Centers for Medicare and Medicaid, and Social Security Administration

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We need viable long-term solutions, and it will require not just a sharper pencil at budget time. It will require more than simply creating longer waiting lines. It will require a fundamental change in our strategy and in our philosophy.

Systems, whether they are government or private, must become more focused on value-of-care as opposed to volume-of-care.

Every nation wrestles with its own version of that problem. Health care on its current course is not sustainable in most nations.

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Systems, whether they are government or private, must become more focused on value-of-care as opposed to volume-of-care. When I refer to value, I am talking about the combination of quality and cost and about encouraging consumers to pursue the highest-quality health care, at the lowest possible prices.

Three years ago, in quite a dramatic departure from Medicare's rather government-centric tradition, we took a significant step toward a value-driven system. Our government implemented the new prescription drug benefit to 43 billion recipients of Medicare. It's called Medicare Part D.

This system is unique because it uses government as a means of organizing an efficient market — not as owner of the system. Rather than making all the coverage and pricing decisions, Medicare Part D gives consumers choices. It gives them the information they need to make choices, to pursue value.

We didn't force people into a single, government-run plan where the government makes all the decisions, where every person has the same plan, where government sets all the rules, and where government determines all the prices. Instead, we focused on organizing the system, balancing inequities, and subsidizing those in hardship.

Rather than government being the risk-bearer, insurance companies share in the risk and are allowed to offer innovative plans. Seniors are allowed to choose the plan that's best for them.

Some people in the United States were skeptical about this, saying it would be too hard for seniors to pick their plan. But they were wrong. The result has been the development of a generation of increasingly skilled health care consumers.

Every year, seniors now have an opportunity to look at their plan and compare it to various alternatives. They decide whether they're happy with their plan. And if they're not, they can change. They get to make the decision. They get to choose the plan that suits their needs.

People have different wants and different needs. Some people wanted the lowest possible cost to them, the lowest possible premium. For them, the market offered plans with highly restricted formularies and strong incentives to use generics.

Other people had different desires. They didn't want to have a co-pay, and they wanted to be able to have access to every brand-name drug. Again, the market responded and gave them choices, as plans competed within that space.

And the market is still responding. The insurance plans compete aggressively on the basis of what their formularies will be. They compete on price. They compete on service. They have to, or they won't be competitive.

They push the pharmaceutical companies hard for the lowest possible prices. Why? Because unless they do, they don't get the business. Competition has made them better.

The results speak for themselves. Ninety-three percent of those who are eligible for the plan have now enrolled in a plan, exceeding nearly every one of our government programs. Even more impressively, 85 percent are happy with their plan. And the other 15 percent are free to choose another one.

And here's perhaps the most impressive part of all: these plans have brought about a 40 percent reduction in costs compared to what the actuaries originally estimated—a 40 percent reduction in costs, widespread enrollment, and happier beneficiaries.

Why does price-reduction take place? This is a complex market, but underscoring all of it is one clear word, and that's competition.

Yet those in our country who want a government-owned system continue to call for the government to negotiate prices.

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The insurance companies compete on price. They compete on service. They have to, or they won't be competitive.

Does Medicare have a basic plan? Yes. Our Congress established a basic plan, but wisely provided for consumers to make choices if it didn't meet their needs.

People make better choices about their own health care than the government.

In other words, they want us to adopt the same price-fixing system for prescription drugs that has moved Medicare to the brink of insolvency. They want us to adopt the same system that has caused Medicare costs to rise three times as fast as GDP across three decades — the same system that has led overall U.S. health care costs to rise twice as fast as GDP in Medicare's powerful wake.

What's often left out of this discussion is a fact that those of you who negotiate prices know well. If you're going to negotiate drug prices, you have to control the formulary. You have to have the leverage of saying, "If you don't lower your price, I'm not going to let people have your product."

Here's the truth: If government is going to negotiate drug prices, the government is going to decide what pills people can buy and which ones they can't. If government doesn't allow consumers to choose between different plans, the government is essentially imposing its decision on everyone.

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You might be interested to know how many people chose the government-designed plan. It is about 10 percent. In other words, 90 percent saw something they didn't like in the government-designed plan, and they chose a different plan.

If you manage a government-designed, government-run plan, you need to ask yourself the question: "If my beneficiaries could choose a different plan, would they?" And if the answer is, "Yes, they would," then maybe we ought to be listening to them and learning from them. That's the value of a market.

People make better choices about their own health care than the government.

Why not let them choose? Giving people information and letting them choose among competing plans inevitably drives the quality up and keeps the costs down. And that's how you achieve value.

I'd like to share another insight with you as the person responsible for running this program. Other than the Part D prescription drug benefit, Medicare fixes prices on virtually every other part of our health care system.

I get stacks of letters. I get them from lobbyists, I get them from members of Congress, I get them from trade associations, from professional associations seeking to use the political process for favorable treatment.

Congress often will respond and, for blatantly political reasons, take actions that ultimately cost taxpayers billions of dollars while diminishing the quality of care that patients have available to them.

For Medicare's Prescription Drug benefit, I don't get stacks of letters; I don't get endless contacts by members of Congress trying to affect the system. Why? Because a fair and competitive process makes those decisions.

Consumers decide. If there's a demand for a particular prescription drug, the marketplace devises a formulary that allows people to get it.

This is a uniquely American debate. But our European friends also have a very serious stake in the outcome of this United States debate about the negotiation of drug prices.

Why? Because if the United States begins to negotiate drug prices in the same way that European systems do, it's going to eliminate an important component from the European health system — and that is American-funded innovation.

Yes, built into the prices that are competitively arrived at in our system is the price of innovation—the price for Americans and for Europeans. American consumers fund nearly all of the cost of investment and research, and we do so for two reasons. The first is we're 45 percent of the world market for prescription drugs. It certainly seems fair that we should pay our share.

The second is that price-fixing negotiations by single-payer systems pose this very clear demand: eliminate any recovery of investment from your price, or we will eliminate you from

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Price-fixing with no recovery for investment ultimately leads to a world without innovation.

our plan. The effect is one of two possibilities: European patients are denied access to important drugs, or no contribution is made to innovation.

Drug companies who have recovered their costs within the United States market accept these terms. They accept them because, once their costs have been covered in the U.S., each foreign sale amounts to additional profit so long as it covers the cost of manufacturing.

Our U.S. Department of Commerce estimates that the price controls of industrialized nations eliminate \$5 to \$8 billion in annual drug research and development. That is money that would otherwise go for market innovation.

Now, is that fair? No, it isn't fair. And it also isn't in the best interest of European taxpayers and citizens. What could be so bad about Europeans beating American drug companies out of \$5 to \$8 billion a year? Simply stated, no research and development, no new drugs.

Perhaps European health care leaders should boldly consider the adoption of more market-driven systems. The result would be more innovative drugs, happier consumers who are getting what they want and what they choose, and market driven prices.

Now, realistically, do I expect that to happen any time soon? No. But it doesn't alter this fact: price-fixing is the road to a world without innovation.

I'll just conclude with this thought: remaining competitive in a global market requires change.

There are three ways we can confront change. We can fight it. If we do, we will fail. We can accept it. If we do, we will survive. Or we can lead it. And, if we do, we will prosper.

May we lead, and may we continue to prosper.

Simply stated, no research and development, no new drugs.

In a global market there are three ways to approach change. You can fight it and fail; you can accept it and survive, or you can lead it and prosper.

We are the United States of America; let us lead.

What is past is prologue...