



**Remarks for Kenneth C. Frazier  
Executive Vice President and President, Global Human Health  
Merck & Co., Inc.**

**FDA-CMS Summit for Biopharm Executives  
Washington, D.C.  
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Good morning.

I'd like to thank the FDA-CMS Summit for inviting me here today. This is a very exciting time in Washington for everyone but perhaps especially for those of us who care deeply about the future of the U.S. health care system and, in particular, its ability to provide access to health care for all.

While I'm here to discuss that important issue, given the fact that so many of the speakers at this Summit are here either from the U.S. Food and Drug Administration itself or from the industry it regulates, I'd be remiss if I did not make a few comments about the future of the agency. All Americans -- and people around the world -- owe a debt of gratitude to the talented and committed public servants at the FDA who work every day to protect the public's health and to ensure that patients have access to the best of new medicines, vaccines, and medical devices.

This has been a very difficult time for the FDA. The new Administration has an extraordinary opportunity to provide the FDA with the leadership, the resources, and perhaps most importantly, the support it needs to do all its important work. As a company, and as an industry, we want and need a strong, independent and effective FDA.

We intend to do our part to encourage the new Congress and the new Administration to provide the FDA with what it needs to do its enormous and important tasks.

Now let me turn to health care reform. In their 2005 book, *Uninsured in America*, authors Susan Starr Sered and Rashika Fernandopulle get beyond the statistics of the uninsured to paint vivid pictures about what it means to be uninsured in the United States today. One story they tell is of a couple in Decatur, Illinois -- Timothy and Denise. Timothy and Denise both worked their entire lives, yet, like so many people today, have no savings and do not own their own home. Timothy had the bad luck of injuring his knee on his job, tearing some cartilage and then getting an infection.

While the hospital emergency room was able to treat the infection, they told Timothy that he needed surgery. And they demanded a down payment of \$1,000 before they would perform it. Timothy and Denise had neither the \$1,000 nor health insurance.

Timothy and Denise also illustrate another larger problem with our health care system today, as they are African-American.

Among the many health disparities in America today is the disparity in access to affordable health insurance. More than 20 percent of black Americans are uninsured, a rate much higher than white Americans. African-Americans make up 12 percent of our workforce yet represent 16 percent of the working uninsured.

That is simply not tolerable. Today, our nation once again finds itself in a time of extraordinary challenge and extraordinary opportunity.

The current financial and economic crisis, now officially labeled a recession, is straining the ability of companies to continue to provide quality, affordable health insurance to their workers and tightening the vise gripping those, like Timothy, who do not have health insurance or the significant savings necessary to pay for urgently needed health care.

At the same time, with the election of a President and Congress committed to significant health care reform and with growing public dissatisfaction with the cost, quality and access to health care, we have an extraordinary opportunity for legislative action on comprehensive health care reform.

Now, it is up to us in the pharmaceutical industry to decide the role that we want to play in this upcoming debate. We face a choice of acting from a place of fear of the potential harms that could occur to us in reform or acting on the hope of what reform could mean to our industry and, more important, to the patients that we serve. Today, I'd like to describe to you why Merck has chosen the path of hope and why we believe that's the right path for our industry.

We've made this choice with our eyes wide open. We understand clearly that we are entering this debate at a time when the pharmaceutical industry's standing is low and we face challenges from many directions.

For years now, politicians, the media, and industry critics have disparaged our prices, our allegedly excessive profits, and our purportedly wasteful marketing expenditures. Most unfortunately, we have also seen critics challenge the integrity of the scientific research that is at the core of our value to patients and society.

These challenges have led to legislative proposals, here and around the world, that could have serious negative impacts on our industry and on our ability to continue to innovate in the interests of patient health.

In my new role overseeing the marketing of Merck medicines and vaccines around the world, I've seen first-hand the negative impact that some of these ideas have had.

Certainly, major health care reform action in the United States could provide a vehicle for the consideration of several harmful proposals, such as drug importation, price negotiation in Medicare Part D, and changes to the patent protection that is a necessary prerequisite to pharmaceutical innovation.

We're also seeing these proposals at a time when Merck and other companies are facing unprecedented business challenges. The rapid and appropriate uptake of generic medicines, challenges to our patents, and setbacks in our pipelines are translating into layoffs as well as difficult research investment choices.

This is arguably the worst time for punitive government actions of the type some are proposing.

While the risks of action to us are clear, so are the risks of inaction. First and foremost, people without health insurance coverage have poorer health and, of course, reduced access to our medicines and vaccines. Those without coverage live with a day-to-day fear that most of us in this room can only imagine.

It is a fear that, like Timothy and Denise, they are only one illness or one accident away from financial ruin or permanent disability.

If that were not enough in itself, as an industry we need to understand that until the nation reforms our health care system, including providing affordable access to quality care, the issues of access to medicines and the price of medicines will remain flashpoints in political and economic discourse. Further, more time without action will only embolden those who advocate anti-competitive approaches such as universal government delivered health care.

This is not the first time that we as a pharmaceutical industry have faced a choice between the risks of action and the risks of inaction.

In the presidential election of 2000, we saw how seniors' access to medicines could provide a powerful political flashpoint. Fueled by images of buses rolling off to Canada, politicians stood before cameras and compared drug prices in the U.S. and across the border. The media was filled with profiles of seniors who testified that they had to make unenviable choices between purchasing their prescription medicines and purchasing food and other necessities of life.

In the face of this onslaught, some within our industry counseled that we had more to lose in creating a Medicare drug benefit than we had to gain.

They feared that with drug coverage would come government control of pharmaceutical prices.

Fortunately, Merck and others within industry saw it differently. We decided that solving the problem of seniors' access to medicines was the right thing to do for both patients and for our industry, despite the risks.

Today, while the end of the story has not been written on the Medicare prescription drug benefit, the early chapters are very encouraging.

By all measures, the Medicare drug benefit has been an enormous success. More than 90 percent of Medicare-eligible Americans now have quality prescription drug coverage. Beneficiaries have a wide choice of affordable prescription drug plans with average premiums less than \$30 a month. Not surprisingly, satisfaction with the program is very high. A recent survey revealed that 9 in 10 beneficiaries are satisfied with the program, a truly remarkable number for a new program. And, perhaps most surprising, the cost of the program to the taxpayers has been far less than the original estimates.

Of course, as you know, there remain concerns about how a new President and a new Congress might seek to change the Medicare Part D program. No program is perfect and we agree that there are changes we could make to further improve the program, especially for low-income beneficiaries. Yet, we remain vigilant to ensure that the program's goals of access to medicines are maintained, as well as the program's structure that ensures that competition, not government price controls, sets the prices that are paid for medicines.

So now, once again, we as an industry face the choice of what role to play as the nation considers major health care change.

At Merck, it is our hope that, as we did with the Medicare prescription drug benefit, we recognize that our best interests and those of the patients we serve lie in action rather than in inaction. This could be one of those rare moments in our history and our politics when we can together work to build a U.S. health care system that is the envy of the world.

What makes this moment possible is not just one election or even one economic crisis. It is made more possible by years of study, discussion, and important experimentation that has yielded what we believe is an emerging consensus for change built around the best of our public and private health care systems.

This is a time when we are seeing former foes in the health care wars sitting down and working constructively together. This is a time when many are recognizing that only through compromise will change be possible. And this is a time when, as President-elect Obama has said, everyone is invited to have a seat at the table.

At Merck, we are prepared to take our place at the table. And we are coming to the table having given these issues some serious thought and having developed some serious proposals.

First and foremost, we support comprehensive health care reform that will ensure affordable access to health care coverage for all Americans. We believe that action toward health care reform and expanded coverage should be built on four broad principles.

First, reforms should rely on competition to improve quality, control costs, and continue to encourage the innovation in medical care that our industry has been so much a part of.

Second, reforms should build on -- and not replace -- the existing mixed system of private and public health care payment.

We believe that there will continue to be important roles for both the government and the private sector in providing and paying for coverage.

Third, there is a need for shared responsibility among all in our health care system, including individuals and employers. Companies like Merck and many others are doing a great job in providing quality choices to our employees and in subsidizing health care coverage. We should ensure that those who have good coverage today can continue to have that coverage in the future.

At the same time, of course, we should make sure that those who are not offered coverage or cannot afford coverage can still obtain the coverage they need.

Fourth, we believe that reform should not only be about coverage, but should also address the critical need to improve the quality of health care in our country and also improve the value that we are getting from our health care expenditures.

Of course, principles are important but specifics are necessary if we are to achieve action.

We know all too well from the lessons of the last major attempt at health care reform in the 1990s that apparent consensus can disappear when the legislative drafting begins.

That's why we are committed to rolling up our sleeves, as we did in advocating for a Medicare drug benefit, to work on the details. While there are a variety of paths to achieving health care reform that would be consistent with our principles, Merck has set forth publicly a detailed proposal that you can find on our website, [www.merck.com](http://www.merck.com).

You will find there that we support enforceable requirements for all individuals to purchase at least a minimum amount of health care coverage. While we understand a mandate is controversial, we think it is a necessary element to achieve fairness and stability in our health insurance system.

In order to ensure that all individuals can afford that coverage, we support government subsidies to low income Americans for the purchase of comprehensive insurance.

Because existing public programs, such as Medicaid and the State-Federal children's health insurance program are effective in getting health care to the poorest of the poor, we support expanding those programs, and we continue to support their use of private sector coverage options, such as the use of private insurance plans. For other individuals who otherwise could not afford insurance, Merck supports providing tax credits so that they can purchase insurance.

Shared responsibility for health care also means in our view a role for employers.

We believe that all employers should be required to offer insurance choices to their employees and, with perhaps some limited exceptions, help them pay for that insurance.

We also believe that, to ensure the availability and affordability of quality health insurance options, we need to reform our health insurance markets. Coupled with a system in which everyone must have insurance, there should be market reforms such as a guaranteed ability to purchase coverage and the elimination of any restrictions on pre-existing conditions.

We also understand that, at least in the short run, health care reform will not come cheaply. Therefore, as a large employer that provides health care, we can support changes to our tax system that would put some limits on the current exclusion of employer provided health care coverage from taxation. Today, our tax system works in a somewhat perverse manner. The higher your income, the more the tax system subsidizes your health insurance. We believe that some change to that system is appropriate to create a fairer distribution of tax benefits and to create resources for expanding coverage to those least able to afford it.

And, because health care reform is not just about coverage and cost, we support actionable steps to enhance quality and value.

That's why Merck has been a vocal supporter of increasing the government's role in developing more and better information on the comparative effectiveness of health care interventions including pharmaceuticals. We also support greater transparency of information about cost and quality throughout the health care system. And, like many others, we support the greatly enhanced use of health information technology including health records.

What would this kind of change mean to the pharmaceutical industry?

Most importantly, we believe this change will mean that more patients will get the right diagnosis at the right time and the right care, including, of course, the right medicines and vaccines. We see this as a health care system with a much greater emphasis on prevention. We believe that the change that I've outlined today would stabilize our employer-based health care system.

And while we support a greater emphasis on value, we believe that health care reform can and should maintain a market-based system for establishing pharmaceutical prices.

With more and better information on the comparative effectiveness of our products and everyone with coverage, there will be greater pressure on us to ensure that we negotiate prices of our medicines that reflect their true value to patients and society.

As I said earlier, we see this change as the right change for patients and for our company. Because of that, at Merck, we will play an active role in this discussion. Already, within our trade association, *PhRMA*, under the leadership of our CEO Dick Clark, we've seen the industry come together.

I am pleased to report that *PhRMA* is among those who share many of our principles. I think it is fair to say that there is a strong consensus among our *PhRMA* member companies on the need for action and the role that our industry can play in encouraging such action. *PhRMA* has begun advocating for health care reform action. And *PhRMA* is reaching out to others to encourage responsible reform including some with whom we've clashed before.

At Merck, we will be educating our employees about the issues I've discussed and the need for action.

We'll be encouraging them to become advocates for health system reform. We're also reaching out to our customers to listen to their views and to explain our positions.

And, as a major U.S. employer, we will be working with our trade associations to advocate the changes that I've described today including changes to our tax system that may not be popular with all companies.

I want to stress once more that we at Merck recognize that health care reform presents some enormous challenges and some serious risks for our industry.

But our choice is as it has been throughout Merck's history: to focus on what's right for the patient. One of our founders and early CEOs, George W. Merck, in a speech he made 58 years ago this week said, and I quote:

"We try to remember that medicine is for the patient. It is not for the profits. The profits follow, and if we have remembered that, they have never failed to appear."

National action on health care reform is the right thing for the patient. If we support it and help to achieve its enactment, we believe, as George Merck did, that it will be the right thing -- not only for patients but also for our company.

Thank you so much for your interest and attention and I'd be pleased to answer your questions.

### **Forward-Looking Statement**

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the risk factors and cautionary statements in Item 1A of Merck's Form 10-K for the year ended Dec. 31, 2007, and in any risk factors or cautionary statements contained in the Company's periodic reports on Form 10-Q or current reports on Form 8-K, which the Company incorporates by reference.

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