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Remarks by

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on

“FDA at a Turning Point:
Meeting the Challenge of a Rapidly Changing World”

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This text contains Dr. von Eschenbach's prepared remarks. It should be used with the understanding that some material may have been added or deleted during actual delivery.

Thank you, President Smith, for that very kind introduction.

I wish my mom and dad could have been here to hear it but I am pleased that my wife Madelyn and my Chief of Staff at FDA, Susan Winckler, are both here at the head table as well as the members of FDA who are with us.

Hopefully my stock will go up both at home and at the FDA.

I am very grateful to the National Press Club for the invitation to be with you today and I am very honored to join the ranks of so many distinguished leaders who have appeared before you and who were instrumental in changing our nation and the world.

Today I would like to talk to you about that changing world, what that change means to the Food and Drug Administration, and the need to re-create the Agency.

Changes in our world are affecting *every* single American in terms of our health and well being. Change is affecting *everything* from the food we eat to the drugs and medical devices we depend upon.

These changes are impacting the Food and Drug Administration and our ability to continue to fulfill our mission to protect and promote the health of every single American. These are changes that are radical in nature and rapid in the rate with which they are occurring. Society has faced radical change before, such as one hundred years ago at the birth of the National Press Club. Science then was unraveling the secrets of the atom and, with the dawn of the atomic age, gave the world the awesome power to alter its destiny.

This change held great promise – but also the potential for tremendous peril.

Radical changes were also occurring in how we lived and worked, with urbanization and industrialization.

Mass production and transportation of food and transformation of medicine held great promise to improve our lives but presented also great peril from contamination of food and marketing of fraudulent drugs.

Our nation had to respond.

One response was the wise decision of Congress to enact and President Teddy Roosevelt to sign the Food and Drugs Act of 1906, which empowered the U.S. Agriculture Department's Bureau of Chemistry, the organization that would later become the FDA charged with protecting and promoting our health.

Over the course of the 20th century, the FDA did its job well and has been and is today recognized as the world's gold standard regulatory agency.

Now, in the first decade of the 21st century, the world is again undergoing radical change, but that change is occurring at a rapid rate that is unprecedented. Once again there is great promise and peril.

Just as with the atom and its nucleus, revolutionary progress in science and technology enables us to study the cell and its nucleus thereby leading to our understanding of genes, molecules and DNA that control life processes and disease. We can clone animals, genetically modify crops, and create X-ray devices that see living biology.

We are now creating medicines that don't just treat the manifestations of disease, but actually alter the biology of the living cell.

Exponential advances in science and technology are again coupled with changes in how we live.

Urbanization has given way to globalization, and the industrial age now embraces the information age. As with the past these changes are filled with promise but also peril as they impact on our health. Society must respond and, I believe, recreate the FDA.

The simple truth as I see it today is that the FDA of the 20th century is not adequate to regulate the food and drugs of the 21st century, a time when we live in a world where we can catch a fish in Chile today and eat it in Chicago tomorrow or when throughout the United States watermelon is in season every day and we expect fresh strawberries in supermarkets in February. We are now a nation that demands foods— ready to eat: cleaned, cut and cored, and even cooked. We now live in a world where medicine cabinets are filled with tablets and capsules that treat nearly every symptom. In offices and clinics we have devices that diagnose with certainty many diseases, and hospitals are equipped with drugs and devices that treat with maximum effectiveness and minimal risk almost all that ails us.

This is a time in which the winds of change in health care in terms of power and pace are not a

gentle breeze but a jet stream. And the FDA must respond to these changes if it is to continue to fulfill its mission of protecting and promoting your health.

This challenge to change FDA is in itself radical in scale and scope because the portfolio of FDA's responsibilities is vast and its reach is enormous—regulating products you and I need and use every day.

By law, the FDA must regulate, except for meat, poultry and some egg products, all the food we eat: vegetables, fruits, fish and the spices that go on them and the bottled water accompanying them. We regulate vitamins and dietary supplements; every medical product from simple aspirin to more sophisticated drugs and biologics for the treatment of acute and chronic diseases; blood products; medical devices from cardiac pacemakers to PET scanners and from surgical masks to surgical robots and linear accelerators. We regulate radiation-emitting equipment including microwave ovens and products that affect not only how we feel but how we look, from toothpaste and underarm deodorant to sun screens and cosmetics.

And our responsibility extends to products not just for humans but also animals: we regulate genetically engineered animals and products from pet food and pet turtles to feed and drugs for livestock.

FDA was created one hundred years ago because change had created peril along with promise, and today FDA must be re-created because the peril and promise from these products is now even greater.

Consider food safety and nutrition. The perils are many. In processed food, we have recently witnessed the risk of botulism in canned chili sauce, and *E.coli* and salmonella contamination in ready-to-eat fresh cut produce.

But the potential promise is great: a bountiful supply of fresh fruit and produce available all year round and processed foods with benefits, such as lowering cholesterol are truly essential prescriptions for health.

We can do more to prevent disease such as genetically engineering crops to improve nutrition and promote health.

Consider drugs and medical devices:

The perils are many with sophisticated and miniaturized devices such as cardiac pacemakers susceptible to breakdown or failure simply because of their complexity. New materials such as nanoparticles and devices that present new unknowns. Drugs and vaccines containing ingredients obtained from sources around the world and manufactured and distributed through complex supply chains as in the recent case of heparin.

But the promise is great.

We can design and target drugs for a genetic defect and halt a disease like leukemia or block molecules from affecting blood vessels and mitigate blindness from macular degeneration. We can create vaccines to protect us from devastating threats like pandemic influenza or develop a recombinant protein to control and prevent bleeding in patients with hemophilia.

Today the peril is real but the promise unlimited.

However, I believe for the FDA to fulfill its mission to protect and promote your health we must respond now. I believe that was my charge when I became Commissioner two-and-one-half years ago.

The challenges I face today are perhaps unlike those of my predecessors, as I attempt to guide this Agency in responding to its day-to-day exhausting responsibilities while simultaneously expending the energy to define and create the reality of tomorrow. FDA staff are the finest, most dedicated, talented people worthy of the dignity of the title “public servant.” But their task is daunting.

Consider the acute risk of pandemic influenza when I arrived in September of 2005 —it was a major public health concern around the globe. It was expected that in the event of an imminent outbreak, FDA would assure the safety and effectiveness of every medical intervention including some not yet invented, like a vaccine for the offending virus.

And in addition to responding to specific issues the FDA needed to have an integrated, comprehensive, and coordinated plan. In the event of a pandemic, every single component of the Agency would be acutely impacted by tasks ranging from the rapid dispersal of vaccines and antiviral drugs to ensuring adequate supply of medical devices such as respirators, and processes to assure the safety of food and safe disposal of infected animal carcasses.

The Agency embraced a strategy to change from the reactive mode of a regulator to a proactive mode of facilitator. We immediately engaged with academia and industry to facilitate product development and to integrate our efforts for appropriate delivery with the private sector and our Federal, State, and international counterparts.

Fortunately we have not had to face the test of an outbreak but one benefit of this comprehensive, multi-disciplinary, integrated approach has been the enhancement of our vaccine manufacturing capacity. Unlike three years ago, when we had only three licensed vaccine manufacturers of influenza vaccine licensed in the U.S., we now have six licensed firms. As a result, rather than a shortage that occurred a few years ago, this year we have excess capacity. In addition, in 2007, we licensed the first influenza vaccine against the h5N1 influenza virus. Because of that demand of a changing world, FDA did change radically and rapidly with great benefit as a result. Today, the pandemic response strategic plan we developed is a model guide.

This theme of the need for radical and rapid change over the past two years has guided a systemic and systematic transformation at FDA that builds on the progress of the past and will extend into the future.

The principles of this systematic and systemic change process include:

One: Selection of the areas of focus based on their critical importance to the mission of FDA. We cannot do everything at once but issues of drug safety, food protection, the scientific foundation for regulatory decisions, work force development and essential infrastructure including facilities and information technologies are our immediate priorities.

Two: A disciplined process for assessment of the problem to obtain the information necessary for devising the appropriate intervention. In some cases analyses were already available like Government Accountability Office reports or were underway as with the Institute of Medicine of the National Academies' Evaluation of Drug Safety.

In other cases they were commissioned: for example, we asked our Science Board to convene a subcommittee of outside experts to do a comprehensive review of our scientific portfolio. We collaborated in the development of a Food Protection Plan while conducting an intensive internal revision of our Agency Strategic Plan. Both plans were released in November of 2007.

Three: Development for each of these strategic initiatives a detailed implementation plan with milestones and outcomes. We were very honored to have launched such a plan--our Response to the IOM Drug Safety report--right here at the National Press Club last year and have already implemented many of the initiatives outlined in the report such as creation of our Risk Communication Advisory committee.

We were pleased this week to announce a major initiative called Safety First which addresses our processes for multidisciplinary determination of risk.

Four: We continue a series of external and internal consultations. In particular, an assessment of our work force has demonstrated a critical need to expand the numbers and skill sets required for our regulatory mission in this new era.

We have embarked on an aggressive recruitment and retention effort with a target of hiring an additional 700 new employees in 2008. This has primarily been made possible by the passage of the Food and Drug Administration Amendments Act of 2007 and incremental increases provided in our appropriations.

In addition we will shortly be launching plans for an FDA Fellowship Program which has the potential to attract up to two thousand professionals of varying disciplines for a two year training program.

Other assessments demonstrated a need for renovation and modernization of our information technology infrastructure, and this year we will spend approximately 250 million dollars on employing modern high performance servers and new software systems that facilitate interoperability across the Agency and expansion of our electronic data bases.

Within the next year we will open an integrated data center on the consolidated FDA campus that is under construction at White Oak. White Oak is also the site for our new state-of-the-art laboratories for the centers dealing with drugs, biologics, medical devices and veterinary medicine—CDER, CBER, CDRH and CVM.

Five: Changes in programs and processes have been accompanied by changes in policy. Again the realities of a radically and rapidly changing world require new ways of thinking as well as doing. FDA can no longer be simply a gate keeper assessing benefit and risk before allowing a product to be delivered to patients or the public, or to rely solely on inspections to verify quality.

It must engage in the Total Life Cycle of the products we regulate whether it is food going from farm to fork or medical products from production to consumption. Engaging in stages of

discovery, development and delivery of products we regulate will enable us to better assure quality. One important aspect of our engagement in the discovery and development part of the product life cycle is our commitment to the FDA Critical Path Initiative. This year we will invest over five million dollars to apply the tools of modern science to the regulatory and development process of regulated products.

With regard to the delivery end of the cycle, we will engage in the monitoring of performance of products in an extensive program of post market surveillance. Soon, we will unveil a new FDA program that we're calling the Sentinel Initiative. It is a collaborative effort with public and private partners that will create a distributed, nation-wide system that will allow FDA to analyze large databases of information about the safety of medical products as they are used by large diverse populations.

Monitoring and detection must be accompanied by enhancing our response to mitigate adverse outcomes. We must enhance our capability for intervention by increasing risk based inspections now using modern scientific tools of detection and expanding our network.

This emphasizes the need for FDA to enhance its collaborations. We are forging multiple partnerships with Federal agencies like Customs and Border Protection, the Centers for Disease Control and Prevention, and the U. S. Department of Agriculture, as well as State agriculture and health colleagues, private sector organizations, and our international counterparts.

As demonstrated by our recent agreements with our counterpart agencies in China, the globalized economy demands nothing less than interoperability, information exchange, and cooperation especially on enforcement matters.

In an age when a border is not a barrier, we have embarked on our initiative: "FDA beyond our Borders." It is an effort to establish an FDA presence overseas and to build capacity at foreign sites – in at least five regions, beginning with China. We must also expand our work with foreign regulators, to share information more fully.

Earlier this week, our experts discussed with 62 representatives of 48 embassies our food and feed protection efforts and our commitment to international collaboration, truly taking FDA beyond our borders.

This requires us to regulate products where they are produced, before they arrive at our borders.

FDA and HHS played a leadership role in the President's Import Safety Working Group.

Under Secretary Leavitt's leadership, the Working Group proposed a plan for improving the safety of all imported products. With the same lifecycle approach across prevention, intervention and response our efforts will further assure the quality of foods drugs and medical devices from abroad.

Change at the FDA truly is underway from policies and procedures to processes and programs. **Rapid** and for some, **radical** change is occurring. For a government agency, it may be described as "revolutionary evolution." For those inside the Agency, it may seem to have the radical nature of a revolution. For those outside the Agency, it may seem to have the pace of evolution.

But the outcomes are clear and will be achieved but not without patience and perseverance.

All must understand that there never will be the end point—because the process of transformation, adaptation, and regeneration must be continuous and ever-evolving; that is the nature of the world in which we live.

To some of you, these initiatives may sound like a collection of individual activities.

They are much more.

They are the first and perhaps the most critical steps in a critical transformation occurring at a critical time in an Agency that is critical to the health of every American.

They are components of a blueprint for change defined by the Strategic Action Plan that was released last fall.

The Plan focuses us on four goals: strengthening the FDA, improving the safety of patients and consumers, increasing access to new medical and food products, and improving the safety and quality of manufactured products and the supply chain. Each of these goals represents a fundamental public health task that is crucial to fulfilling our mission.

It is no secret in Washington that as the FDA's responsibilities have grown; the resources devoted to them have not kept pace. Strengthening the FDA for this new century will require an investment, providing our agency with a budget and authorities that are commensurate with the scale and scope of our mission.

We are on a trajectory of budget increases granted by Congress in 2007 and 2008 and those proposed by the President for 2009. This trajectory must continue and, as justified, must accelerate.

Plans and resources at FDA are necessary but not sufficient. We cannot transform the Agency ourselves. It's a transformation that requires commitment from others.

It is time to not just be critical about what is not being done, but to collaborate on what must be done.

In the next three to five years, from others we need the following:

From the Congress, we need authority to better regulate the food supply. Our Food Protection Plan calls for **ten** new legislative authorities, and I call on Congress to grant those new authorities by Memorial Day. I will continue to make my staff available day or night to work with Congress on these important initiatives—we need this legislation.

From the industries whose products we regulate, we expect strong corporate responsibility and compliance with regulatory standards as well continued support of the user fee programs with amounts appropriate for the services rendered. These payments bolster our ability to review product applications promptly – so that life-saving medical interventions reach patients sooner. New user fees must, like existing fees, consider all costs of the service at issue.

From our stakeholders, we need their full backing for the Reagan Udall Foundation established by Congress as an independent 501c(3) organization to support the mission of the FDA.

From the public, we are looking for support and patience, as well as trust and confidence in our work. We at FDA are committed to serving the nation and, although these changes will take time, their benefits will be long lasting to protect and promote your health.

We're looking forward to a re-created FDA, with an efficient regulatory pathway that enhances discovery, development and delivery of lifesaving products.

We will have greater scientific understanding of product mechanisms of action and targets to assure you of their benefit/risk and proper use, and we will have earlier and more precise responses to emerging issues.

We will know more, and communicate sooner.

In these remarks, I've attempted to explain three things:

- How the world has rapidly and radically changed
- Why these changes have brought FDA has to a turning point
- And what is being done to re-create the FDA

I hope you share with me the commitment to this effort.

As FDA Commissioner I am aware of the need for these changes to avoid the peril of failing in our mission to protect your health.

As a physician and researcher, I am aware of the need for change for the FDA to achieve the promise of being the bridge and not the barrier to delivering life-saving solutions to eradicate and prevent diseases that threaten you, now and in the future.

But most of all, as a grandfather concerned about the future of his six grandchildren, I am aware of the need for radical and rapid change.

About a month ago, I traveled with Secretary Leavitt to India to meet with our counterpart government officials as well as leaders of the food and drug industries to discuss how to best assure the quality of products produced there for export to you here in the U.S.A.

While there in Delhi I had the opportunity to visit a neighborhood and to vaccinate babies and small children for polio. Afterwards I handed out lollipops to some of the children, and suddenly I was faced with a mob of grasping hands and squealing voices that grew more rapidly than my ability to dispense the lollipops -- until that moment came when there was nothing more to give to them.

I will never forget the out stretched hands and those big eyes and little faces whose smiles turned to sad stares because I had nothing more to give them.

As I look at the faces of my grandchildren. I know that their expectations will go beyond our past that developed a vaccine for polio to their future in which food and drugs will be a personal

prescription for health, and I know that FDA must radically and rapidly change so that their smiles of expectation will not turn to stares of sadness -- because without the FDA of the 21st century protecting and promoting their health, there will be nothing more we can give them.

Thank you.