

Mr. Chairman, Senator Kennedy, and Members of the Committee, I am Dr. Andrew von Eschenbach, and I am honored to be here this morning to seek your support for my confirmation to be Commissioner for Food and Drugs, to lead the Food and Drug Administration. In the 11 months since President Bush appointed me as Acting Commissioner, I have become acutely aware of the Agency's need for strong and permanent leadership with a Commissioner that is not only the choice of the President but also confirmed by the United States Senate.

I appreciate this opportunity to earn your trust and support by sharing my vision for the future of this vitally important public health agency, by helping you to get to know me better as a person, and by highlighting the experience and dedication I bring to this role.

To know me, it is important for me to introduce a few special people who are here with me today. First and foremost is my first date in the 6th grade, Madelyn, who 39 years ago finally agreed to be my wife and mother of our 4 children – Nonna to our five grandchildren and one on the way – you should know that I am blessed by her support and the support of our family as I embark upon this challenge.

I want to introduce a few key members of FDA's senior leadership:

- Mr. Patrick Ronan, Chief of Staff
- Dr. Janet Woodcock, Deputy Commissioner for Operations
- Dr. Scott Gottlieb, Deputy Commissioner for Medical and Scientific Affairs
- Mr. David Boyer, Assistant Commissioner for Legislation

They are representing the Center Directors and Office Directors who lead the FDA as well as the Agency's workforce of over 12,000 incredibly talented and highly trained professionals and staff who epitomize the true meaning of the word public servant.

It is important for everyone to know that if confirmed, their support and guidance will be my greatest asset in leading the FDA.

My fellow Texan and my friend Senator Hutchison graciously outlined my career as a physician, and as I come before you today, reflecting on that career, I am struck by the fact that so much has changed – from my early years training as a urologic surgeon, to a career at the University of Texas MD Anderson Cancer Center as an oncologist, researcher and educator, to four and a half years ago becoming the Director of the National Cancer Institute, and now as the President’s nominee to lead the FDA. I am struck by how much has changed in my life, but in fact one critical element in my life has not changed.

When I began my career in medicine 40 years ago, my singular aspiration was to accept the trust that others placed in me to use my skills to save their lives and improve their health.

Today, as I seek the Senate's confirmation to lead the FDA, I remain as committed as ever to that very simple, but profoundly important ideal and purpose. It is emphatically apparent to me that as Commissioner of FDA, my role and the FDA's role has always been and will always be - no matter how much we change over time – to cherish the trust of patients and the public and that our every single action, decision or activity must be directed to preserving their lives and protecting their health.

This year the FDA celebrates its 100th birthday and a proud tradition of service in protecting and promoting public health.

As the FDA regulates almost twenty five percent of all the products Americans consume, its talented and dedicated employees continue to set the Gold Standard that is emulated around the world but never equaled. As a nation we are blessed that because of our Food and Drug Administration we go to bed each night not worrying about the safety of the food we eat or the effectiveness of the medicines we gave our grandchildren.

This standard of achievement must not change. But the world around us is changing and the FDA of today is faced with new challenges and the FDA of tomorrow will encounter incredible opportunities.

During my career as a researcher I have witnessed exponential progress in science and technology that is revolutionizing our very concepts of health and disease. But, as a physician, I am also painfully aware that as we sit here today we struggle - to make available safe and effective new treatments for life-threatening conditions like cancer, Parkinson's, Alzheimer's and HIV/AIDS, to prepare against the risk of pandemic flu and to deal with emerging threats to food safety.

Today we are faced with unprecedented challenges and unprecedented opportunities across a continuum of discovery, development and delivery of interventions and products that represents the fruits of a revolution in science and technology but more importantly the solution to the many problems that threaten our health and well being. And central to addressing these challenges and seizing the opportunities is the FDA.

While the Agency's first century was truly remarkable, the FDA of the 21st Century must incorporate modern management tools and processes to meet the challenges of today, while creating the scientific tools and technologies to address the ever-evolving, increasingly complex regulatory issues of the future.

To accomplish this vital goal, the Agency needs strong, permanent leadership, and efficient, strategic management – I am here asking for your support of my nomination, because I believe I can provide both.

Let me briefly outline for you my strategic focus for leading this Agency into the 21st Century.

FDA is positioned as the critically important bridge between scientific discovery and development of products AND the delivery of these solutions to patients and the public.

We can, and must, find ways to integrate new modern Information technologies to streamline our regulatory processes to make them more efficient, rigorous and transparent, in order to ensure the public we serve of the safety and efficacy of those products.

The FDA of the 21st Century must be prepared to respond to the new opportunities and challenges of science and technology. Through initiatives like Critical Path to Personalized Medicine, we are working to improve the tools we use, to more effectively evaluate new products and processes. For example, through the use of biomarkers, we will be able to predict, earlier and more accurately, both the safety, as well as efficacy, of drugs, biologics and devices.

This is the pathway that will take us into the era of personalized medicine, where health care is tailored to each individual patient, and where the safety of medical products is enhanced by our improved understanding of how they interact with different patients, different drugs, and under different conditions.

By enhancing both our internal and external collaboration, we can create synergies and enhanced efficiencies to allow us to better communicate and carry out FDA's critical public health mission. Moving forward, it won't be enough just to do the right thing – we must be committed to doing it in the right way.

Above all, I am committed to maintaining the long-standing traditions and values of an agency whose processes and decisions are guided by sound science and vigorous analysis of evidence and based on the best interests of the patients and public we serve.

Much work remains to fully equip FDA to face the challenges and seize the opportunities ahead, but I am confident that we are on the right path. And if confirmed, I believe I can provide the leadership and management that will guide this important public health agency proudly and effectively into its second century of service.

As a physician, one other thing in my life has not changed -- I continue to speak with patients and offer advice and consultation. A few weeks ago I spoke with a young mother who happened to be celebrating her daughter's birthday when I returned her call. She shared with me that she had a tumor for which she had already been treated with surgery and chemotherapy but the tumor was growing and threatening her life and her hope of being there for her daughter's next birthday. The question she wanted to ask me was "IS THERE ANYTHING ELSE".

Senators and Members of the Committee, millions of people are asking if there is anything else. Anything else for cancer, Alzheimer's, AIDS, diabetes, Avian flu—anything else to protect our food supply, improve nutrition, alleviate obesity, keep our animals healthy and cosmetics safe. The fact is that there can not be anything else without this FDA—a modern, efficient and effective FDA.

I know the FDA is capable of fulfilling its mission to assure hope that one day there will indeed be something else. FDA is the Agency that can assure Americans hope.

Through strong management and leadership, we have the ability to translate innovations into safe and effective new interventions that protect and promote human health. In this task, the Agency cannot, and will not fail.

It would be the fulfillment of my aspiration to have your trust and the trust of the American people to have the privilege to lead the FDA -- to save lives and assure the health of our nation and the world. If confirmed, I look forward to working closely with this Committee on the many important issues that we'll address together.

Again, thank you for the opportunity to come before you today. I'm happy to answer any questions the Committee may have.