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Introduction

Mr. Chairman and Ranking Member Murray, I want to thank you and members of the Committee for inviting me here today to discuss my nomination to be Commissioner of Food and Drugs in the office of the Food and Drug Administration (FDA). I'm honored to be accompanied by family today. Sitting behind me are my dad, a WWII Veteran, my mom, a 7 year survivor of multiple myeloma and my wife of 42 years and high school sweetheart, Lydia. My three children and my granddaughter Brooke are also with us. The support of my family and their feedback have been essential to my career success and moral compass.

I am honored to have been nominated by President Obama to lead the FDA. Thank you all for your willingness to share with me your perspectives on ways the FDA can better serve the American people. My primary goals, if confirmed, would be to work with you to build on the excellent workforce, relentlessly focus on the completion of priority projects, and continue to develop the science base needed to give consumers and patients even more confidence that their food is safe and their medical products are safe and effective. I also believe that we need to continue to improve our efforts to give patients and clinicians an accurate understanding of the benefits and risks of medical products.

My service as Deputy Commissioner for Medical Products and Tobacco has underscored for me both the opportunity and the gravity of this undertaking. Amid ongoing revolutions in biological science and information technology, we must continue to strengthen the FDA's vital work in protecting the American people while encouraging innovations that hold promise to improve their health. If confirmed, it would be an honor to lead this outstanding workforce in this remarkable time.

Background

My career has been dedicated to advancing the public health as a physician, leader, and researcher. But, like each of you, my understanding of our health system was shaped by more than just my professional life. Our first daughter was born with a serious congenital heart defect requiring open heart surgery as an infant. I still vividly remember the inspirational work of her doctors and the uncertainties of that experience—including the shocking discovery that one of our daughter's cardiologists was an imposter with faked medical credentials. My family has experienced firsthand how important it is to find a critical balance between innovative treatments and appropriate safeguards for patients. The American people need access to cutting edge treatments, but also must be able to trust the information they are given about that treatment.

As a medical student, I worked with one of the first computerized medical databases and witnessed the potential for computer technology to inform decisions about health and healthcare. When I started in cardiology, heart attack was the leading cause of death in the U.S. and our understanding of the cause of this leading cause of death in America was limited. It was agonizing that one of six patients with a heart attack died during their first hospitalization. This intensely personal experience of dealing with a catastrophic illness and its consequences on

victims of the disease and their families drove us to be relentless about inventing and developing effective treatments. Together with a global network of doctors and nurses, and with an extraordinary team of researchers, computer scientists, and statisticians, I had the privilege to serve as a leader on efforts to develop "clot busting" drugs that restore blood flow to the heart, improve the recovery of the heart muscle and help prevent future heart attacks. We also worked together to develop and evaluate life-saving technologies, including balloon angioplasty, cardiovascular stents, and implantable defibrillators, that have helped millions of Americans. These efforts have decreased the risk of death from heart disease by more than half. This condition that was once a death sentence is now treatable thanks to drugs and medical products, highlighting for me the importance of bringing these advances to patients as fast as safely possible. Much of my work has been at the intersection of public health and research, including large-scale efforts to improve our national clinical trial research infrastructure and innovative community-based projects undertaken in close collaboration with underserved patients and their communities.

Indeed, it is not enough to develop new treatments. We must prove they are safe and effective, and deploy them in a systematic way that reaches all Americans, and eventually the global population. Our initial quality registries for bypass surgery, angioplasty and heart attack have become global standards, including adoption of derivatives of our quality measures by CMS, to improve the public health by advancing evidence based therapies and reducing medical errors.

Leading the FDA

A successful FDA is a critical factor for better public health in this changing world. We are currently witnessing a revolution in biomedical science and information technology that

empowers consumers to make choices about their health and health care. Today our food safety system is undergoing the most comprehensive update since it was established and we are working to ensure that medications prescribed to animals do not reduce their effectiveness in humans. Against this backdrop of revolutionary change, the FDA must be prepared to set policies that channel these innovative technologies for safe and effective use—protecting the public while approving products with clear benefit.

I firmly believe that the best way to make this progress is for different sectors in today's health care ecosystem to collaborate. I led efforts at Duke University Medical Center to help academic researchers collaborate with industry in a documented and transparent manner that *retained their independence and primary role in caring for patients*. Similarly, the United States, and indeed the entire world, depends on a strong, unbiased FDA that can work with industry to advance critical technologies while still making independent determinations to ensure that scientific potential is translated into safe and effective products. To advance, we must find common ground with industry and academia on the science without compromising this fundamental role of the FDA.

More recently, I have had the pleasure of jointly leading multiple projects along with patients, consumers and community leaders, to the great benefit of research and public health. The emergence of consumers and patients as active participants in the process of developing therapies and devising protocols for evaluation is an important theme to improve the relevance of our work to the people we serve.

The Importance of the Workforce and Infrastructure

My first priority as Commissioner would be to strengthen and better support FDA's talented and dedicated workforce. However, the products we evaluate are increasingly complex. Sustaining the quality of FDA's scientific workforce may be more important than any particular policy because it is our day-to-day decision making that protects the public without impeding technological progress. FDA scientists are making decisions every single day about hundreds of products – but as technology advances these decisions become more complex. Americans must be able to depend on a strong FDA workforce that keeps up with the rapidly changing world.

Completion of Critical Priorities

My next priority as Commissioner would be to carry our critical priorities over the finish line. With your guidance, the FDA has embarked on an ambitious agenda to keep pace with our changing society. The Food Safety Modernization Act will enhance our ability to assure Americans of the safety of the food supply. The Deeming Rule for tobacco products will be the basis for continuing our success in reducing tobacco-related deaths. Several high priority initiatives are underway, including the Combating Antibiotic Resistant Bacteria (CARB) initiative, medical counter measurement development, and the Precision Medicine Initiative to name a few. And, of course, the user fee programs that have been so successful in providing resources for review of medical products are entering a period of renegotiation.

Focusing on the Science Base

My third priority as Commissioner would be to further develop the science base that informs FDA's decision making across drugs, devices, food safety, and more. If we build the right infrastructure, FDA can realize the potential of revolutionary advances in biological and

information sciences that will unlock greater amounts of useful evidence about food, tobacco and medical products at dramatically lower cost.

We must also take advantage of the astounding opportunity afforded by the fact that the majority of Americans have an electronic health record and smart phones. The groundbreaking Sentinel system demonstrates the power of evidence to inform FDA's decision making and act quickly on safety issues and we have a similar plan for medical device surveillance. I am committed to the development of a national system for surveillance and evidence generation that will improve patient safety and provide a much more efficient way to understand the benefits and risks of medical products when used in practice.

In addition, the proliferation of the internet allows many patients, advocates, and caregivers to be reached directly, both to impart information and to solicit their perspectives and experiences. I am greatly encouraged to see that FDA expects industry to involve patients directly in the process of technology development and assessment, but recognize that we are just beginning to understand the *science* of consumer engagement. Further, as ever-growing amounts of information become available to consumers about the benefits and risks of medical products, we must ensure that it is high-quality information.

Finally, we cannot forget that while the FDA has the well-being of Americans as its mission, we are operating in a global environment. Because health and disease do not recognize national boundaries, the FDA must be in constant communication with the global scientific and regulatory communities. We should continue to develop sophisticated and robust information systems for monitoring the safety and quality of medical products and food produced outside of our borders in concert with our global colleagues.

Summary

The FDA is poised to leverage the acceleration in biomedical knowledge to lead to a new era of enhanced safety and effective therapies, and, if confirmed, I would be honored to lead the Agency in this exciting time. Thank you for allowing me to testify before you today and I am happy to take your questions.