

You were nominated on September 17. My staff has spent two months carefully reviewing everything you submitted and has not found anything that would call into doubt your ability to lead the FDA fairly and impartially.

You come here today with impressive qualifications. You are one of the nation's leading cardiologists and have been a professor at one of the nation's top medical schools for over 30 years. You are an expert on clinical research and have been recognized by the Institute for Scientific Information as one of the top 10 most cited medical authors, with more than 1,200 peer-reviewed publications. You have experience managing large organizations, including in your current position supervising all of the FDA's work on medical products and tobacco, and in your past work as the founding director of the Duke Clinical Research Institute.

Moreover, you have conducted scores of important clinical trials, and you have advised and worked on research with some of the nation's leading pharmaceutical and biopharmaceutical companies. So you understand how research gets done in the real world, where there are opportunities for the FDA to help address challenges, and where the FDA needs to get out of the way.

I'm eager to hear about your priorities, and how you intend to manage an organization as large and diverse as the FDA. I also think everyone on this committee will have some questions for you. Here are a few of mine.

First, I would like to hear what you will do to help ensure that affordable drugs are available to American patients. The FDA's job, of course, is not to set drug prices. It is to make sure that drugs are safe and effective. And I hope you'll agree with me on that. But FDA can help the market lower drug prices by approving generic drugs and other products as quickly as it possibly can, so there is more choice and competition in the market.

There are thousands of applications for generic drugs sitting at the FDA, awaiting approval. Addressing this backlog will allow lower-cost drugs to be available for patients. Approval times have gotten worse instead of better. In 2011, the FDA published the median approval time on its website, and it was 30 months. Since then, the FDA has stopped publishing the statistics online, but the Generic Pharmaceutical Association surveyed its members and estimates that the median approval time is now about 48 months. This is despite generic drugmakers agreeing in 2012 to give the FDA approximately \$1.6 billion in user fees over 5 years, nearly \$1 billion of which the FDA has already collected. I'm eager to hear what you think the FDA can do to improve.

Second, there has never been a more exciting time to lead the agency. We know more about biology and medicine than ever before, and that's not likely to stop anytime soon given advancement of regenerative cell therapies, 3D printing, and the president's Precision Medicine Initiative—which is aimed at developing our knowledge so that medical treatments and devices can be tailored to individual patients. For example, Smith & Nephew, a device company I toured in Memphis a few weeks ago, uses 3D printing to make tools that doctors use in approximately 25% of knee replacements.

Your job, if confirmed, will be to make sure that FDA regulation is appropriate. Too much regulation could reduce investment in these areas in its track, and not enough regulation could lead to patients getting therapies that are not safe or effective.

Your job also will be to make sure the FDA keeps up with science and relies on the expertise outside the FDA when appropriate.

Doing that will require you to manage a large and complex organization—not just on the big policies that make headlines, but on the less flashy stuff like hiring and training scientists on the agency's core mission, and integrating information technology in the right ways.

There is work to be done. Medical products take more time and money to discover, develop, and reach American patients than ever before, and we hear stories about drugs and devices that are available to patients outside the U.S. before they become available here, often because it is difficult for manufacturers to navigate the FDA's often unclear approval requirements. It often takes over a decade to develop a drug that gains marketing approval in the U.S., and, according to one recent study, the costs have nearly tripled in the last ten years. In 2003, it cost an inflation-adjusted \$1 million in capital and out-of-pocket expenses; in 2014, it cost over \$2.5 billion.

In this Committee, we are working on legislation to help get safe cutting-edge drugs, medical devices and treatments into Americans' medicine cabinets and doctors' offices more quickly, and we hope to move on that by the end of the year. I want to hear what you think the FDA can do to build its capacity and fix the impact of its regulations so that the FDA is a partner in innovation, rather than a barrier.

Thank you, and I look forward to hearing your testimony on these important issues.

#### ADDITIONAL STATEMENTS

##### RECOGNIZING THE 50TH ANNIVERSARY OF THE UNIVERSITY OF CALIFORNIA, SANTA CRUZ

• Mrs. BOXER. Mr. President, I ask my colleagues to join me in congratulating the University of California, Santa Cruz on its 50th anniversary and recognizing the outstanding faculty and staff for their immense contributions.

For 50 years, UC Santa Cruz has educated, inspired, and helped shape the futures of generations of young people, fostering an environment to produce not only good scholars but also good citizens.

Modeled after historic institutions like Oxford, from its earliest days, students have been encouraged to ask questions—to learn how to think for themselves and debate the status quo inside and outside the classroom. Today the university counts among its alumni some of the world's most prolific and influential leaders on everything from organic farming to ocean health, from women's rights and medical research.

A half century after its founding, UC Santa Cruz is a world-renowned research facility at the center of many critical scientific breakthroughs, such as producing the first working draft of the human genome, helping global researchers develop a vaccine for the Ebola virus, and playing a leading role in cancer genome research. The university is also home to one of the world's top marine mammal research centers. Its internationally recognized faculty includes 14 members of the National Academy of Sciences, 26 fellows of the American Academy of Arts and

Sciences, and recipients of the Presidential National Medal of Science and the Benjamin Franklin Medal from the Franklin Institute, one of the oldest and most prestigious science awards in the world.

Anyone who is lucky enough to have visited the UC Santa Cruz campus is immediately struck by its beauty. Nestled between the Pacific Ocean and redwood forests, the campus offers students a spectacular backdrop to their education. Students hike trails to class, elephant seals can be heard in the background, and stunning sunsets can be seen from university grounds. These breathtaking surroundings have attracted a creative and passionate student body that has proudly embraced environmental, social, and political causes—and a sense of humor. In 1986, the students selected their now-famous official mascot—the Banana Slugs.

Since 1965, UC Santa Cruz has created an atmosphere of discovery and activism, shaping minds, pushing the frontiers of knowledge, and making our world a better place. I congratulate Chancellor George Blumenthal and the faculty, staff, alumni, and students of UC Santa Cruz on this 50th anniversary and wish this extraordinary institution continued success in the future.●

##### TRIBUTE TO MARY CRAWFORD

• Mr. DAINES. Mr. President, in honor of National Adoption Month, I want to recognize one member of Montana's community who has opened her home and heart to be an adoptive parent. Mrs. Mary Crawford is what I believe one of the best Montana has to offer.

As an original cosponsor of a resolution to designate November as National Adoption Month and November 21 as National Adoption Day that passed the Senate unanimously this week, I could find no better time than this to honor Mary. This month we honor selfless individuals like Mary who have dedicated themselves toward comforting, protecting, and improving the lives of children they have welcomed into their homes.

Like most foster parents who later become adoptive parents, the process isn't easy, but the resolve of both Mary and husband to continue to provide a loving home for nine children is nothing short of admirdable. Mary has provided a family which has made a huge difference in these children's lives—giving them a family for life, beyond just their childhood years. These children are safe today in the arms of loving, adopting parents because of Mary.

Montana has kids who are ready and waiting to be adopted. In fact, there are 415,000 children currently in the U.S. Foster Care System, and 108,000 of those are waiting to be adopted. Mary has taken tremendous steps in providing six children with a forever home to give them the stability and love that she and her husband could provide.