

Chairman Alexander, Ranking Member Murray, Members of the Committee: Thank you for the invitation to testify this morning.

I'm honored to appear before you today as the President's nominee to be the next Commissioner of Food and Drugs.

I come before you today humbled by the realization that the lives and futures of families like mine are affected by the decisions made by FDA.

Should you choose to confirm me, I'll make it my mission to fight for those families every single day, and ensure that FDA puts their interest first in everything we do.

I've seen the importance of FDA's work as both a doctor and a patient.

I graduated from Wesleyan University, in Middletown, Connecticut; and went on to graduate from the Mount Sinai School of Medicine, where I also completed a residency in Internal Medicine.

I've had the honor to serve in senior roles at both CMS and FDA.

I practiced medicine as a hospitalist physician, taking care of hospitalized patients.

I've tried to ease suffering and illness as a physician, and I've had both visited upon me—I am a cancer survivor, I was treated for cancer during my last tour at FDA, so I know the importance of what American medicine does -- and what the FDA does -- for every one of us.

For the last 10 years, I've been a policy analyst and an entrepreneur, starting and building businesses.

I've advised and invested on very early stage medical technology and healthcare services companies with the hope that some of these innovations could improve the medical technology that we use, and the systems through which we deliver care.

Some of these endeavors were successful. Some were not. For many others, it's still too early to tell.

That's the unpredictable nature of innovation in this dynamic sector.

It's a dynamism that I've come to know well from working on the regulatory, policy, clinical, and business aspects of these enterprises.

I'm proud of the projects I've worked on, and what I've learned in the process. The things I've done – my accomplishments, my failures, and everything in between - have shaped who I am today.

Collectively, they've helped inform my values and my perspectives.

But among other things, they've taught me the need for an absolutely objective regulatory watchdog over this field.

If confirmed, I'll lead the FDA as an impartial and passionate advocate for public health.

I know what's at stake here. People's lives are literally on the line when it comes to the decisions FDA makes, its oversight, and its enforcement of Congress's laws.

And the American people deserve to trust that the agency is led in an impartial manner -- guided only by the science that informs its work -- and an abiding faith to the public health.

That is the mandate by which I would lead this agency, if I were fortunate enough to win your approval.

I'll respect the intent of Congress.

I'll make sure the laws you passed are implemented in a timely fashion and in the way you intended.

And every decision I make will be guided by the advice of career experts.

I'll be guided by the scientific rigor that the public deserves, and the rigor that the hard challenges before this agency demand.

It's to take on these challenges that I seek this role.

We're at an inflection point in biomedical science.

New technologies give us a fundamental chance to cure many intractable diseases.

We have more opportunities to improve our diets and our health with the foods we eat.

In areas where there's an inherent, obvious, and seemingly unavoidable risk related to certain consumer products – whether its combustible tobacco or dangerously addictive opioid drugs – we have the opportunity to help consumers move to less risky alternatives.

This owes to the foresight of Congress, in envisioning paths to reduced harm as an animating principle in FDA regulation.

I want to build on these opportunities and achievements.

And I want to use the authorities Congress recently included in the 21<sup>st</sup> Century Cures Act to develop a template to lean forward in these areas.

We need to make sure we're getting the most bang for our regulatory buck: That means being cognizant of risks and being sure that we're not adding to consumer costs without improving consumer safety.

We must constantly ask ourselves "are we doing everything we possibly can? Does FDA have the policies and processes in place to play its part in tackling the important public issues of our day?"

We should be reminded always, that we save lives by allowing good things to happen, but we also save lives when we keep bad things from happening. FDA's enforcement tools are a bedrock of its mission.

And we should reject a false dichotomy that it all boils down to a choice between speed and safety.

If FDA is leaning forward in areas of new technology, if it's investing in good tools for doing its own work, and better science for evaluating regulatory questions – in other words, if we're doing our jobs and leveraging the authorities you have given us in new Congressional mandate -- we can have better efficiency, and better safety, and also remain faithful to FDA's gold standard for regulatory conduct.

I've seen FDA's positive impact in my prior roles at the agency.

I'm seeking this new role because I'm drawn to FDA's unique spirit of public health protection that inspires its work and its workforce.

I'm drawn to the opportunities we have to leverage FDA's platform -- and its new authorities and resources -- to enable advances in medicine and science to safely reach consumers.

And I'm drawn by the challenges the agency confronts as it tries to enable Americans to make the most of this unique moment in science.

I hope to earn your confidence and support in delivering on these opportunities.

Thank you again for the opportunity to appear before you this morning.

I would be happy to answer any questions.

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