FDA's plan to engage the public in the agency's new effort to strengthen and modernize FDA's regulatory framework

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We're at a moment of extraordinary opportunity to improve the public health. New innovations are giving us fundamentally better ways to address disease. Some of the same technology is providing consumers with a broader selection of foods that can improve peoples' diets, and products that can expand their choices. At the same time, we also face a lot of new challenges. The steps FDA takes to advance these opportunities, and address uncertainties, will directly impact the lives of families. As part of our commitment to protect and promote the public health, we're undertaking a comprehensive review of our regulations. Our aim is to ensure that our policies and regulations keep pace with the challenges we face in protecting consumers, and the opportunities we have to improve their lives. As in all our actions, science will remain FDA's North Star when it comes to our role in devising regulatory policy.

Over the past few months, FDA has announced a number of broad policy efforts to address public health opportunities in areas such as regenerative medicine, tobacco products, and access to affordable medicines. As with everything that we do, this work is rooted in our mission to protect and promote the public health, foster safe and effective innovation that can benefit patients, adopt regulatory approaches that enable the efficient development of new innovations, and provide for a safe, healthy and nutritious food supply. For example, we're looking at places where FDA's rules concerning new drugs are being used in ways that may create obstacles to the timely entry of generic competition. We want to make sure our policies aren't being misused in ways that thwart the competition that Congress intended when it created the modern generic drug framework. We know that vigorous generic competition can help benefit patients by lowering drug costs, which improves access to medicines. It's one example of where a closer analysis of our existing policies can help make sure our regulations are having their intended purpose.

As part of my commitment to help oversee the development and implementation of key policy issues, and to help advance these broader policy efforts, I've been working closely with FDA

Commissioner Scott Gottlieb, M.D., and other senior agency colleagues, to explore ways to modernize our regulations in a manner that will benefit all Americans. To achieve this, we're not only looking at what new regulations or policies we need in order to be most effective in fulfilling our public health responsibilities. We're also taking a closer look to see if we need to revise, update, and in some cases eliminate existing regulations to help us better keep pace with scientific advancement and the people that we serve. We need policies that are as modern as the products that we're being asked to evaluate, and a regulatory framework that uses efficient tools to achieve our vital consumer protection role.

This comprehensive review is a large undertaking given the breadth of our public health mission and the fact that FDA-regulated products account for about 20 cents of every dollar consumers spend each year. It involves the support of FDA's senior leaders and many of our staff. FDA has long played a vital role in protecting and promoting public health, and since its founding in 1906, the scope and charge of the agency's work has grown to include many products that Americans rely on every day. Over time, the agency has also assumed an increasingly global footprint. Along the way, we've taken many steps to modernize our policies and practices and evaluate our portfolio of regulations to make sure they're keeping pace with our challenges. But our 100-plus-year history lends itself to a closer examination of the regulations that have guided our work. Some have been in place for decades, and may not reflect the most up-to-date approach to achieving our public health mission. We have a lot of ground to cover. Today, FDA's regulations comprise more than 4,000 pages in the Code of Federal Regulations. Some regulations may not adequately reflect advances in science, technology or changes in industry practice. Others may be geared toward products and practices that have largely ceased to exist. In a world of increasing challenges and opportunities, we need to be risk-based in everything we do in order to make sure we're using our resources efficiently. Our goal is to have regulations that reflect modern risks and opportunities, and use the full scope of our authorities to achieve our consumer protection mission.

As part of this process we're asking ourselves and others to think about how current regulations could be reshaped to achieve our public health objectives through more efficient approaches. We are opening a number of public dockets to solicit feedback from patients, consumers, health providers, caregivers, industry, health groups, academia, as well as state, local and tribal governments, and public health partners. We're also exploring other opportunities to solicit input from stakeholders on this effort. We believe that engaging both internal and external stakeholders are critical to focusing our attention on where our policies might need updating; to ensure FDA's work maximizes our public health purpose.

Our approach also aligns our efforts with the Administration-wide goal for federal regulatory reform to improve how government serves the American people. At FDA we take seriously our responsibility to protect and promote the public health. This will be our guiding principle. We'll use this opportunity to make sure our regulations reflect the new benefits that science and technology offer to advance opportunities for patients to improve their lives, and to strengthen our mandate to protect consumers. We look forward to your input and will continue to communicate our plans as we move forward on this endeavor.

For more information on how to provide input on FDA's regulations, please visit:

- Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration
- Review of Existing Center for Drug Evaluation and Research Regulatory and Information Collection Requirements
- Review of Existing Center for Biologics Evaluation and Research Regulatory and Information Collection Requirements
- Review of Existing Center for Devices and Radiological Health Regulatory and Information Collection Requirements
- Review of Existing Center for Tobacco Products Regulatory and Information Collection Requirements
- Review of Existing Center for Food Safety and Applied Nutrition Regulatory and Information Collection Requirements
- Review of Existing Center for Veterinary Medicine Regulatory and Information Collection Requirements