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FDA commissioner outlines steps to spur biomedical innovation, improve health of Americans

FDA Commissioner Margaret A. Hamburg, M.D., today released a blueprint containing immediate steps that can be taken to drive biomedical innovation, while improving the health of Americans.

Titled "Driving Biomedical Innovation: Initiatives for Improving Products for Patients," the blueprint addresses concerns about the sustainability of the medical product development pipeline, which is slowing down despite record investments in research and development.

"The Obama Administration is committed to encouraging the entrepreneurs and businesses that are modernizing and strengthening our health care system," said HHS Secretary Kathleen Sebelius. "The innovation blueprint is another part of our effort to help businesses grow and keep Americans healthy."

"America is at an important crossroads, where the science before us presents unprecedented opportunities to create new and better medical products and to promote better health for the public," said Hamburg. "Our innovation blueprint highlights some of the initiatives FDA will be implementing to ensure that these opportunities are translated into safe and effective treatments that can help keep both American patients and American industry healthy and strong."

While FDA has long been committed to promoting innovation with a number of efforts underway already this year, Dr. Hamburg recognized the need to create an FDA-wide framework to address the changing scientific landscape. This blueprint launches the Innovation Initiative, identifying additional steps the agency can take immediately to address the most pressing concerns facing patients and industry.

The report's proposals stem from a review of FDA's current policies and practices, as well as months of meetings with major stakeholders nationwide, including key industry leaders, small biotech, pharmaceutical and medical device company owners, members of the academic community, and patient groups.

The blueprint focuses on implementing the following major actions:

- rebuilding FDA's small business outreach services
- building the infrastructure to drive and support personalized medicine
- creating a rapid drug development pathway for important targeted therapies
- harnessing the potential of data mining and information sharing while protecting patient privacy
- improving consistency and clarity in the medical device review process
- training the next generation of innovators
- streamlining and reforming FDA regulations.

The blueprint was released during the commissioner's appearance at the 3rd annual Washington Ideas Forum, sponsored by The Atlantic magazine in partnership with the Aspen Institute and the Newseum.

For more information:
Innovation
www.fda.gov/innovation
White House blog posting
http://www.whitehouse.gov/blog/2011/10/05/innovation-food-and-drug-administration

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