FDA STATEMENT

For Immediate Release: Feb. 13, 2013
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FDA Commissioner Margaret A. Hamburg's Statement on the Institute of Medicine's Report "Countering the Problem of Falsified and Substandard Drugs"

The U.S. Food and Drug Administration commends the Institute of Medicine (IOM) for its thorough discussion and recommendations outlined in its report, ***"Countering the Problem of Falsified and Substandard Drugs* (/web/20170126130150/http://www.iom.edu/Activities/Global/CounterfeitDrugs.aspx) (/web/20170126130150/http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**." The report identifies causes and public health consequences of substandard and falsified drugs and recommends a range of strategies to address the problem and to promote global dialogue and action.

The IOM report spotlights a critical global public health issue. Falsified and substandard medicines adversely affect the lives of millions around the world, and the issue must be elevated to the highest levels of international discourse.

In order to meet the challenges of today's global marketplace, the FDA is transforming from a predominantly domestically focused agency to one that is fully prepared to help ensure product safety and quality within a globalized world. In this context, many of the IOM recommendations support actions and efforts already underway at the FDA, including advancing technology, strengthening global regulatory capacity, strengthening surveillance, developing science-based standards and engaging in global dialogue.

The FDA engages in numerous efforts to combat substandard, falsely-labeled and counterfeit medical products globally. These include overseas presence in 12 countries in seven regions; active engagement with the World Health Organization's new Member State Mechanism; and participation in the Asia Pacific Economic Cooperation (APEC) Regulatory Harmonization Steering Committee (RHSC) roadmap aimed at improving global medical product quality and supply chain integrity. In 2011, the FDA added to these efforts by commissioning the IOM to undertake the study released today.

The FDA recognizes that all countries need to work together to ensure safe medicinal products for their citizens due to the increasing complexity of the global economy. The FDA remains committed to engaging with multiple stakeholder groups to advance global solutions and minimize exposure of consumers to unsafe products.

For more information:

- **Countering the Problem of Falsified and Substandard Drugs (/web/20170126130150/http://www.iom.edu/Activities/Global/CounterfeitDrugs.aspx) (/web/20170126130150/http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **FDA Global Initiative (/web/20170126130150/http://www.fda.gov/AboutFDA/GlobalInitiative/default.htm)**

- Counterfeit Medicine (/web/20170126130150/http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/default.htm)

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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