EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

May 17, 2012
(Senate)

# STATEMENT OF ADMINISTRATION POLICY

**S. 3187 – Food and Drug Administration Safety and Innovation Act**

(Sen. Harkin, D-IA, and 1 cosponsor)

The Administration strongly supports passage of S. 3187, the Food and Drug Administration Safety and Innovation Act, which will help speed safe and effective drugs, medical devices and biosimilar biological products to patients.

Building on proposals developed by the Administration in partnership with the pharmaceutical and medical device industries and consumer groups, S. 3187 reauthorizes the prescription drug and medical device user fee programs as well as creates new user fee programs for biosimilar biological products and generic drugs. The biosimilar approval pathway was created by the Affordable Care Act, and the generic drug user fee program was proposed in the 2013 President's Budget to help increase patient access to affordable medicines.

S. 3187 also enhances the tools available to the Food and Drug Administration to address drug shortages by requiring additional early notification of potential shortages, an action the Administration called for in the 2011 Executive Order on drug shortages. In addition, provisions in the bill help address the challenges of globalization by enhancing the safety of the drug supply chain, increase incentives for the development of new antibiotics, renew and enhance mechanisms to ensure that children's medicines are appropriately tested and labeled, and expedite the development and review of certain drugs for treatment of serious or life-threatening diseases and conditions.

Promoting innovation, safety, and access to medicines and devices is critical to the Nation's health, and the Administration supports this bipartisan legislation that contributes to this goal.

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