SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR & PENSIONS

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Lamar Alexander of Tennessee - Chairman

Bring Safe Drugs and Medical Devices to Patients Faster

Getting safe and effective treatments into Americans' medicine cabinets and doctors' offices more quickly

The Problem:

- Today discoveries do not come to the Food and Drug Administration's (FDA) door for six, eight, ten, or even twelve years. **And the cost to get a single drug from the laboratory through the approval process to a patient's medicine cabinet is, according to some estimates, about $1 billion**—other estimates say it's double that or even more.

The Solution:

The Senate health committee has passed 19 bipartisan bills, and has worked to combine those bills with the House-passed 21st Century Cures Act to help **take advantage of this exciting time in science by bringing safe drugs and medical devices to American patients more quickly.**

Highlights of the Senate health committee-passed 'Cures' agenda—all passed with unanimous or overwhelming support—include:

- Building off the successful expedited review pathway for breakthrough drugs at the FDA—for example, the first drug ever approved to **actually cure some forms of Cystic Fibrosis**—and replicate it for medical devices;

- **Shortening the development of new treatments for superbugs** that cause infections that run out of control and resist treatment by common antibiotics;

- Preventing combination products—from Band-Aids with Neosporin to life-saving heart stents coated with blood thinners—**from being caught in regulatory red tape at the FDA;**

- Helping advance therapies for patients with serious or life-threatening rare genetic diseases by allowing innovators to rely on their own data used for previously approved therapies—in lieu of starting from scratch.