United States Senate

Washington, DC

Senators Burr and Coburn Introduce PATIENTS' FDA Act

FOR IMMEDIATE RELEASE
Tuesday, April 17, 2012

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WASHINGTON, D.C. – Today, U.S. Senators Richard Burr (R-NC) and Tom Coburn (R-OK) introduced the Promoting Accountability, Transparency, Innovation, Efficiency and Timeliness at FDA (PATIENTS' FDA) Act, a bill to help make sure that the FDA fulfills its mission to ensure that patients have access to cutting-edge, life-saving drugs and devices as quickly as possible. Meaningful Congressional oversight will ensure that the FDA is held accountable for its performance goals and is fulfilling its public health mission on behalf of patients in a predictable and timely manner, including decisions on life-saving drugs and devices. This will help keep medical innovation and job creation from going overseas, which jeopardizes American patients' access to the most cutting-edge medical therapies and advances.

"America's patients want access to the latest, most effective life-saving treatments. This bill will ensure that Congress and the American people hold the FDA accountable for meeting its performance goals so that cutting-edge medical therapies approved by the FDA reach patients as quickly as possible," Senator Burr said. "Government red-tape at the FDA is stifling scientific investment and innovation, which is a disservice to North Carolina's medical innovators and even worse can delay patients' access to medical therapies. Our bill will help identify areas where the FDA needs to do better."

"Last month, GAO gave us a report confirming what we already suspected: the FDA is taking longer and longer to make final decisions on life-saving medical devices and not meeting vital performance standards due to a complete lack of congressional oversight. When a government agency consistently shows signs of failing to meet its public mission and is failing to help some of the very people it was intended to protect, there is no one else to blame but Washington. Instead of harming life-saving innovation, the PATIENTS' FDA Act ensures a rigorous, careful, transparent,

and accountable system, and more importantly, gives patients the access to care that they deserve," Senator Coburn said.

The PATIENTS' FDA Act will enable Congress to fulfill its duty to the American people by ensuring that the FDA is promoting the public health through its review and regulation of medical products. The FDA's work on behalf of patients is supported not only by user fees, but also by taxpayer dollars. Thus, Congress has a critical oversight role in ensuring the FDA is meeting its requirements under the law. User fees and performance goal agreements are negotiated between the device and drug industries and the FDA, but Congress has a responsibility to determine whether or not the FDA is meeting not only its negotiated performance goals, but the metrics necessary to ensure that the FDA is acting in the best interest of patients and taxpayers. Thus, the PATIENTS' FDA Act is designed to complement the proposed agreements negotiated between the FDA and the drug and device industries by ensuring appropriate transparency and accountability in the FDA's review and decision processes.