Advancing Breakthrough Devices for Patients Act

Senators Burr, Bennet & Hatch

"*…Our job is to ensure the safety and efficacy of FDA-regulated products and to take real steps to foster the scientific innovation that will lead to tomorrow's new breakthrough products…Innovation is not just about new ideas, but is about making sure that those ideas truly translate into the products and opportunities that people need and count on. Moreover, it's about changing systems replacing outmoded or insufficient patterns with new, better, more effective ones.*"

- FDA Commissioner, Dr. Margaret Hamburg, April 5, 2011

Background

Advances in our understanding of diseases and conditions have led to major breakthroughs for patients and hold tremendous potential for advancing targeted and more effective therapies. In 2012, Congress enacted the Advancing Breakthrough Therapies for Patients Act as part of the FDA Safety and Innovation Act of 2012 (P.L. 112-144). Building on the success of the Breakthrough Therapy designation for drugs, this legislation applies the similar principles and "all hands-on-deck" approach to devices, while also complementing and enhancing the existing tools, such as priority review, currently in place for devices.

Designation for Expedited Development and Priority Review of Devices

The Advancing Breakthrough Devices for Patients Act will encourage and spur innovation on behalf of patients by providing greater regulatory certainty and predictability and clarifying the path forward for breakthrough devices. This bipartisan legislation amends the Food, Drug, and Cosmetic Act to require FDA, at the request of a device sponsor, to expedite the development of and provide for priority review of devices that represent breakthrough technologies, for which no approved alternatives exist, offer significant advantages over existing approved or cleared alternatives, or the availability of which is in the best interest of patients. By setting out a clear process by which a device sponsor may request designation for expedited development and priority review, this legislation will help to clarify the path for devices to receive priority review and reach American patients in as timely a manner as possible. If the FDA determines that a device meets the necessary "breakthrough" criteria, then the agency shall take key actions to expedite the development and priority review of such designated devices, which may include taking steps to ensure that the design of clinical trials is as efficient as practicable, when scientifically appropriate, and agreement on clinical protocols.

Regulatory Certainty

In order to promote regulatory certainty with respect to breakthrough devices, the bill also requires FDA to issue final guidance on authorities relating to breakthrough devices.