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**Measure included in larger, bipartisan bill to reauthorize fee programs for medical devices & drugs**

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WASHINGTON – A measure introduced by Congressman Charles F. Bass (NH-02) last fall to make it easier for medical device manufacturers to create devices for individuals with rare diseases unanimously passed the House Energy and Commerce Committee this morning.

The measure was included in a larger, bipartisan legislative package, H.R. 5651, which reauthorizes user fee programs for prescription drugs and medical devices, establishes user fee programs for generic drugs, and reforms certain Food and Drug Administration (FDA) programs. The legislation could be considered on the House floor as early as next week.

**Bass** said:

"The legislation that passed the Committee today is extremely important in ensuring high standards of safety in the drug manufacturing process as well as spurring innovation in the health care industry.

"I am also pleased that my legislation to make it easier for medical device manufacturers to develop products for patients with rare diseases was included in the overall bill. Providing incentives to manufacturers to invest in the development of medical devices will encourage new innovations in this field and lead to a better quality of life for the 20 million American patients with rare diseases.

"With the enhanced financial incentives and resources available to the FDA included in the user fee agreements, we will see shorter approval times for drugs and devices and more successful products available to patients. These regulatory improvements will increase transparency and market involvement and encourage even more development of innovative and life-saving drugs and devices."

**Peter L. Saltonstall, the President and CEO of the National Organization for Rare Disorders**, said, "NORD applauds Congressman Bass's commitment and work on behalf of the rare disease community in prioritizing this issue during the debate. We are very pleased with the inclusion of this language which will, in turn, allow investment in the development of medical devices that are specifically intended to help the rare disease community. We hope the debate continues smoothly and that this proposed legislation is swiftly signed into law."

Specifically, Bass' measure (H.R. 3211), which was included in the overall FDA user fee bill passed by the Committee this morning, would repeal the outdated profit cap on Humanitarian Use Devices (HUDs), which are innovative medical devices used to treat rare diseases. The "no-profit" cap on the sale of these devices discourages manufacturers, particularly smaller

companies, from pursuing new developments in the industry, growing their businesses, and creating new jobs. While the no-profit cap was lifted for pediatric devices five years ago, it has not been lifted for adult devices.

In 2010, the FDA conceded the scope of the remaining unmet medical needs for American patients, testifying to Congress that "there are still an estimated 20 million Americans suffering from rare diseases for which there are no approved therapies available." Lifting the no-profit cap on adult humanitarian use devices will spur innovations in this industry and benefit patients suffering from rare diseases.

**Bass** concluded, "Drug safety and medical innovation is a nonpartisan issue, and the fact that this legislation passed unanimously today after an open and deliberative process signifies that Congress can find common ground to help the American people."

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