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Measure included in larger legislative package to reauthorize FDA user fee programs

June 20, 2012

WASHINGTON – Congressman Charles F. Bass (NH-02) praised final passage of bipartisan legislation in the House of Representatives today that includes a provision he sponsored to make it easier for medical device manufacturers to create and produce devices for individuals with rare diseases.

This afternoon, the House passed by voice vote the conference report for the Food and Drug Administration Safety and Innovation Act, which reauthorizes current 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 bill now heads to the Senate, which is expected to take it up before July 4th, before it can be signed into law.

Bass said:

"This legislation reflects the bipartisan work of both the House and the Senate to ensure drugs and medical devices are safe and give manufacturers the flexibility they need to produce more successful products for patients.

"I am also very pleased that my Humanitarian Device Reform Act was included in the final package. With a close friend's wife suffering from a rare disease, I know the pain that individuals and families experience as a result of there being no appropriate treatment or cure, and that's why I worked with New Hampshire businesses and stakeholders to craft a bill that will make it easier for medical device manufacturers to develop products that can ease the suffering of these patients.

"This legislation is a win-win for patients, medical device manufacturers, and job creators, and I urge the Senate to pass the final conference report without delay."

Specifically, Bass' measure (H.R. 3211), which was included in the final conference report for the FDA user fee bill, would repeal the outdated profit cap on Humanitarian Use Devices (HUDs), which are innovative medical devices used to treat rare diseases.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.

Video of Bass' floor speech in support of the legislation can be found here .

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