West Wireless Health Institute Applauds House Passage of Bill to Streamline FDA Medical Device Approval Process, Expedite Mobile Medical App Guidance

The Associated Press

The West Wireless Health Institute (WWHI) today applauded the U.S. House of Representatives for passing legislation that ensures patients will have timely access to safe medical devices at reduced costs.

(Logo: http://photos.prnewswire.com/prnh/20120606/DC19778LOGO) Currently, the FDA's de novo process forces manufacturers of low-risk medical devices to submit a 510(k) application, complete a standard review, and obtain a "Not Substantially Equivalent" finding before they can submit a request to have the device reclassified from Class III into Class I or II. This results in rare use of the de novo process and unnecessarily delays the ability of industry to get innovative technology into the hands of patients at lower costs. WWHI worked with California Representatives Brian Bilbray and Lois Capps to improve this process as part of the "Food and Drug Safety and Innovation Act" (H.R. 5651).

"We commend Representatives Bilbray and Capps for their leadership in ensuring that new, innovative, low- to moderate-risk devices will reach patients more quickly by streamlining the FDA approval process," said Dr. Joseph Smith, Chief Medical and Science Officer of the West Wireless Health Institute. "Common sense policies create clear regulatory pathways and expedite the entry of new technologies into the health care system to lower the cost of care. Many wireless devices lack predicates so the de novo reform is particularly helpful for them, and more importantly, it benefits patients with timely access to new medical devices." Last fall, the WWHI President testified before the House Energy and Commerce Committee on the importance of streamlining FDA's de novo approval process. Those recommendations were later incorporated into the legislation offered by Reps. Bilbray and Capps and passed as part of the FDA bill today. The legislation also clears the way for the FDA to issue mobile medical app guidance, rather than place a moratorium on FDA guidance exempting most mobile apps, smartphones, and distributors from excessive testing requirements. "Mobile apps have revolutionized countless industries by putting the power of complex technologies into consumers' hands, yet regulators haven't issued clear guidance on the medical use of apps," said Smith.

"Providing expedited guidance and a clear pathway for mobile medical apps will get low-cost solutions like these into the hands of patients without needless delay." ABOUT THE WEST WIRELESS HEALTH INSTITUTE The West Wireless Health Institute (www.westwirelesshealth.org) is the only medical research organization in the world focused on lowering health care costs through technology and innovation. The

Institute was founded in 2009 by the Gary and Mary West Foundation, and is based in San Diego, California, the global center for health care innovation.

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