Biopharmaceutical and Medical Device Associations Strongly Support Senate Bill to Exempt FDA User Fees from Sequestration

Business Wire

Today, Sen. Mark Pryor (D-AR), chairman of the Senate Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies, and Sens. Roy Blunt (R-MO), Daniel Coats (R-IN), Al Franken (D-MN), and Jerry Moran (R-KS) introduced S. 1413 to exempt future Food and Drug Administration (FDA) user fees from sequestration. A similar bill, H.R. 2725, was introduced in the U.S. House of Representatives earlier this month by Representatives Leonard Lance (R-NJ), Anna Eshoo (D-CA), Mike Rogers (R-MI) and Doris Matsui (D-CA).

The Advanced Medical Technology Association (AdvaMed), Biotechnology Industry Organization (BIO), Generic Pharmaceutical Association (GPhA), Medical Imaging & Technology Alliance (MITA) and Pharmaceutical Research and Manufacturers of America (PhRMA), trade associations representing biopharmaceutical and medical device companies, praised Sens. Pryor, Blunt, Coats, Franken, and Moran for their efforts to prevent the sequestration of future FDA user fees and urged Congress to find a bipartisan solution for releasing sequestered FY13 user fees as Congress continues its work on the FY14 appropriations process.

“Our member companies make the medicines and technologies that diagnose and treat thousands of conditions, ranging from cancer to HIV/AIDS to heart disease to diabetes. Bringing novel and generic medicines, medical devices and diagnostics to patients requires a sufficiently-funded FDA that has the resources required to keep pace with scientific advances.

“Last year, Congress passed the FDA Safety and Innovation Act (FDASIA), which reauthorized the Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee Act (MDUFA), and created the Generic Drug User Fee Act (GDUFA) and Biosimilar User Fee Act (BsUFA). User fee levels were increased to provide much-needed improvements to the regulatory review processes at FDA in order to facilitate timely patient access to safe and effective new and generic medicines, medical devices and diagnostics.

“However, sequestration is preventing FDA from accessing nearly $83 million in industry-paid user fees in the current fiscal year. These user fees cannot, by law, be used for any other purpose and their sequestration does not decrease the nation’s deficit. Preventing FDA from fully accessing these user fees only serves to exacerbate the severe budgetary constraints of a historically underfunded agency, to the detriment of patients and public health.

“We call on the Congress to quickly consider and pass this important legislation and

to continue to work to release the user fees from FY2013 which have been sequestered.”

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