Background

Congress reauthorized the Food and Drug Administration’s (FDA) authority to collect medical device user fees in July 2012 (PL 112-144, the “Food and Drug Administration Safety and Innovation Act” or FDASIA). This is the third authorization in the history of the medical device user fee program, originally enacted in 2002.

Industry and FDA negotiators met for over a year to come to terms on a new user fee package. These negotiations resulted in an agreement which Congress included in the reauthorization. In addition to the underlying user fee agreement, a number of legislative proposals were included with the goal of improving the FDA’s operations. Taken together, the user fee agreement and the accompanying legislative reforms hold the potential to improve consistency and predictability in the device review process, and to maximize the opportunity for success at the agency. This result is a good one for patients, industry and the FDA.

At the same time, although a good user fee agreement and legislative reforms may be important conditions for improving FDA performance, success will depend on whether the agency is appropriately funded and able to access the user fees provided by industry.

The Impact of Sequestration

The across-the-board automatic sequestration cuts that went into effect on March 1, 2013 reduced FDA’s budget by approximately $209 million for FY13. The cuts applied not just to FDA’s standard appropriated dollars but also to the agency’s ability to use the fees it collects from companies submitting applications for review and approval of medical devices. For FY13, FDA was unable to access approximately $2.85 million in medical device user fees.

Fortunately, the Omnibus Appropriations legislation passed in January 2014 retroactively restored these sequestered user fees to FDA, and due to the Murray-Ryan underlying budget agreement, there were no sequestration cuts for FY14 or FY15.

However, going forward into FY16 and beyond, additional medical device user fees are at risk since sequestration cuts could come into effect once more. This situation requires a permanent fix. Industry and FDA cannot negotiate the next user fee agreement (negotiations are expected to begin at the start of FY16) under a cloud of sequestration uncertainty. Industry needs certainty that 100 percent of industry-paid user fees will reach FDA, and FDA needs certainty in how much of the user fees they will receive in order to commit to the goals that underlie the agreement.
User fees are fundamentally different from appropriated funding. They are not taxpayer funds, but rather voluntary fees paid by industry for its own regulation. These fees are designed to ensure that FDA can conduct timely reviews of medical devices that are intended to improve patient health. Subjecting user fees to sequestration cuts makes almost no impact on reducing the deficit, but barring FDA from using these funds does damage the agency’s ability to perform.

If user fees continue to be subject to sequestration cuts, the real losers are American patients. An inefficient device review process means innovative products get to market more slowly, harming the ability of physicians and health care providers to use them in patients who need medical technology the most.

Legislation has been introduced to correct this situation. H.R.1078, the “Food and Drug Administration Safety Over Sequestration Act of 2015” (Reps. Lance and Eshoo) will ensure that FDA receives 100 percent of industry-paid user fees.