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Senate passes legislation to ensure no halt in FDA reviews

August 3 2017, by Kevin Freking

Drug and medical device makers would pay higher user fees under legislation the Senate approved and sent to the president on Thursday. The revenue raised would help pay for the government reviews required to bring their products to the market.

Senate Majority Leader Mitch McConnell, R-Ky., said the bill's passage will ensure the review of medical devices and medicine won't come to a screeching halt in a few weeks. The current law governing these fees expires Sept. 30.

The legislation cleared the Senate on a vote of 94-1. The bill also includes measures to help an array of patient groups around the country such as children with cancer and people with hearing problems.

The legislation rejects the Trump administration's recommendation to fund FDA reviews entirely through user fees. Doing so would have upended several months' worth of negotiations over the fees, which will generate between $8 billion and $9 billion over five years. The administration had argued that "in an era of renewed fiscal restraint, industries that benefit directly from FDA's work should pay for it."

The House approved the bill last month. It is one of the final measures the Senate planned to consider before lawmakers leave Washington for their August recess.

The legislation covers much more than user fees. In a bid to improve

treatment options for children in cancer, the bill requires companies developing cancer drugs for adults to also study their suitability for children when there is an indication it could help kids as well.

Patient groups say there is little market incentive for the pharmaceutical industry to develop pediatric oncology drugs because the population is small compared to the adult population. Most drugs used for pediatric cancer were specifically approved for adults, and the advocacy group Kids v Cancer reports that there are almost 900 drugs in the adult cancer pipeline, but only a handful in development for children.

The bill also instructs the FDA to revise its regulations to establish a category of hearing aids that could be sold without a prescription. The idea behind the change is to give people with mild to moderate hearing loss greater access to hearing aids in the same way that people can buy reading glasses. Supporters said the measure will drive down the cost of hearing aids.

The lone "no" vote came from Vermont Sen. Bernie Sanders.

Sen. Ron Johnson, R-Wisc., lifted objections to taking up the bill after securing a vote for separate legislation aimed at allowing terminally ill patients to get investigational medical treatments where no alternative exists. Johnson's legislation also passed the Senate on Thursday.

While the FDA user fee bill had widespread support, the Project on Government Oversight, a watchdog group, said Congress should rethink a system that leaves the FDA so beholden to industry for funding and the terms of the funding.