

# House OKs bill bolstering medical research, drug approvals

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The House easily approved a sweeping biomedical bill Wednesday that would help drug and medical device companies win swifter government approval of their products, boost disease research and drug-abuse spending and revamp federal mental health programs.

The compromise, which envisions spending \$6.3 billion over the next decade, was condemned by consumer groups and some Democrats as a present to drugmakers that promised only paltry spending increases for underfunded federal programs.

But their objections were overwhelmed by an alliance among Republicans, many Democrats and the White House for a 996-page measure that bore wins for both parties. The Senate's expected final approval next week would mark an uncommon episode of cooperation between the GOP-run 114th Congress—which plans to adjourn next week—and President Barack Obama in their dwindling days in office.

The vote was 392-26.

"We are on the cusp of something special, a once-in-a-generation opportunity to transform how we treat disease," said Rep. Fred Upton, R-Mich., chairman of the House Energy and Commerce Committee and an author of the legislation.

Not everyone agreed.

Rep. Rose DeLauro, D-Conn., said that while the bill contained "noble goals that I share," its relaxation of some standards for federal drug approvals was dangerous and "neglects the very people clinical trials are meant to help, that is the patients."

No. 2 Senate Democratic leader Richard Durbin of Illinois said he was "totally underwhelmed" by the bill's extra money, and said its cuts in a disease prevention fund created under Obama's health care law to finance new medical research displayed "a warped sense of justice."

But Democratic hopes—and leverage—for winning more money and consumer protections faded with Republican Donald Trump's presidential election triumph. Senate Majority Leader Mitch McConnell, R-Ky., flatly said his chamber will send the measure to Obama, and Durbin said he expected Senate passage.

In a written statement, White House spokesman Josh Earnest said the bill "is not perfect" but contains "advances in health that far outweigh these concerns." He said the Senate should approve it quickly.

The bill includes an additional \$4.8 billion over the next 10 years for the National Institutes of Health. The medical research agency spends around \$32 billion annually, and supporters complain that spending cuts imposed by Congress and rising research costs mean its budget has eroded in value since the early 2000s.

"A couple billion dollars doesn't go very far in cancer research" over 10 years, said Lisa Plymate, a director of the liberal-leaning National Physicians Alliance.

Much of the NIH money would be for Obama's precision medicine initiative, aimed at tailoring drugs for people's genes and lifestyles, and research on cancer, a focus of Vice President Joe Biden, whose son Beau

died of the disease in 2015.

The bill would also sharpen the federal focus on mental health efforts, such as creating new posts for government officials who would coordinate such initiatives. But it has little new money for those programs.

"We didn't get everything we needed," said Rep. Tim Murphy, R-Pa., sponsor of those provisions. "We'll keep pushing that."

The measure included funds and an accelerated Food and Drug Administration approval process for techniques aimed at regenerating cells. McConnell has supported those provisions, but critics have condemned the treatments as ineffective.

The Food and Drug Administration would get \$500 million to streamline approval processes for drugs and medical devices. States would get \$1 billion over the next two years for preventing and treating abuse of addictive drugs like opioids, a problem that is surging in GOP and Democratic represented communities around the country.

"The No. 1 thing we can do right now is to make sure we're dedicating resources to expand access to treatment all across the country," Michael Botticelli, director of the White House's Office of National Drug Control Policy, said in a conference call with reporters.

Democrats and consumer groups were upset with the bill's streamlining of some Food and Drug Administration processes, including making it easier for companies to win approval for some antibiotic drugs, some medical devices considered breakthroughs and for fresh uses of some existing medicines.

Rep. Frank Pallone of New Jersey, top Democrat on the Energy and

Commerce panel, acknowledged Democrats' complaints that it would take future legislation to actually provide the money the bill promises. He said he would pressure Republicans to approve the funds and said of the overall measure, "The benefits outweigh my concerns."

The bill was backed by scores of patient groups and industry organizations including PhRMA, representing leading pharmaceutical firms and AdvaMed, the trade association for device makers.

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