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Biomedical research bill becomes law, but critics raise concerns over long-term implementation

Susan Jaffe

The overwhelming support for the law marks a stark contrast from the Affordable Care Act, another landmark health reform bill Obama signed in the second year of his presidency. Republicans promise to repeal it as soon as the new Congress convenes next month and Donald Trump is sworn in as president. But before the promised elimination of the ACA, Congress took \$3.5 billion from its Prevention and Public Health Fund to pay for most of the new law.

The Cures Act passed with approval from 87 percent of the House of Representatives and 94 percent of the Senate. The vote came within a month of what many Americans consider one of the most unprecedented and divisive presidential elections in US history.

"This bipartisan law is a Christmas miracle," said Sen. Lamar Alexander, a Tennessee Republican and the chairman of the Senate's health committee, in an op-ed this week.

The law "shows the government at its best," said Vice President Joe Biden at the White House signing ceremony. "And it shows that our politics can still come together to do big, consequential things for the American people." Obama appointed Biden to head his **Cancer Moon Shot** initiative to find ways to speed up cancer research, prevention, and cures.

"I believe that the United States of America should be the country that ends cancer once and for all," Obama said before signing the law. "This bill will bring us even closer, investing in promising new therapies, developing vaccines, and improving cancer detection and prevention. Ultimately, it will help us reach our goal of getting a decade's worth of research in half the time."

Among the few dissenting lawmakers, was Sen. Elizabeth Warren, the progressive Massachusetts Democrat who argued that the bill would weaken oversight of pharmaceutical companies. "I will fight it because I know the difference between compromise and extortion," she said shortly before the Senate voted last week.

Dr Michael Carome, director of Public Citizen's Health Research Group, a consumer advocacy group, said the law could weaken the standards of evidence for drugs seeking FDA approval for new indications other than their original approved use. However, the Pharmaceutical Research and Manufacturers of America, which represents many of the leading US biopharmaceutical research companies, said the law's "pro-patient, science-based reforms" would promote competition and "the timely review and approval of new treatments."



President Barack Obama signs the 21st Century Cures Act, Tuesday, December 13, 2016

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Connecticut Representative Rosa DeLauro, a Democrat, also criticized the bill because it failed to deal with the "excessive prices" of prescription drugs. And she is concerned that there is no guarantee that the Cures Act will get the money Congress promised.

The law gives the \$4.8 billion to the National Institutes of Health over a ten-year period for Obama's cancer, precision medicine and brain research initiatives. Another \$500 million goes to the Food and Drug Administration, also spread out over a decade, and \$1 billion will help state programs to treat opioid abuse. However, Congress must approve the funds every year before they can be spent.

Representative Diana DeGette, a Colorado Democrat who attended the bill signing is confident the money will be provided. She said there is a strong bipartisan commitment in Congress for the biomedical research the law targets. As a member of the House of Representatives Energy and Commerce Committee, she worked closely with the Republican chairman, Fred Upton of Michigan, for over three years to secure that support.

But some health advocates worry that as Congress faces mounting budget pressures in the next ten years, lawmakers could be tempted to use the Cures Act money to justify keeping NIH's overall funding stagnant, or even make cuts. "It is going to be hard to find money to increase NIH's base discretionary budget," said Emily Holubowich, executive director of the Coalition for Health Funding, which includes health-care provider, patient advocacy, public health, and scientist groups. "This new cures fund gives them a little bit more of an excuse to say we're going to hold NIH flat because there are other priorities that need to be funded."

This post was updated on December 16, 2016.