21st Century Cures Act includes intiatives to boost mental, physical health.

WEDNESDAY, Dec. 7, 2016 (HealthDay News) -- The U.S. Congress has passed sweeping bipartisan health care legislation intended to expand medical research and speed up approval of new drugs and medical devices.

The $6.3 billion bill, called the 21st Century Cures Act, is a complex grab bag of initiatives amounting to nearly 1,000 pages that President Barack Obama is expected to sign into law.

In a statement released Wednesday, Obama signaled his support for the bill.

"We are now one step closer to ending cancer as we know it, unlocking cures for diseases like Alzheimer's, and helping people seeking treatment for opioid addiction finally get the help they need," he said. "This bill will make a big difference, and I look forward to signing it as soon as it reaches my desk."

The Senate passed the bill today by a vote of 94-5, and the House passed an almost identical version on Dec. 1, at 392-26.

The bill contains $4.8 billion in spending over 10 years for new research at the National Institutes of Health, including:

- $1.8 billion for the cancer research "moonshot" championed by Vice President Joe Biden.
- $1.56 billion for the BRAIN Initiative, a project to create new technologies that will allow for comprehensive mapping of the human brain.
- $1.4 billion for the Precision Medicine Initiative, a project supported by Obama to collect genetic data on one million American volunteers that will be used to help develop new treatments.

The bill authorizes the NIH to finance high-risk, high-reward research using special procurement procedures, rather than through conventional grants and contracts, *The New York Times* reports. The agency also will establish "Eureka prize" competitions to advance medical research.

The nation's prescription drug abuse crisis also is addressed in the legislation. States will receive grants worth $1 billion over the next two years for drug abuse prevention and treatment programs.

New positions at the U.S. Department of Health and Human Services will be established to coordinate mental health and substance abuse research and treatment.

A number of provisions in the 21st Century Cures Act also are aimed at swift approval of new drugs and devices. These would allow the U.S. Food and Drug Administration to:

- Rely on data summaries and "real world evidence" instead of hard clinical trial evidence when weighing the approval of existing drugs for new uses. Right now, for example, the FDA now must consider "patient experience" and anecdotal data in its review process.
- Use a "limited population" approval pathway for new antibiotics that would rely on a risk-benefit analysis weighing the needs of patients facing severe and untreatable infections against the possible harms to them.
- Expand its programs for expedited approval of breakthrough medical technologies for patients with life-threatening diseases that have limited treatment options.

Many have applauded the new measures, but critics say these the moves could raise the risk of harmful treatments getting to the marketplace.

"The FDA over all these decades has developed a way to know what products work and which ones don't, but in the last decade they have been pushed to lower those standards," Diana Zuckerman, president of the National Center for Health Research, told *U.S. News & World Report*. "With this bill, they'd lower them even more."

Other provisions strengthen privacy protections for genetic research participants; promote more pediatric research; improve the usability of electronic health records; and strengthen the FDA's ability to hire, train and retain experienced staff scientists.
Many medical associations and advocacy groups have praised the action by Congress, including the American Society for Clinical Oncology, the American Society of Human Genetics, the Coalition to Stop Opioid Overdose, the American Psychological Association, the American Psychiatric Association and the American Heart Association.

"This landmark legislation will spur development and delivery of promising new treatments for patients," ASCO President Dr. Daniel Hayes said in a statement. "Recognizing the tremendous effort and dedication that went into advancing this legislation, we're thrilled the bill will soon be headed to President Obama for his signature."

But watchdog group Public Citizen decried the law, claiming it gives too much leeway to pharmaceutical and medical device makers.

"It is sorely disappointing that Congress gave Big Pharma and the medical device industry an early Christmas present by passing the 21st Century Cures Act," said Dr. Michael Carome, director of the organization's Health Research Group.

"This gift -- which 1,300 lobbyists, mostly from pharmaceutical companies, helped sell -- comes at the expense of patient safety by undermining requirements for ensuring safe and effective medications and medical devices," Carome said in a statement.

More information
Details on the 21st Century Cures Act can be found at the website of the U.S. Congress.
SOURCES: Dec. 7, 2016, news releases from: The White House; American Society of Clinical Oncology (ASCO); Public Citizen; *The New York Times*; *U.S. News and World Report*