

U.S. Senate Confirms Dr. Robert Califf to Lead FDA

The agency will be tackling thorny topics including food safety, biologic drugs and how to regulate e-cigarettes



By Reuters Staff

WASHINGTON (Reuters) - The U.S. Senate voted overwhelmingly on Wednesday to confirm Dr. Robert Califf as head of the Food and Drug Administration, an agency that regulates everything from food and drugs to tobacco, cosmetics and dietary supplements.

Califf, 64, a well-regarded cardiologist and researcher, takes the helm at the FDA when lawmakers are pressuring the agency to speed the approval process for drugs and medical devices and finalize a proposed rule giving it authority to regulate e-cigarettes.

The FDA is also attempting to implement sweeping new regulations to improve food safety and has begun to tackle the approval process for biosimilars, which are cheaper versions of biologic drugs.

The U.S. House of Representatives recently passed the 21st Century Cures Act, which would require the FDA to consider more flexible forms of clinical trials. The Senate is considering a similar bill.

The rate of new drug approvals at the FDA is higher than it has been in decades. Last year the agency approved 45 new drugs, the most since 1996. From 2006 through 2014 it has averaged about 28 new drug approvals per year.

Lawmakers and patient groups want the FDA to move even faster. Califf has worked on many high-profile clinical studies and has said he is eager to make the clinical trial process more efficient.

Four senators, including Democrat Edward Markey of Massachusetts and Joe Manchin of West Virginia, opposed Califf's nomination. They took the opportunity leading up to the vote to lambaste the FDA for what they said was a lax approach to approving potentially addictive opioid painkillers.

Democratic presidential candidate Bernie Sanders was also among the senators who opposed the nomination, saying Califf's ties to the pharmaceutical industry made him unfit to regulate it impartially.

Califf joined the FDA as a deputy commissioner a year ago. Previously he held senior positions at Duke University, where he founded a large academic research center that received more than half its funding from the drug industry. He has said the funding never compromised his research.

Califf's confirmation was widely expected. He fills the position left by Dr. Margaret Hamburg, who stepped down after six years as commissioner. Dr. Stephen Ostroff has filled the post on an interim basis.