Dr. Robert M. Califf was approved by the Senate on Wednesday to be the commissioner of the F.D.A. Credit: Win Mcnamee/Getty Images

WASHINGTON — President Obama’s pick to run the Food and Drug Administration, Dr. Robert M. Califf, was finally confirmed for the job by the Senate on Wednesday, in a vote of 89 to 4, after weeks of opposition from a handful of lawmakers who had blocked his nomination over what they said was the agency’s poor record on prescription painkillers.

An epidemic of abuse of painkillers has swept the United States, with deaths from overdose of prescription opioids quadrupling since the late 1990s. Some senators used the opportunity presented by Dr. Califf’s nomination to question the F.D.A., the agency in charge of approving the drugs. In speeches on the Senate floor over several days this week, they appealed to their colleagues to vote against Dr. Califf, arguing the agency he had been tapped to run had approved too many of the opioid drugs and had ignored the advice of its own expert panels, which have occasionally recommended against approval.

“F.D.A. stands for Food and Drug Administration, but over the last 20 years it really stands for ‘fostering drug addiction,’ ” Senator Edward J. Markey, Democrat of Massachusetts, said in a speech on the Senate floor on Tuesday. “We have to have an honest discussion about the role that agency is playing.”

He added: “It is not really a debate over Dr. Califf at all. This a debate over the agency.”

In response, Kevin Griffis, a spokesman for the Department of Health and Human Services, which includes the F.D.A., said in an email: “The F.D.A. takes seriously its role in combating the opioid epidemic. Earlier this month, the F.D.A. launched a far-reaching plan that leverages its science-based approach, focusing on policies aimed at reversing the epidemic. As part of this effort, during the approval process, the agency..."
plans to re-examine the risk-benefit paradigm for opioids to ensure that it considers their wider public health effects.”

Dr. Califf, a cardiologist and clinical researcher from Duke University, was not expected to encounter much opposition. That he did is evidence of the growing frustration with the prescription drug epidemic and the increasingly urgent debate in states over what to do about it. This weekend, the National Governors Association said it would devise treatment protocols to reduce the use of opioids that were likely to include numerical limits on prescriptions.

In addition to Mr. Markey, Senators Joe Manchin III, Democrat of West Virginia; Kelly Ayotte, Republican of New Hampshire; and Richard Blumenthal, Democrat of Connecticut, gave impassioned speeches on the topic, urging their colleagues to vote against Dr. Califf. Theirs were the four votes against Dr. Califf on Wednesday.

The confirmation process had many surprises. Dr. Califf was nominated by a Democratic president, but encountered his fiercest opposition from Democrats. During hearings before the committee that evaluated him, his strongest support seemed to be among Republicans.

Dr. Califf has been a consultant to drug companies and ran a research institute at Duke that received a majority of its funding from the pharmaceutical industry. Such ties raised concern that he was too close to the industry he was being called on to regulate. Many medical experts countered that the industry was a principal financier of research in the United States and that working with companies did not present an inherent conflict.
Mr. Griffis, the Health and Human Services spokesman, said Dr. Califf’s nomination was being supported by 135 organizations, including the American Heart Association, and cited an endorsement in the New England Journal of Medicine that said Dr. Califf, who has been serving as deputy commissioner of the F.D.A. since March, had a proven record of independence.

As F.D.A. commissioner, Dr. Califf will be steering an agency that regulates about a quarter of every dollar spent in the United States. It is at the center of some of the most difficult health policy questions facing the country. A crucial decision on how to regulate electronic cigarettes is expected soon, and Congress is halfway through a substantial overhaul of the way the agency approves drugs and medical devices.

The F.D.A. has been under fire regarding opioids for some time. Hillary Clinton publicly condemned the agency’s decision last summer to allow prescriptions of OxyContin, a powerful painkiller, to be given to children. Its approval in 2013 of a drug called Zohydro brought public outcry over what critics saw as yet another opioid in a market already flooded with them.

Feeling the pressure, the F.D.A. announced a plan this month that it said would help curb abuse, but critics were skeptical. The measures included convening expert panels before approving some new opioids; strengthening requirements to study a drug after it has come to market; and increasing access to pain management training for doctors and other prescribers.

Mr. Markey said he was not satisfied with the agency’s actions, arguing, for example, that it should convene an outside panel of experts for any new opioid, not only certain ones, and he refused to lift his hold from Dr. Califf’s nomination. But Mr. Markey and the other opposing senators ultimately remained in the minority, and the Senate finally forced a vote.
Center for Tobacco Products

Inaugural Year and Looking Ahead

In 2009 the USA Legislature gives the FDA the power to PROTECT, PRESERVE + SERVE the Tobacco Industry

a Dark Day for Humanity

Presented by
Lawrence R. Dayton, M.S.P.H., M.D.
Director, Center for Tobacco Products

June 29, 2010
There are frauds trying to cheat you.

There are well-intentioned people who hurt you.

There are very rich people trying to own you.

They are lying about things.

Some people need help to provide services to you.

FDA motto: "Protecting and Promoting Your Health."

---Why We Need Regulations---

A True History of the FDA

By Laura Jensen, M.D.  Prof. of Medicine Emeritus, D. Sc., F.C.C.

There clearly are frauds and charlatans plotting and scheming to get money from people selling deceit. And in health care people get desperate or they are gullible and become easy targets.

There are some well-intentioned dim-witted people making remedies and devices for sale to the people. And these people need control, rules and regulations to protect the people.

There are very rich people who try to push remedies and devices onto people without proper control and validation of their sales claims. The extreme gravity of this story will really AMAZE you. REALLY!!

Addiction SUBSTANCE

A state in which an organism engages in a compulsive behavior

- behavior is reinforcing (rewarding or pleasurable) BUT the substance is destructive and unhealthy

- loss of control in limiting intake

We Must Stop Prescription Drug Addiction

Medical EXPOSE

http://www.medicalexpose.com/