# New FDA official inherits raft of projects, challenges

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One of the nation's leading medical researchers joined the Food and Drug Administration on Monday, taking on the agency's No. 2 leadership job at a critical juncture for prescription drugs, medical devices and tobacco products.

Dr. Robert Califf comes to the job of FDA deputy commissioner after more than 30 years as a researcher and administrator at Duke University. But Califf, 63, is no stranger to FDA issues. For years he served on committees that advise the FDA on scientific and medical matters. And he was considered for the agency's top job at least twice, under the administrations of Presidents George W. Bush and Barack Obama.

The timing of his appointment has raised speculation that he may eventually be nominated to lead the agency. The week after announcing Califf's new position, FDA Commissioner Margaret Hamburg said she would be leaving the agency after nearly six years on the job. Currently, the FDA's chief scientist is serving as acting head of the agency.

A leading expert in cardiology and medical study design, FDA watchers say Califf would be a natural fit for the job.

"In terms of running clinical trials, there's nobody better in cardiovascular medicine than Rob Califf," says Ira Loss, an industry analyst. "So why not put the best guy out there in charge?"

Regardless of his job title, Califf will inherit a raft of projects and

potential challenges, including unfinished tobacco regulations and proposals from Republican lawmakers focused on streamlining product reviews. Here's a look at what awaits the FDA's newest leader:

REPUBLICAN REFORMS

With oversight of drugs and medical devices, Califf will need to respond to legislation from Congress designed to accelerate approvals for those products. A nearly-400 page draft bill released by House Republicans in January includes dozens of proposals designed to streamline FDA reviews, such as allowing the agency to approve drugs based on early-stage research. Such proposals, backed by industry, could shave years off product development times, boosting company profits.

Califf's work at Duke's Translational Medicine Institute has focused on new approaches to structuring clinical trials. A presentation he delivered last May advocates "disrupting clinical research," suggesting he might be open to some of the proposals for remaking drug and device regulations. But FDA watchers say Califf will need to work with Congress to identify which ideas have scientific merit.

"I think Califf will be good to give the real world opinion to these guys who are listening mostly to industry," said Loss.

STRETCHED BUDGET

Another challenge will be making sure Congress funds whatever new duties it assigns the FDA. For years, FDA scientists have taken on increasing responsibilities with few additional resources. For instance, the FDA is now implementing new regulations for compounding pharmacies, specialty businesses that were previously outside FDA's jurisdiction. Though the additional oversight is expected to cost $25 million, the agency has not received any new funds to carry out this

work.

"It's coming to the point where you can't run the agency anymore if you're getting new responsibilities but without additional funding," said Wayne Pine, a former FDA official who now consults for Apco Worldwide, a public relations firm.

TOBACCO REGULATION

Many of the biggest challenges are still ahead on the agency's efforts to regulate tobacco. The FDA must assess the science for what would best improve public health, but it cannot ban nicotine or cigarettes outright.

While the FDA has made some progress since it was granted authority to regulate the industry in 2009, it has yet to issue final regulations on popular electronic cigarettes, as well as cigars, hookah, nicotine gels, pipe tobacco and dissolvable tobacco.

Last April, the FDA for the first time proposed a set of regulations for e-cigarettes, including banning sales to minors and requiring health warning labels, as well as approving new products. The agency has said its proposal sets a foundation for regulating the products, but the rules wouldn't immediately ban the wide array of flavors or styles of e-cigarettes or curb marketing. There's no timetable for the final rules.

The industry also is awaiting the agency's newest proposals for graphic warning labels for cigarette packs, the first of which were shot down by legal challenges. The FDA also is continuing to evaluate the public health impacts of menthol cigarettes.

The agency faces an April deadline to submit reports to Congress on the public heath impact of raising the minimum tobacco purchase age to over 18, and how well the public understands the health consequences of

using tobacco products. It's also in the middle of evaluating a request by smokeless tobacco maker Swedish Match to certify its General-branded pouches of tobacco as less harmful than cigarettes under the agency's "modified risk" tobacco product application process.