FDA boss rumored to be in line for new post

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The head of the Food and Drug Administration, who has been on the job for a little over a year, appears to be the Bush administration's front-runner to lead the agency that runs Medicare.

Rumors emerged in recent weeks that FDA Commissioner Mark McClellan has been tagged to head the Centers for Medicare and Medicaid Services. Yesterday, the Wall Street Journal, citing anonymous sources, predicted that the appointment is imminent.

The speculation is being met with mixed emotions by many in the drug industry who recall waiting about two years for President Bush to fill the FDA post.

During that leaderless period, drug companies complained bitterly that the lack of FDA leadership resulted in slower approval times for experimental drugs and unexpected rejections of some new drug applications.

"I think his leaving, if it happens, is a concern," said Gary Lyons, chief executive of Neurocrine Biosciences, a San Diego biotech that expects to seek FDA approval for an experimental sleeping pill later this year. "He is just such a strong leader and in a short time has had a great impact.

"The question is what is the succession plan – I just hope a successor will be named more quickly so there is not this big void," Lyons said.

McClellan, who took the FDA job in November 2002, has earned high marks from the pharmaceutical and biotechnology industries for his reorganization of the agency and commitment to speeding drug approval times.

The industry also embraced McClellan for his strong stance against importing low-cost Canadian drugs, which undercut the prices drug companies charge in the U.S. market.

Many patients, consumer activists and state governments have urged the federal government to allow such imports as a means to combat rising prescription drug costs in the United States, which lacks the government price controls other countries impose.

A spokesman for the Biotechnology Industry Organization, the nation’s leading trade association for the biotech industry, said the drug industry has been pleased with the job McClellan has done.

"This is all still speculative, but we hope that if there are any changes at the FDA, that the course McClellan set for the agency continues," said Dan Eramian of BIO.

McClellan, who is both a physician and an economist, is considered a staunch Bush ally who has support among both Republicans and Democrats in Congress.

As head of the Centers for Medicare and Medicaid Services, the agency that reimburses for drugs prescribed to Medicare recipients, McClellan could help smooth the course for implementation of the Medicare drug-benefit bill, some drug industry experts said.

That new Medicare law has come under increasing fire from some policy-makers, consumer activists and Democratic presidential hopefuls, most recently for its shifting price tag.

Last month, the Bush administration said that Congress grossly underestimated the cost of prescription drug benefits and other aspects of the reform, which was signed into law Dec. 8. Before the law was passed by Congress, the Congressional Budget Office estimated it would cost $395 billion in the decade from 2004 to 2013. The White House now puts the cost at $534 billion.

Critics of the plan say a considerable portion of the cost translates into bigger profits for drug companies.

About 60 percent of the Medicare dollars that will be spent to buy more prescriptions will remain in the hands of drug makers as added profits — or about $139 billion over eight years, according to one report released last fall by the Health Reform Program at Boston University’s School of Public Health.

McClellan, who has been accused by some health care consumer groups and others of a too cozy relationship with the drug industry, is unlikely to cause the drug industry much discomfort over reimbursement issues, some critics predict.

"McClellan needs to worry about the health of people whose physicians prescribe drugs that they can't afford, instead of posturing and pontificating about the danger of importing Canadian drugs," said Alan Sager, co-author of the Health Reform report. "He's a transmitter. He'll transmit the political decisions from Congress or the President, but there isn't much willingness or ability there to act independently."

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