

Trump Nominates FDA Head to help get drugs to people earlier

Dr. Scott Gottlieb is a conservative health policy expert with deep ties to the pharmaceutical industry.



WASHINGTON, March 10 (Med Expo) - U.S. President Donald Trump has chosen Dr. Scott Gottlieb, a conservative health policy expert with deep ties to the pharmaceutical industry, to lead the U.S. Food and Drug Administration, a White House official said on Friday.

If confirmed by the Senate, Gottlieb would be in charge of implementing Trump's plan to dramatically cut regulations governing food, drugs, cosmetics, dietary supplements and tobacco.

Gottlieb is well known on Capitol Hill, where he has testified multiple times on hot-button health issues, including complex drug pricing matters, and is viewed favorably by drug companies and pharmaceutical investors. A former FDA official, Gottlieb also sits on the board of pharmaceutical companies.

"Thank God it's Gottlieb," Brian Skorney, an investment analyst at Robert W. Baird, wrote in a research note. "We view this as a favorable development for the sector."

Gottlieb, 44, is a resident fellow at the conservative American Enterprise Institute think tank and a partner at a large venture capital fund. He is a former FDA deputy commissioner who has frequently advocated a loosening of requirements needed for approval of new medical products.

“Scott knows how the agency works and he will move it forwards, though maybe not always in ways the agency is comfortable with,” said John Taylor, a lawyer and president of compliance and regulatory affairs with the consulting firm Greenleaf Health and a former acting FDA deputy commissioner.

Gottlieb was chosen over Jim O’Neill, a libertarian investor close to Silicon Valley billionaire Peter Thiel, a PayPal co-founder who now advises Trump on technology and science matters. O’Neill’s stated view that drugs should be approved before being proven effective generated widespread alarm.

Gottlieb, who declined to comment on the nomination, is unlikely to up-end the FDA in the way O’Neill might have, but he is nonetheless expected to bring significant change, including moving the agency to increase flexibility in the clinical trial development process.



In this he will be supported by the recently passed 21st Century Cures Act which instructs the FDA among other things to consider the use of “real world evidence” to support new drug applications. This could include anecdotal data, observational studies and patient reports

“People don’t want to take chances with safety, but there’s increasingly some clamor to be more flexible on the efficacy side,” said Kathleen Sanzo, who leads the FDA practice at the law firm Morgan, Lewis & Bockius. “You need to have some signal of efficacy. The question is, how much?”

One of Gottlieb’s priorities will likely be to streamline the process for approving generic versions of complex, difficult-to-copy therapeutics. He has stated publicly that he does not believe the FDA has good tools or policies to move such products and has advocated the creation of different approval standards.

A survey conducted by Mizuho Securities USA Inc of 53 pharmaceutical executives found that 72 percent favored Gottlieb over other potential candidates. Many described him as knowledgeable, experienced and balanced.

“He will be a pragmatic leader with an eye toward both expedited approvals and safety,” one executive wrote.

Others were less sanguine, citing his deep ties to industry, including his seat on multiple pharmaceutical company boards, as potential conflicts of interest.

Dr. Michael Carome, director of Public Citizen’s Health Research Group, said Gottlieb “has spent most of his career dedicated to promoting the financial interests of the pharmaceutical industry.” If confirmed, he added, “he will have to be recused from key decisions time and time again.”

CLINICAL TRIAL FLEXIBILITY

The FDA has attempted to push back against moves to sideline randomized clinical trials, long considered the gold standard. In January it issued a report documenting 22 cases in which drugs that appeared to show promise in early trials turned out to be either ineffective or unsafe or both in larger trials.

But it has already moved to decrease the requirements for proving that a drug works.

Last year, Dr. Janet Woodcock, the agency's powerful head of pharmaceuticals, ordered the approval of Sarepta Therapeutics Inc's drug to treat Duchenne muscular dystrophy based on little more than a hint of efficacy.

In doing so she overrode the recommendation of a panel of outside advisors and top scientists at the agency and set what some say is a precedent for approving drugs based on minimal data.

"How can you say it's OK for this company but not that company?" Mark Mansour, a partner with the law firm Mayer Brown LLP said. "The administration is going to be pushing for quicker approval of drugs for all sorts of diseases with similar, vociferous patient populations who are crying out for a solution."

Other companies that may benefit from Gottlieb's presence are manufacturers of electronic nicotine delivery systems such as e-cigarettes. The American Enterprise Institute has consistently argued that there is no evidence to show that the risk of vaping comes near to the risk of smoking. Between 2005 and 2007 he was FDA deputy commissioner for medical and scientific affairs. Previously he was a senior advisor to the commissioner and acted as the agency's director of medical policy development.



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