SCOTT GOTTLIEB

FORMER FDA COMMISSIONER

NationalJournal

Life in Brief

Born: June 11, 1972

Hometown: East Brunswick, NJ

Current Residence: Westport, CT

Education
- MD, New York University
- BA, Economics, Wesleyan University

Family
- Married, Allyson Nemeroff
- 3 Children

Work History
- Resident Fellow, American Enterprise Institute, 2003-2017, 2019-Present
- Partner, New Enterprise Associates (NEA), 2007-2017, 2019-Present
- Commissioner, US Food and Drug Administration, 2017-2019
- Managing Director, T.R. Winston & Company, 2013-2017
- Policy Advisor, FDA, 2003-2007

Professional Affiliations
- Board Member, Pfizer
- Board Member, Illumina
- Board Member, Aetion
- Board Member, Tempus
- Board Member, Leukemia & Lymphoma Society (2012-2014)

Confirmation Hearing
- Confirmed May 9, 2017 with 57-42

Quick Summary

Physician with policy research and investment experience, Gottlieb gained bipartisan support as Trump's FDA Commissioner thanks to tight regulations on tobacco and opioids and supporting biotech innovation. Influential private sector voice who has Administration's ear on public health policy

- Strong supporter of medical innovation; helped implement 21st Century Cures Act to accelerate medical product development and approved the first gene-therapy cancer treatment as FDA Commissioner
- Helped combat high drug prices by accelerating pathways for generic versions of complex drugs to enter the market; currently writes research on lowering costs at think tank AEI
- Involved with new drug development and advises pharmaceutical and biotech companies on how to navigate regulations as partner of venture capital firm NEA
- Balancing policy regulations and entrepreneurship, Gottlieb is invested in pharma and biotech while also writing policy research to lower drug costs
- Strives to be overly transparent, frequently releases statements and is regular contributor on cable news; avid Twitter user and responds to current public health and pharma industry news

Approach and Motivations

Balances safety concerns with pushing for responsible health care innovations

- Cancer survivor whose treatment experience further demonstrated the importance of American health care system and the FDA
- Strives to balance desire for certainty when approving new drugs with the need to promote innovation by releasing new treatments
- Background in economics and experience in investment banking help inform regulatory practices and understanding of the costs of research and development

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Policy Positions and Areas of Focus

Heavy focus on fostering innovation while combatting misuse and surging prices

Curbing Addiction: *Tightened regulations on tobacco industry and opioids*

- Worked to strictly regulate availability of e-cigarettes; banned flavored pods to limit teen use
- Introduced regulations to reduce tobacco levels in combustible cigarettes to nonaddictive levels
- First Major move at FDA was withdrawing Opana ER, an opioid by Endo, from the market after it was linked to misuse
- Issued guidance to further develop anti-addiction medications and admonished insurers for not covering current available drugs

Drug prices: *Introducing more generics* to *compete with high cost patent-protected drugs*

- Believes the best way for the FDA to lower drug prices is by promoting available competition
- Worked to decrease time for generics to enter market by streamlining biosimilar approvals and ensuring manufacturers of generics can access samples of branded drugs
- Critical of Trump's International Pricing Index, claims it would be difficult to implement and easy for drug companies to manipulate
- Pushed for reclassification of insulin that would take effect in 2020 that would allow biosimilars to enter the market faster and help lower costs
- After leaving FDA, Gottlieb returned to think tank AEI to study affordable solutions to innovative treatments, including gene therapies

Biotech: *Sees gene therapy and medical devices as the future of health care*

- Invests in gene therapy and biopharma companies as partner of NEA
- As FDA director, pushed to make new regulations and approval process for new treatments like gene therapy
- Released a plan for FDA to focus on digital health products after taking office in 2017
- Predicts that 20 new gene and cell therapy treatments will be approved by 2025

Core Communities

Connections to other researchers and top industry officials

Administration Officials: *Worked in Bush 43 and Trump Administrations*

- Worked as senior adviser for medical technology to former Bush 43 FDA Commissioner Dr. Mark B. McClellan; currently working together at AEI
- Partnered with Seema Verma and Patrick Conway at CMS on policies to lower drug prices
- Served on President Trump's White House transition team; worked closely on HHS transition with Eric Hargan and Nina Owcharenko
- Partnered with HHS Secretary Alex Azar on vaping initiatives

Pharma Executives: *Serves on boards of prominent companies*

- Serves on Pfizer's Regulatory and Compliance and Science and Technology committees
- Director at Illumina, a biotech company working on genetic variation and biological function analysis
- Board member of Tempus, a technology company building a library of clinical and molecular data
- Special Partner at venture capital company NEA, works on health care, devices, biopharma, and services teams; NEA investments include Crisper Therapeutics and Collective Health

Leading Academics and Researchers: *Co-publishes with other thought leaders*

- Publishes op-ed about public health with Harvard professor Marc Lipsitch
- Partners with Michael Strain, AEI researcher on political economy, to write about intersection of health and economics
- Works with Caitlin Rivers, senior scholar at John Hopkins Center for Health Security, on Coronavirus response recommendations

Relevant Financial Information

Limited campaign contributions; financial disclosures highlight ties to pharma

Political Donations

- Contributes $625 a quarter to Pfizer Inc. PAC since Sept. 2019

Disclosures

- Received over $150,000 in payments to advise Vertex Pharmaceuticals between 2013-2015
- Received over $90,000 in consulting fees from GlaxoSmithKline, LLC in 2014
- Received $200,000 in payments from various pharma companies in 2015, and $150,000 in 2016

Publications, Media, and Speaking

Prominent figure in national media; publishes research for think tanks

Publications: ***Publishes op-eds on innovation in health care***

- Favorite Subjects: Price controls and biotech innovation, biosimilars, COVID-19
- Preferred Outlets: Wall Street Journal

Media: ***Regular contributor for CNBC***

- Preferred Outlets: Squawk Box, Face the Nation, former Forbes contributor
- Favorite Subjects: Opioid crisis, lowering drug prices, COVID-19
- Social Media Habits: Active on Twitter

Speaking: ***Engages with think tanks***

- Favorite Subjects: Regulations, biosimilars, tobacco use, gene therapy
- Preferred Audience: Brookings

Congressional Testimony: ***Testified 19 times while FDA Commissioner***

- Testified before Senate Committee on Health, Education, Labor and Pensions to give updates on FDA policy changes

Family and Personal Background

Close relationship with his family

- Mother worked as a Hebrew teacher and father is a physician and Vietnam War veteran
- Wife, Allyson, formally worked as national advertising director for New York Sun
- Gottlieb has 3 daughters, the oldest two are twins
- When working at FDA, commuted every week from his family home in Connecticut to spend weekends with his family

Criticisms and Controversies

Ties to pharma questioned in confirmation hearings

- Faced criticism due to his connections to medical device and pharma industry; expressed intent to recuse himself for one year from any agency decisions involving the companies with which he was affiliated

COVID-19 Response

Prominent media figure, has been informal advisor to White House Coronavirus Task Force

Actions: ***Publishes recommendations for government officials***

- Reopening recommendations include slowing opening up by region, increasing testing capabilities, reserve health care capacity, and implement contact tracing
- Co-authored guidance for governors for reopening during COVID-19 with other public health officials through the John Hopkins School of Public Health
- Published recommendations for a national COVID-19 surveillance system to achieve containment; coauthors include Mark McClellan, Farzad Mostashari, Caitlin Rivers, and Lauren Silvis
- Published op-eds in Wall Street Journal on recommendations for keeping workers safe as people return to work and how employers will need to ramp up testing for employees

Messaging: ***Reliable expert on cable news***

- Frequently appears on Squawk Box and other CNBC programming to discuss COVID-19 response
- Frequently draws on his medical experience to answer questions around safety precautions and how the virus spreads
- Emphasizes the need for more and better testing to help control and reduce the virus spread
- Follows conservative estimates from other public health officials; has spoken out against Trump officials when messaging contradicts public health recommendations