Scott Gottlieb

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Scott Gottlieb is an American physician who serves as commissioner of the Food & Drug Administration.[1][2][3][4] Prior to assuming his current position, he was a clinical assistant professor at New York University School of Medicine, a resident fellow at the conservative think tank the American Enterprise Institute, and an internist at Tisch Hospital.[5]

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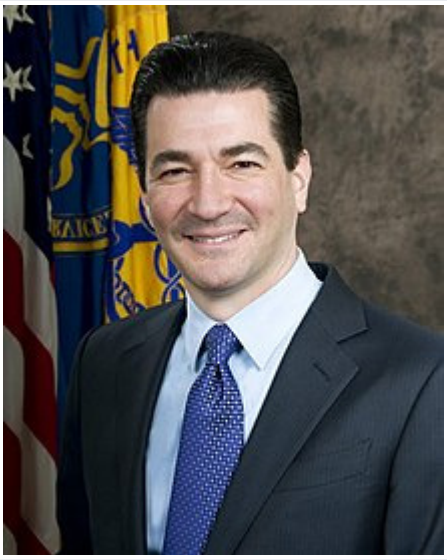

Commissioner of Food and Drugs	
Incumbent	
Assumed office	
May 11, 2017	
President	Donald Trump
Preceded by	Robert Califf
Deputy Commissioner of Food and Drugs	
In office	
2005–2007	
President	George W. Bush
Personal details	
Education	Wesleyan University Mount Sinai School of Medicine

Early life and education

Gottlieb grew up in East Brunswick, New Jersey, the son of Stanley, who is a psychiatrist, and Marsha Gottlieb.[6] He received his bachelor's degree in economics from Wesleyan University. After completing his undergraduate education, he worked as a healthcare analyst at the investment bank Alex. Brown & Sons in Baltimore. Gottlieb attended medical school at Mount Sinai School of Medicine and completed his residency in internal medicine at the Mount Sinai Hospital. He was married in a Jewish wedding ceremony.[7]

U.S. government work

Gottlieb has worked in multiple roles for the federal government of the United States, including as Deputy Commissioner for Medical and Scientific Affairs at the U.S. Food and Drug Administration (FDA), in which capacity he served from 2005 to 2007.[8] He helped initiate the early development of the FDA's generic drug user fee program and the agency's release of the Physician Labeling Rule. He also worked on development of the FDA's policies related to the tentative approval of fixed dose combination drugs for the treatment of HIV/AIDS under the PEPFAR program. He was appointed to the Senior Executive Service and granted a top secret security clearance during his appointment as the FDA's Deputy Commissioner for Medical and Scientific

Affairs. He was also a a member of the White House Biodefense Interagency Working Group, which was convened after the September 11 attacks to help draft a strategic plan for the development of U.S. biodefense countermeasures. While working for the FDA, Gottlieb had to recuse himself from working on planning for a possible bird flu because he had done consulting work for companies whose products may be used to combat the bird flu.[9] Before becoming the FDA's Deputy Commissioner, Gottlieb served as a senior advisor to the FDA Commissioner and as the FDA's Director of Medical Policy Development.[10] While Commissioner of FDA, Gottlieb has advanced initiatives on addressing drug pricing[11] "in ways that the agency hasn't done before" according to the Wall Street Journal.[12] He also committed to make fighting the crisis of opioid addiction one of his highest priorities as Commissioner.[13] Under Gottlieb's leadership, "The FDA stirred up a hornet's nest with an unprecedented request to Endo International plc to remove voluntarily its opioid pain medication, a tamper-resistant reformulation of Opana ER (oxymorphone hydrochloride), from the market."[14]

In 2013, Gottlieb was appointed by the Senate Minority Leader Mitch McConnell to serve as a member of the Federal Health IT Policy Committee which advises the U.S. Department of Health and Human Services and is responsible for making recommendations on the meaningful use standards as part of the HITECH Act.[15] He has testified as an expert witness before committees of the United States House of Representatives and the United States Senate on issues related to FDA regulation,[16] healthcare reform,[17] and medical innovation.[18] Gottlieb is on the editorial board of the Food and Drug Law Institute's publication Food and Drug Policy Forum.[10][19]

Nomination and confirmation as FDA Commissioner

In 2016, members of President-elect Donald Trump's transition team said Trump was considering Gottlieb to head the FDA as its Commissioner.[20] Gottlieb worked as an advisor to, and then a member of Trump's transition starting in the summer of 2016. He was previously a senior advisor to the 2016 presidential campaign of Wisconsin Governor Scott Walker.[21] In early March 2017, news of the nomination plan emerged.[2]

In advance of confirmation, Gottlieb expressed his intention to recuse himself "for one year from any agency decisions involving about 20 health care companies he worked with" under an ethics agreement, including such companies as Vertex Pharmaceuticals, Cell Biotherapy, GSK, Bristol-Myers Squibb,[22] New Enterprise, TR Winston, MedAvante and Glytec.[23] The nominee testified before Committee on Health, Education, Labor and Pensions (HELP).[24] There, Gottlieb equated the spread of opioid addiction with the previous epidemics of Ebola and Zika virus.[25][26] Supporting the nominee and addressing the opioid crisis on the Senate floor before the confirmation vote, Majority Leader Mitch McConnell said in part, "I'm sure he'll be an ally to states that continue to struggle" with the crisis "because the FDA has a critical role to play." *Politico* also assessed that, among other expectations and possible positions, Gottlieb is "expected to push the boundaries of FDA reviews and using new authority" to streamline approvals using the 21st Century Cures Act.[27] On May 9, 2017, Gottlieb was confirmed by the Senate[23] by a vote of 57-42.[28]

On July 28, 2017, Gottlieb delayed application deadlines on the newly deemed tobacco products, including premium cigars and electronic cigarettes, and announced that FDA would take steps to regulate nicotine levels in combustible cigarettes to render the combustible cigarettes "minimally or non-addictive,"[29] causing shares of tobacco company Altria that day to initially decline by 19%.[30] *The New York Times* called the action a "marked departure from the White House's rejection of evidence on climate change and its stated zeal for deregulation," noting that "The Food and Drug Administration is turning out to be the odd agency defying corporate interests."[29] In an editorial, the editors of the *Washington Post* called the action "one of the most important public-health initiatives of the century" and "an ambitious long-term strategy to finally end tobacco's cycle of addiction and death, a scourge that has taken the lives of millions of Americans over centuries of cultivation and consumption."[31]

Other roles

Gottlieb was a member of the Public Policy Committee to the Society of Hospital Medicine,[32] was an adviser to the National Coalition for Cancer Survivorship. He has been a venture partner at New Enterprise Associates since 2007,[19] and was an independent director at Tolero Pharmaceuticals,[33] and Daiichi Sankyo Inc,[34] and a member of GlaxoSmithKline's product investment board.[19] He was a senior healthcare advisor to BDO and also a partner at T.R. Winston, a Los Angeles-based merchant bank with a focus on healthcare.[35]

He has also worked as a senior policy advisor to the Administrator at the Centers for Medicare & Medicaid Services, where he worked on implementation of the Medicare Prescription Drug, Improvement, and Modernization Act and the Medicare Part D drug benefit, and helped advance the agency's coverage policies related to new medical technology.[36] From 2012 to 2014, Gottlieb was on the policy board of the Leukemia and Lymphoma Society.[36] He has served as an advisor to Cancer Commons.[37]

Writing

Gottlieb is a former member of the editorial staff of the *British Medical Journal* (BMJ) and was a member of the editorial board of a section of the *Journal of the American Medical Association* (JAMA) from 1996 to 2001.[38]

He is a regular contributor to the editorial page of the *Wall Street Journal* and writes regularly for *Forbes*.[39] In his various writings, Gottlieb was a frequent and early critic (https://www.wsj.com/articles/SB124208383695408513) of the Affordable Care Act. He wrote an editorial (https://www.wsj.com/articles/SB10001424052702303918804579105092032930278) in the Wall Street Journal, the day of the health plan's launch, predicting the ensuing problems with the healthcare.gov website.

Gottlieb wrote another editorial in the Wall Street Journal arguing that patients who received Medicaid had worse outcomes, including death, with conditions like head and neck cancer than patients who had no insurance coverage at all.[40] Critics said that his article was based on "a classic misunderstanding: confusing correlation for causation", a limitation explicitly mentioned in all the papers he cited. Politifact called it "mostly false."[41][42][43][44]

Gottlieb also appears regularly on CNBC[45] and Fox News.[46]

Personal life

Gottlieb is a survivor of Hodgkin's lymphoma.[1] He is married and has three daughters.[6]

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External links

- Appearances (https://www.c-span.org/person/?scottgottleib) on C-SPAN
- Scott Gottlieb (https://twitter.com/ScottGottliebMD) on Twitter

Political offices		
Preceded by **Robert Califf**	**Commissioner of Food and Drugs** 2017–present	**Incumbent**