



MAY 30, 2017 BACKGROUND

Dr. Scott Gottlieb, Commissioner of the Food and Drug Administration (FDA)

INTRODUCTION

Scott Gottlieb is a non-practicing physician and Fellow with the American Enterprise Institute (AEI). He is also known as a venture capitalist, columnist for publications including *The Wall Street Journal* and *Forbes*, consultant, and former official with the FDA and the Centers for Medicare and Medicaid Services (CMS). He was confirmed by the U.S. Senate on May 9, 2017.

POSITION

Commissioner of the FDA

EDUCATION

B.A. from Wesleyan University; M.D. from the Icahn School of Medicine at Mount Sinai; Resident, Internal Medicine Residency Program at Icahn School of Medicine at Mount Sinai

AGE

45

PROFESSIONAL HISTORY

- Resident Fellow, AEI (2003 – present)
- Venture Partner, New Enterprises Associates (2007– present)
- Member, Federal Health IT Policy Committee (2013 – present)
- Clinical Assistant Professor, NYU School of Medicine (2011 – present)
- Columnist and Blogger, *Forbes* (2005 – present)
- Senior Advisor to the Center for Healthcare Excellence and Innovation, BDO Consulting LLC (2016 – present)
- Member of the Policy Board, Society of Hospital Medicine (2011 – present)
- Managing Director, T.R. Winston & Company (2013 – present)
- Independent Member of the Product Investment Board, GlaxoSmithKline (2010 – present)
- Independent Member of the Board of Directors, American Pathology Partners (2012 – present)
- Independent Member of the Board of Directors, MedAvante (2007 – present)
- Independent Member of the Board of Directors, Glytec (2013 – present)
- Independent Member of the Board of Directors, Daiichi Sankyo, Inc. (2015 – present)

PROFESSIONAL HISTORY, CONTINUED

- Independent Member of the Board of Directors, Gradalis (2015 – 2017)
- Independent Member of the Board of Directors, Tolero Pharmaceuticals, Inc. (2015 – 2016)
- Independent Advisor, Vertex Pharmaceuticals (2007 – 2016)
- Independent Member of the Board of Directors, Aptiv Solutions (2012 – 2014)
- Member of the Policy Board, Leukemia & Lymphoma Society (2012 – 2014)
- Independent Member of the Board of Directors, Bravo Health (2009 – 2011)
- Independent Member of the Board of Directors, Molecular Insight Pharmaceuticals (2007 – 2010)
- Deputy Commissioner for Medical and Scientific Affairs, FDA(2005 – 2007)
- Senior Adviser to the Administrator, CMS (2004)
- Director of Medical Policy Development, FDA(2004)
- Senior Adviser to the Commissioner, FDA (2003 – 2004)
- Medical Staff Writer, British Medical Journal (1998 – 2003)
- Investment Banking Analyst, Alex Brown & Sons (1994 – 1995)

FAMILY

Married to Allyson Nemeroff, who worked in newspaper publishing. They have three daughters.

SUMMARY

Dr. Gottlieb has been described as a “deregulator,” and his public comments and comments during his Senate confirmation hearing speak to this focus. His goal for the FDA has been described as returning more decision-making to physicians, coupled with a less burdensome regulatory process. As FDA commissioner, Dr. Gottlieb will look to speed up the regulatory process on approval of drugs and devices, where appropriate, while working to ease the regulatory burden in general.

RESPONSE TO DR. GOTTLIEB TO DATE

Overall, Dr. Gottlieb’s nomination and confirmation have been met with support. Some have expressed concerns relative to his conflicts of interest from his various board positions for companies whose products he will regulate at FDA; however, there have been no concerns of competency or qualification to run the agency.

Elected and other government officials

- [Sen. Lamar Alexander \(R-TN\), Senate Health, Education, Labor and Pensions \(HELP\) Committee Chairman](#): “It’s critical to have the right person in charge of the FDA, an agency that affects virtually every American and regulates about a quarter of all consumers spending in the United States. Dr. Gottlieb has impressive qualifications helping American patients as both a physician and in his previous roles at the FDA. I look forward to meeting with Dr. Gottlieb and scheduling a hearing to discuss his plans to implement 21st Century Cures and work with Congress to bring safe and effective drugs and medical devices to patients more quickly and to protect the nation’s food supply.” ([Statement](#))
- [Sen. Patty Murray \(D-WA\), Senate HELP Committee Ranking Member](#): “Today I met with President Trump’s nominee for FDA commissioner, Scott Gottlieb, to discuss the FDA’s critical role in public health. I made clear that the next FDA Commissioner’s vision for the agency must be one based in science and fact, not partisan politics. I am deeply concerned about Mr. Gottlieb’s extensive ties to the pharmaceutical and biomedical industries and asked him to address potential conflicts of interest that may arise during his tenure at the FDA. I pushed him to commit to making decisions that are in the best interest of public health, and asked how he plans to ensure that his industry ties and the radical views of the Trump administration will not affect his decision-making should he be confirmed. President Trump promised to “drain the swamp,” and as it stands, Mr. Gottlieb’s ties to the companies and industries he will regulate do exactly the opposite. It is critical that the FDA have independent leadership focused squarely on putting patients and families first, and I look forward to a thorough, rigorous vetting and hearing process to determine whether Mr. Gottlieb is appropriate for this role.” ([Statement](#))
- [Sen. Richard Burr \(R-NC\)](#): “Dr. Gottlieb has the experience and knowledge necessary to guide the Food and Drug Administration toward achieving its public health mission. I was pleased to vote at Committee today, and look forward to a full Senate vote for Dr. Gottlieb to lead the FDA during such an exciting time for innovation in our country.” ([Statement](#))
- [Rep. Rosa DeLauro \(D-CT-3\), House Appropriations Labor, Health and Human Services, Education, and Related Agencies \(LHHS\) Ranking Member](#): “President Trump’s decision to nominate Mr. Gottlieb as Commissioner of the FDA sends a dangerous message that he is committed to rolling back regulations and opening the floodgates to potentially dangerous drugs and medical devices. We have worked diligently to ensure that the FDA is an effective and lifesaving watchdog over our nation’s food and drug supply and we cannot afford to roll back our progress—not when American lives are on the line. With Mr. Gottlieb’s nomination, I am extremely concerned that President Trump will use the FDA as his go to agency for his plan to repeal two existing regulations for every new regulation proposed. We have these regulations in place to ensure that our nation’s drug supply is safe, effective, and life-saving. Now that Mr. Gottlieb will oversee the FDA, he must remove himself from any pharmaceutical industry ties—of which he has many—and work for the American people, not for the drug and medical device industries.” ([Statement](#))

- [Sen. Johnny Isakson \(R-GA\)](#): “Dr. Gottlieb has a strong history of both clinical and policy expertise in the field of medical innovation,” said Isakson. “His work on programs to encourage the development of new cures, generic drugs, medical countermeasures, and vaccines and his vast knowledge of health information technology make him a qualified candidate to reform the FDA and help lead the charge to bring innovative medicine and medical technology to patients in the 21st century. I look forward to meeting Dr. Gottlieb and to participating in his confirmation hearing.” ([Statement](#))

Industry, advocacy, think tank, and political organizations

- [Stephen J. Ubl, President and CEO, Pharmaceutical Research and Manufacturers of America \(PhRMA\)](#): “PhRMA congratulates Dr. Gottlieb on his nomination to serve as Commissioner of the U.S. Food and Drug Administration. His extensive experience as a physician and breadth of health care knowledge will help ensure the FDA continues to play a vital role in protecting public health and innovation in the Agency’s review and approval of new medicines for patients in need. We look forward to working with Dr. Gottlieb in his new role and engaging with him and the Agency as they seek to modernize the drug discovery and review process and advance competition in the biopharmaceutical market.” ([Statement](#))
- [Scott Whitaker, President and CEO, Advanced Medical Technology Association \(AdvaMed\)](#): “AdvaMed congratulates Dr. Gottlieb on his nomination as FDA Commissioner. His medical credentials, combined with years of service in leadership roles at both CMS and FDA make him a strong choice to lead this key agency. Our industry applauds Dr. Gottlieb’s commitment to innovation in medical technology and his recognition of its important role in providing the best care possible for patients. Specifically, we look forward to working with Dr. Gottlieb and his team on the medical device user fee reauthorization in the coming weeks and months in our mutual pledge to continued patient access to life-changing technologies.” ([Statement](#))
- [Mark Leahey, President and CEO, Medical Device Manufacturers Association \(MDMA\)](#): “Dr. Gottlieb is a leading expert on fostering medical technology innovations, and MDMA congratulates him on his nomination to be the next FDA Commissioner. He has dedicated his career to helping patients, and has shaped policies that improve access to lifesaving and life changing treatments. While the United States remains the global leader in medical technology innovation, there is still much more work to be done. Dr. Gottlieb has a proud history of guiding the FDA towards improvements that result in better patient care and lower overall costs to the system, and as a physician he has a unique insight on how all stakeholders can work together to achieve our common goals. If approved by the Senate, MDMA looks forward to working with him to ensure that patients have timely access to safe and effective medical technologies, and that the United States continues to lead the world in solving the challenges facing the health care ecosystem.” ([Statement](#))
- [Chester “Chip” Davis Jr., President and CEO, Association for Accessible Medicines](#): “President Donald Trump’s nomination of Dr. Scott Gottlieb to lead the Food and Drug Administration signals he is serious about increasing access to safe, effective and affordable medicines for Americans while taking a market based, competitive approach towards lowering drug costs. Dr. Gottlieb is one of the most formidable thought leaders in the medical field and makes an excellent choice to lead the agency responsible for ensuring the public health of the millions of patients FDA serves. Dr. Gottlieb has advocated for effectively addressing the backlog of generic drug applications pending at FDA and ensuring that quality products are approved at their earliest possible date; thus, increasing competition to lower costs of drugs and biologics for millions of Americans. We stand ready to work with the President, Dr. Gottlieb and his entire team to ensure that generic medicines continue to keep lifesaving treatments within reach of all Americans. We strongly urge the Senate to move forward with his confirmation in order to begin addressing the important task of lowering prescription drug costs for Americans.” ([Statement](#))
- [Biosimilars Forum](#): “The Biosimilars Forum congratulates Dr. Scott Gottlieb on his nomination as the next Commissioner of the FDA. If confirmed, we look forward to working with him to advance policies that will bring safe and effective new biosimilars to patients promptly so that that these potentially life-saving drugs get into the hands of those patients who need them most.” ([Statement](#))
- [Patrick Hope, Executive Director, Medical Imaging & Technology Alliance \(MITA\)](#): “MITA congratulates Dr. Scott Gottlieb on his nomination as the 23rd Commissioner of the Food and Drug Administration (FDA), which plays a critical role in assuring the quality and safety of medical imaging equipment. We look forward to working with Dr. Gottlieb to ensure patients have access to the safest and most advanced medical imaging technologies.” ([Statement](#))

- [Pamela G. Bailey, President and Chief Executive Officer of the Grocery Manufacturers Association](#): “Scott Gottlieb is an excellent choice to lead FDA. His experience as FDA deputy commissioner and in other key FDA positions will enable him to quickly step into this important role after his confirmation. His appointment will be good for American consumers, the safety of their food and the role of continuous innovation. The Grocery Manufacturers Association and its member companies are committed to working with the Trump Administration and Scott Gottlieb to help assure the safety of our food supply, strong science-based nutrition policies, and the integrity and effectiveness of food labeling policies.” ([Statement](#))
- [Mary Woolley, President and CEO, Research!America](#): “Americans deserve a leader at the Food and Drug Administration who will hold high the agency’s solemn responsibility for assuring that products seeking the agency’s stamp of approval are safe – and in the case of medical products – effective. As a physician, clinical professor and former FDA official, Scott Gottlieb brings a wealth of relevant experience to the job. It would be difficult to find a nominee who is more knowledgeable about the challenges entailed in balancing the demand for faster medical progress with the potentially tragic consequences if FDA cuts corners. The agency faces significant challenges and opportunities as it begins to implement the 21st Century Cures Act, advances efforts to ensure the patient voice is incorporated into regulatory decision-making and pursues other timely initiatives. The FDA needs a strong leader committed to securing the resources and expertise the agency requires to keep pace with 21st century science, carrying on the legacy of visionary leadership and conscientious stewardship that have characterized previous FDA commissioners.” ([Statement](#))
- [Susan Peschin, President and CEO, Alliance for Aging Research](#): “The Alliance for Aging Research supports the nomination of Dr. Scott Gottlieb to be the next FDA commissioner. The FDA requires a strong leader who has deep knowledge of the regulatory process and understands how it affects patient access to new medical products. We believe that Dr. Gottlieb’s expertise as a former regulator and physician will serve the FDA well and benefit the health of the American public. The Alliance is pleased that the Senate Health, Education, Labor, and Pensions Committee will consider Dr. Gottlieb’s nomination later this week. We urge swift action after this hearing to confirm his nomination.” ([Statement](#))
- [Marc Boutin, CEO, National Health Council](#): “The National Health Council (NHC) supports the nomination of Dr. Scott Gottlieb as Commissioner of the U.S. Food and Drug Administration (FDA). Dr. Gottlieb’s experience as a patient, as well as being a former Deputy Commissioner of the FDA and Senior Advisor to the Administrator of the Centers for Medicare and Medicaid Services (CMS), uniquely qualify him for the position. Based on our previous work together, we know Dr. Gottlieb has a long-standing commitment to bringing the voice of the patient into the medical product development process and look forward to his leadership in this area. We urge the Senate to swiftly approve his nomination.” ([Statement](#))
- [Dr. Michael Carome, Director, Public Citizen’s Health Research Group](#): “President Trump’s FDA pick Scott Gottlieb is entangled in an unprecedented web of Big Pharma ties. He has spent most of his career dedicated to promoting the financial interests of the pharmaceutical industry and the U.S. Senate must reject him. Gottlieb’s ties span decades, and he currently is serving or has recently served on five pharmaceutical companies’ boards including GlaxoSmithKline – one of the world’s largest pharma companies. Between 2013 and 2015, Gottlieb received a total of at least \$413,000 from multiple pharma and medical device companies, most for consulting and speaking fees.” ([Statement](#))
- [Becky Martin, Advocacy Director, National Physicians Alliance](#): “The National Physicians Alliance (NPA) opposes the nomination of Dr. Scott Gottlieb for commissioner of the Food and Drug Administration given his lack of experience in public health, lack of focus on public health concerns over the course of his career, and his extensive financial dealings with drug, device, and other health-care related corporations. The NPA is a multi-specialty group of doctors from across the country, dedicated to putting our patients’ interests first. We are a non-profit, and take no funds from pharmaceutical or medical device companies. Within NPA a group of us, including several former FDA medical officers, focuses on FDA issues. We work to strengthen the FDA approval process so that the public can trust information about treatments they are prescribed.” ([Statement](#))

Food Safety

- “The nature of food processing had changed substantially in America. Much of it owed to corresponding changes in food packaging and the logistics for faster shipping. The scope of outbreak from foodborne illness no longer has a clear geographic boundary.” ([Forbes article](#))
- *Food Safety Modernization Act (FSMA)* – During his confirmation hearing, Dr. Gottlieb noted that he considers FSMA to be necessary to ensure the safety of the nation’s food supply and stated that he plans to protect and promote public health as Congress intended when writing the law.
 - “I think FSMA was a significant advance in terms of giving the agency the authorities it needed and the resources it needed to ensure the food supply is safe. My mandate is going to be to make sure FSMA is implemented in the proper way and that we’re striking the right balance with respect to that implementation.”
 - Dr. Gottlieb was also asked by Sen. Lisa Murkowski (R-AK) if he would re-visit the issue of genetically modified salmon, which he said he would. She also asked if he would study a January FDA guidance urging consumers to limit their intake of certain fish because of mercury concerns, which he noted he would.
- Nutrition Labeling – During his confirmation hearing, he said, “I’m philosophically in favor of trying to make sure we do these things efficiently not only because it imposes undue costs on manufacturers if they’re constantly updating their [nutrition facts] labels but we also have to keep in mind it causes confusion for consumers if the labels are constantly changing, so you want to consolidate the label changes . . . as a matter of public health so the information is conveyed accurately and efficiently to consumers. So this is something that I do care about and I look forward to working on it if I’m confirmed.”
 - Dr. Gottlieb said he would be “delighted” to work on the issue of coordinating the deadlines for the two labeling changes.
 - Dr. Gottlieb also noted that he is open to delaying the implementation of the new Nutrition Facts Label until it can be coordinated with the deadline for companies to disclose the presence of genetically modified ingredients in foods.
- Antibiotic Resistance – During his confirmation hearing, Dr. Gottlieb referred to his time as a physician and the loss of patients to antibiotic-resistant infections to express his understanding of the ongoing problem. He recognized that congressional statutes have been the driving force behind the FDA taking steps to address the issue, both on the development side and with the use of anti-infectives in animal feed.

Drugs

- Prescription Drug Prices
 - During his confirmation hearing, Dr. Gottlieb diffused questions regarding his views on prescription drug pricing, noting that the FDA can’t take the price of drugs into account in the approval process. However, he did note that the FDA can play a role in lowering prices because of the barrier to entry created by required FDA approval of generics.
 - In a March 2016 column, Dr. Gottlieb wrote that then-candidate Trump’s plan to import drugs from Canada or foreign countries an “aged concept.” Dr. Gottlieb also discussed the prevalence of sophisticated counterfeit drugs, noting that a drug importation scheme would require regulatory oversight, potentially with no cost savings. ([Forbes](#))
 - Dr. Gottlieb noted in one interview that “there’s not really a drug cost problem in the U.S., except for a small subset of specialty drugs that cost a lot but are providing a lot of benefit.” ([CNBC](#))
 - » “What we have is an under-insurance problem,” he said. “People are now under-insured, especially for catastrophic drugs if they get a disease like cancer or something like that because of these new [narrow] formulary designs . . . popularized by the Affordable Care Act.”

- Dr. Gottlieb has noted that pharmacy benefit managers (PBMs) have played a role in the rise of drug prices, but did not suggest a legislative solution. ([Forbes](#))
- Drug Approval Process
 - “We should reject a false dichotomy that it all boils down to a choice between speed and safety,” Dr. Gottlieb said at his confirmation hearing.
 - Five years ago, Dr. Gottlieb wrote that the FDA sometimes displayed an “unreasonable hunger for statistical certainty” and that its staff was sometimes too cautious in reviewing new drug applications. ([National Affairs](#))
 - During his confirmation hearing, Dr. Gottlieb said it might be possible to “modernize how we do clinical trials” — for example, through greater use of special procedures for “breakthrough therapies” that promise a substantial improvement over existing treatments. The pathway for breakthrough drugs, Dr. Gottlieb said, “has had a really positive impact on the ability of patients with unmet needs to get safe and effective therapies in a timely way.” ([New York Times](#))
 - Writing in Massachusetts newspaper [South Coast Today](#) last year, Dr. Gottlieb praised the 21st Century Cures Act (which was signed into law in December 2016), and said that it would help smooth the way for quicker approvals by zeroing in on results from small trials and interim study results instead of waiting for more traditional clinical trial findings. “These are interim endpoints that can be used to more quickly gauge a medicine’s benefit,” he wrote.
 - Further insights about his views come from an article he penned in 2012 for [National Affairs](#), in which he criticized the FDA for setting up too many regulatory hurdles. There, he argued that extensive clinical trial requirements may have a chilling effect on bringing new therapies to market. “These demands also further entrench established players, and the limited competition from new market entrants means that existing drugs remain hideously expensive,” he wrote. He blamed such requirements on an institutional culture that he said values “an excessive desire for certainty,” and does not trust the doctors who do the prescribing.
 - » “He called for a fundamental change to that culture, whereby FDA employees who review the science involved in drug evaluations would delegate final approval decisions to another part of the agency or an outside group—so that the same individuals are not acting as both judge and jury. Dr. Gottlieb also suggested that final approval decisions be made by a committee composed of the agency’s most senior scientists, who he believes might be more comfortable with uncertainty than junior scientists.
 - “Longer, larger trials that require drug makers to evaluate ‘hard’ endpoints (like how long a cancer patient lives) rather than ‘surrogate’ endpoints (like a drug’s ability to shrink tumors) give FDA reviewers more statistical confidence. Reviewers prefer these drawn-out trials because they insulate the FDA from critics who say that it isn’t focused enough on safety. But bigger trials increase the time needed to develop a drug, keeping it out of the hands of patients,” he wrote in [The Wall Street Journal](#) in 2010.
 - In 2012, Dr. Gottlieb suggested that the FDA should follow the lead of its European Union counterpart and let “a body of politically appointed (and therefore politically accountable) officials ... ultimately [decide] on whether a new drug should be approved.” ([Los Angeles Times](#))
 - At a May 2016 conference, Dr. Gottlieb said, “Making drug testing more efficient could ultimately lower the costs that need to be recouped after a drug is approved.” ([Bloomberg](#))
- Generic Drugs
 - In an article he authored in October 2016, Dr. Gottlieb wrote, “Congress should modernize the generic drug framework to accommodate complex drugs. It could start by giving FDA more discretion to rely on a broader complement of data for evaluating generic copies to complex drugs. This could mean granting FDA the ability to ask for more than just bioequivalence and bioavailability data when it comes to making judgments around sameness as it relates to complex drugs.” ([AEI](#))
 - » “Congress could also give FDA more discretion to allow generic copies to have minor differences in their labeling, to account for small variations between a branded drug and the proposed generic copy. This could address situations where the instructions for use might be marginally different, but where FDA has reviewed data to demonstrate that these differences would not trigger patient confusion or present other public health risks.”

- Speed up Review of Generic Products
 - » Dr. Gottlieb supports review vouchers and has called to prioritize generic applications.
 - “The FDA should prioritize applications for generic categories where competitors are exiting. Companies that pursue copies of ‘abandoned’ generics could receive a voucher that gives them expedited review of another generic drug. The value of this voucher would give firms more incentive to market copies of low-volume generics.” ([AEI](#))
 - » In past speeches, Dr. Gottlieb has indicated a link between lowering prices and speeding approval. He’s praised the FDA cancer division’s efforts in getting drugs approved faster, and suggested that other parts of the agency need to emulate its approach, particularly for rare genetic diseases. ([Bloomberg](#))
- Increasing Generic Competition
 - » In a speech on March 6, 2017, at a conference in Orlando, Florida, Dr. Gottlieb talked about overhauling the rules for complex generic drugs with which brand-name companies have been able to create “monopolies in perpetuity.” He also discussed the need to inject competition in situations where decades-old drugs are provided by one generic supplier, allowing speculators to buy the drug and significantly increase the price. ([Bloomberg](#))
- Vaccines
 - At his confirmation hearing, Dr. Gottlieb said there “is no causal link between vaccination and autism.”
 - » Also during his hearing, Dr. Gottlieb stated, “This is one of the most exhaustively studied questions in scientific history. I think we need to come to the point where we can accept “No” for an answer, and come to the conclusion that there is no causal link between vaccinations and autism.”
 - He also has said, “The scientific community has thoroughly debunked any association behind autism and the measles vaccine, and public statements that cast doubt on that make Americans less safe.” ([CNBC](#))
- Right-to-try Laws
 - He noted during his confirmation hearing that he supports right-to-try legislation. ([AEI article](#))
- Breakthrough Therapy Designation
 - In a 2016 speech, Dr. Gottlieb praised the FDA’s oncology division for embracing the methods and spirit of the Breakthrough Therapy law. He also noted, “there are regrettably parts of FDA that I believe are well behind the curve in making these same accommodations.” ([AEI](#))

Medical Devices

- Devices
 - During an interview, Dr. Gottlieb noted, “FDA’s approach to regulating devices, in contrast to its requirements governing drugs, was designed by Congress to recognize that not all devices pose the same degree of risk. Therefore, the volume of data that the FDA requires should be closely matched to the risk of the product in question.” ([WSJ](#))
 - » During the same interview, he said, “The problem today is the FDA has deviated from the original spirit of that idea. It’s trying to apply a much more uniform and drug-like approach to its regulation of medical devices, increasing the hurdles that new products must clear. At the same time, the FDA is treating more low-risk devices like they were high risk.”
 - » He also noted that, “The FDA is trying, in too many cases, to answer these questions by requiring longer and larger trials in people and large animals like pigs and sheep.”
 - » Dr. Gottlieb supports off-label marketing of medical devices, including Class III devices. ([Stat News](#))
- Digital Health
 - In an article, Dr. Gottlieb stated that, “FDA is often too easily distracted by attractive areas like iPhone apps that nonetheless pose relatively low risks and could be ably addressed by other regulatory agencies.” ([Forbes](#))

- In an interview with *The Wall Street Journal*, Dr. Gottlieb noted, "The FDA also is showing a desire to classify more things that merely inform consumers as medical devices. One example is seen in the FDA's approach to consumer apps, like those found on an iPhone. A lot of these apps are really low risk." ([WSJ](#))

Affordable Care Act (ACA) Reform

- Dr. Gottlieb has been critical of the ACA, and noted that it didn't "fulfill the expectations that were set out." ([Managed Care Magazine](#)) In particular, he noted that the law didn't attract as many people to the exchanges as predicted nor did it meet the savings to consumers as had been estimated. In the same piece, Dr. Gottlieb noted that the essential health benefits were one component of why he deemed the exchanges a failure.
- Dr. Gottlieb has also criticized the ACA for its impact on physicians, noting that the law favors "the consolidation of previously independent doctors into salaried roles inside larger institutions, usually tied to a central hospital, in effect ending independent medical practices." ([The Wall Street Journal](#))
- Dr. Gottlieb believes that Americans should have access to catastrophic health insurance if they "don't get health insurance through employers, or Medicare and Medicaid, should be eligible for a refundable tax credit that can be used to enroll in a health-insurance plan. The credit would be set at a level comparable to the tax benefits available to individuals with employer-sponsored insurance plans. The subsidy would be enough to make a basic level of catastrophic coverage easily affordable for all Americans." ([AEI](#))
 - Further, he believes in high-risk pools as a means to accommodate people with pre-existing health conditions, and stated that "well-run and properly funded high-risk pools can help address the inevitable cases of expensive claims for the remaining uninsured."
 - Additionally, he calls for allowing access to health-savings accounts.
- Dr. Gottlieb believes that the market needs stabilization with respect to insurance competition. He recommends modifying the caps on health-plan operating margins as a way to encourage more insurers to get into the system. ([AEI](#))
- Dr. Gottlieb also has been critical of the trend in mergers, particularly among the big insurers. He said that this trend is "a direct consequence of ObamaCare, reflecting the naïveté of its architects and the fulfillment of their myopic vision." ([The Wall Street Journal](#))

Opioid Crisis

- During his confirmation hearing, Dr. Gottlieb told senators that the nation's opioid crisis is a "public health emergency on the order of Ebola and Zika" and requires dramatic action by the agency and the rest of government.
- Dr. Gottlieb described the FDA as "complicit, even if unwittingly" in helping to fuel the opioid epidemic. Officials, he said, "didn't fully recognize the scope of the emerging problem" several years ago and needed a new strategy to combat the issues involved.
- Developing that strategy, he added, would be his "highest and most immediate priority" and would involve taking a hard look at the FDA's framework for approving painkillers and pressing for greater availability of non-addictive painkillers.

Cellular and Gene Therapy

- Novel Technologies
 - Dr. Gottlieb wrote that the "FDA needs to organize more of its regulatory activities around programs centered on areas such as regenerative medicine and gene editing. It needs to more closely adjust its regulatory approach to address the unique nature of the different risks that it's trying to address." ([Forbes](#))

Off-Label Promotion

- In general, Dr. Gottlieb has advocated for loosening restrictions on communications from drug and medical device manufacturers on off-label uses of their products, according to an interview by BNA with Michael Carome, Director of Public Citizen’s Health Research Group. ([BNA](#))

Use of Biomarkers:

- “... we need a more systematic and inclusive process for qualifying biomarkers and measures of disease activity that can form the basis of regulatory approvals.” ([AEI](#))

About the District Policy Group

The bipartisan District Policy Group at Drinker Biddle is comprised of 15 lobbyists, public policy specialists, grassroots coordinators and other experienced government relations professionals—including former Congressman Dr. Phil Gingrey (R-GA).

Our team’s extensive experience comes from working on Capitol Hill, within trade associations and advocacy organizations, and in the private sector. We have a long record of success in delivering insightful political and policy analyses, developing meaningful policymaker relationships, and advancing and achieving our clients’ federal public policy goals.

For each representation we undertake, we carefully assemble a team of professionals with the specific experience, knowledge and relationships needed to meet the client’s unique needs. We are nationally recognized for our lobbying work in health care, and also represent clients in other industries, such as agriculture, trade, environment, transportation and manufacturing.

Primary Contacts



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Ilisa Halpern Paul leads the District Policy Group and has more than 25 years of experience in government relations, advocacy, and policymaking in non-profit, academic, federally-funded, and government settings. Ilisa’s practice centers on advising clients with respect to advancing their federal legislative, regulatory and programmatic policy agendas. Her work has earned her the recognition as one of The Hill’s Top Lobbyists of 2015 and 2016, as well as a feature story in *The Hill* regarding her rise to success.



The Honorable J. Phillip Gingrey, M.D., Senior Advisor

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Phil Gingrey is a senior advisor in the District Policy Group at Drinker Biddle. Dr. Gingrey is a former U.S. Congressman who served Georgia's 11th congressional district from 2003 to 2015. Throughout his 12 years in Congress, Dr. Gingrey served on numerous influential committees, including the House Committee on Energy & Commerce, which focused on issues such as energy, health care, telecommunications, environment and interstate commerce. As such, he is uniquely positioned to provide public policy and government relations counsel to clients on issues related to health care, energy and environment, education, communications, and life sciences. Also during his Congressional tenure, Dr. Gingrey served on the Committee on Education and the Workforce and the Committee on Armed Services.



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Jodie Curtis focuses on federal policy, appropriations, and regulatory issues. She has more than 20 years of experience in government, Congressional affairs and representing the legislative and regulatory interests of for-profit, non-profit, and global organizations. Prior to joining the firm, Jodie served as an assistant director with a large national non-profit health care advocacy organization, deputy chief of staff for U.S. Representative Thomas M. Barrett (D-WI), executive assistant for U.S. Representatives Lynn Rivers (D-MI) and Peter Barca (D-WI), and district director/legislative assistant for Wisconsin State Senator Barbara Ulichny.



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Laura H. Phillips has been a leader in the telecommunications market for more than 25 years. She counsels wireless and wired technology entrepreneurs on issues related to the development of new technologies, including the development of spectrum auctions, network interconnection, access, universal service and Voice over Internet Protocol (VoIP). She also represents clients in regulatory matters stemming from communications service convergence, the growth of wireless services and the Internet. Laura is chair of the firm's Government and Regulatory Affairs Practice Group.