

William B. Schultz

Partner

Described in *Chambers USA* as a “thought leader” in health care pharmaceutical matters, William B. Schultz focuses on complex regulatory issues and provides strategic advice to companies and public interest organizations. He represents providers and individuals before the U.S. Department of Health and Human Services (where he served as general counsel), other federal agencies, and the courts.

Bill also assists generic drug companies, nonprofit organizations, and other clients before the Food and Drug Administration, where he served as Deputy Commissioner for Policy.

He has argued numerous cases in the federal trial and appellate courts, including three in the United States Supreme Court.

As general counsel at HHS from 2011 to 2016, Bill served as counsel to two HHS secretaries on all legal matters and managed an office of 500 lawyers across eight offices, covering 10 regions across the country. HHS administers \$1 trillion per year in federal programs, including Medicare, Medicaid, the Affordable Care Act, the FDA, the National Institutes of Health, and the Centers for Disease Control. The office of general counsel is responsible for all litigation where HHS is a party, ensuring regulations and policy decisions are consistent with the law, reviewing legal issues involving appropriations, and ensuring ethical rules are followed.

Prior to joining HHS, for ten years Bill was a partner at Zuckerman Spaeder.

From 1999 to 2000, Bill was deputy assistant attorney general at the U.S. Department of Justice, where he was responsible for overseeing all civil division appellate litigation and the department’s tobacco litigation team.

From 1994 to 1999, Bill was deputy commissioner for policy for the FDA, where he was the principal advisor to the Commissioner on all significant policy issues and was responsible for the development and management of all regulations.

From 1989 to 1994, Bill was the counsel to the Subcommittee on Health and the Environment (Rep. Henry A. Waxman, chairman), Committee on Energy and Commerce, U.S. House of Representatives, where he worked on health care, FDA,



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Practice focus

- Health Care
- Food and Drug

Education

- University of Virginia School of Law, J.D., 1974
- Yale University, B.A., 1970

Languages



ZUCKERMAN
SPAEDER

tobacco, and trade legislation.

From 1976 to 1989, Bill was an attorney with the Public Citizen Litigation Group, where he litigated law reform cases on state and federal constitutional law, antitrust and administrative law, voting rights, product liability, nuclear power, and food and drug law, and where he argued dozens of appellate cases, including several in the U.S. Supreme Court.

Bill taught at Georgetown University Law Center for 10 years (Food and Drug Law and Civil Litigation). He regularly speaks about health care issues and has authored numerous articles on health care and other topics.

Government service

- General Counsel
 - U.S. Department of Health and Human Services
- Deputy Assistant Attorney General
 - U.S. Department of Justice
- Deputy Commissioner for Policy
 - U.S. Food and Drug Administration
- Counsel
 - Subcommittee on Health and the Environment, House Committee on Energy and Commerce
 - U.S. Congress

Professional leadership

- Member, Committee on Science, Technology & Law, National Academy of Sciences
- Leadership Council, Yale School of Public Health
- Vice Board Chair, National Health Law Program (NHeLP)
- Board, Center for Science in the Public Interest
- Board, Historical Society of the District of Columbia Circuit

Recognitions

- Chambers USA: America's Leading Lawyers for Business, Healthcare: Pharmaceutical/Medical Products Regulatory



(Washington, DC)

- The Best Lawyers in America, FDA Law
- Super Lawyers (Washington, DC)
- The National Law Journal, Litigation Trailblazer, 2020
- Law360, Health MVP of the Year, 2019
- FDA Distinguished Alumni Award, 2017
- National Law Journal, 100 Most Influential Lawyers in America, 2006

Bar admissions

- District of Columbia
- Virginia

Court admissions

- U.S. Supreme Court
- U.S. Court of Appeals, District of Columbia Circuit
- U.S. Court of Appeals, Federal Circuit
- U.S. Court of Appeals, Third Circuit
- U.S. Court of Appeals, Fourth Circuit
- U.S. Court of Appeals, Fifth Circuit
- U.S. Court of Appeals, Sixth Circuit
- U.S. Court of Appeals, Ninth Circuit
- U.S. District Court, District of Columbia
- U.S. District Court, Eastern District of Virginia
- Court of Appeals of the District of Columbia
- Supreme Court of Virginia

Clerkships

- Hon. William B. Bryant, U.S. District Court for the District of Columbia

Representative matters

- Represents several hospital trade associations and hospitals in litigation regarding Health and Human Services regulations and management of the 340B program which requires drug companies to give nonprofit hospitals that serve patients with inadequate medical care billions of dollars in discounts.
- Regularly provides strategic advice to regulated companies and trade associations.
- Regularly represents generic manufacturers in navigating the regulatory requirements at FDA and in litigation regarding generic drug approvals.
- Represents tobacco advocacy and other public interest organizations.
- Represents individual and nonprofit organizations in connection with investigations by the HHS Inspector General.
- Worked extensively on regulations implementing the Affordable Care Act and litigation involving the Act, as well as regulations and litigation related to FDA and other HHS programs.
- Provided strategic advice to clients subject to Congressional investigations.
- Represented a state in one of the first cases against the makers of OxyContin, helping to secure a large settlement.
- Advised the New York City Board of Health on preemption case brought to block implementation of its requirement for labeling in restaurants.
- Served as an arbitrator in a complex contract matter.

