Margaret "Peggy" Dotzel

Partner

Washington, DC
+1 202.778.1998
202.822.8106 - Fax
mdotzel@zuckerman.com

Peggy Dotzel focuses her practice on complex regulatory issues and provides strategic advice to generic drug companies, start-up drug and biologic companies, hospitals, trade associations, and public interest organizations. Also trained as a pharmacist, she handles all aspects of food and drug law, including litigation, administrative actions, and legislative and policy matters as well as counseling and litigation on other Department of Health and Human Services (HHS) related matters.

Prior to joining Zuckerman Spaeder, Peggy served as Acting General Counsel and Deputy General Counsel at HHS.

As Acting General Counsel at HHS, Peggy managed over 500 attorneys and support staff and oversaw all legal advice provided by the Office of General Counsel, which is responsible for all litigation and ensuring that decisions in the program areas – which include Medicare, Medicaid, the Affordable Care Act, the FDA, the National Institutes of Health and the Centers for Disease Control – are consistent with the law. She also provided legal counsel directly to the Secretary and other senior level Department officials. From 2011-2016, in her role as deputy general counsel, Peggy oversaw litigation and legal advice provided by the Office of General Counsel on matters related to, among other things, generic drugs and biosimilars, the Indian Health Services, the 340B program, Ryan White, community health centers, the Substance Abuse and Mental Health Services Administration, Medicare program integrity, and implementation of the Affordable Care Act. She also served as the Department liaison with the HHS Office of the Inspector General.

Peggy served as counsel at Zuckerman Spaeder from 2006-2011. From 2000-2003, she served as Associate Commissioner for Policy at the Food and Drug Administration, where she oversaw the development of major FDA policy initiatives and worked with HHS, the White House, and Congress on issues relating to FDA's regulatory policy. From 1999-2000, Peggy was the Acting Associate Commissioner for Policy, and from 1995-1999 she was a Senior Policy Advisor at the Food and Drug Administration. She started her legal career as a law clerk to Judge Jerry Buchmeyer in the Northern District of Texas. Following her clerkship she spent five years at a large Washington, DC law

Practice focus

- Health Care
- Food and Drug
- Pro Bono

Education

- University of Texas School of Law, J.D., with honors, 1989 Order of the Coif
- Temple University School of Pharmacy, B.S., *summa cum laude*, 1983

Languages

firm. Prior to attending law school, Peggy practiced as a hospital pharmacist.

Peggy received her B.S., *summa cum laude*, from Temple University School of Pharmacy and earned her J.D., with honors, Order of the Coif, at the University of Texas School of Law.

Government service

- Acting General Counsel
    - U.S. Department of Health and Human Services
- Deputy General Counsel
    - U.S. Department of Health and Human Services
- Associate Commissioner for Policy
    - U.S. Food and Drug Administration
- Acting Associate Commissioner for Policy
    - U.S. Food and Drug Administration
- Senior Policy Advisor
    - U.S. Food and Drug Administration

Recognitions

- The Best Lawyers in America, FDA Law; Health Care Law

Bar admissions

- District of Columbia
- Texas (inactive)

Court admissions

- U.S. Supreme Court
- U.S. Court of Appeals, District of Columbia Circuit
- U.S. District Court, District of Columbia

Clerkships

- Hon. Jerry Buchmeyer, U.S. District Court for the Northern District of Texas

Representative matters

- Represents hospitals and trade associations in judicial challenges related to the 340B drug discount program.
- Regularly provides legal and strategic advice to generic, biosimilar and start-up manufacturers navigating the regulatory processes at FDA.
- Provides strategic advice in connection with investigations by the HHS Office of the Inspector General.
- Provides strategic advice to clients on Medicare reimbursement issues.
- Worked extensively on regulations implementing the Affordable Care Act and litigation involving the Act, as well as regulations and litigation related to HRSA, SAMHSA, FDA and other HHS programs.
- Represented a generic drug manufacturer in the U.S. Supreme Court in a case addressing whether federal laws preempted state failure to warn actions against generic manufacturers.
- Represented a biotech company in connection with litigation brought by a brand company challenging the FDA's approval of a generic product co-developed by our client.
- Represented a generic drug manufacturer in a challenge to FDA's grant of 180-day exclusivity that would have blocked approval of that manufacturer's generic drug for 180 days.