

Leading **LAWYERS** Eleven of the D.C. Area's Top Food and Drug Attorneys

William Schultz

Zuckerman Spaeder

William Schultz believes in fighting the good fight.

From the start of his career at Public Citizen to his stints on Capitol Hill, at the Food and Drug Administration, and in the Department of Justice, Schultz, 57, has made serving the public's interest a touchstone of his work life.

Now a partner at Zuckerman Spaeder, he represents generic-drug makers and small biotechnology companies as well as state governments and nonprofit groups. "It's not a traditional food-and-drug practice," he notes.

For example, the Campaign for Tobacco-Free Kids turns to Schultz for lobbying and litigation advice. "There's no one like him," says William Corr, executive director of the campaign. "He has an integrity and dedication to law and public service, trying to move the law in the food-and-drug practice in a positive direction from a public-health standpoint."

Schultz represented the Elizabeth Glaser Pediatric AIDS Foundation and the American Academy of Pediatrics (as intervenors) after the U.S. District Court for the District of Columbia in 2002 ruled that the FDA had exceeded its regulatory authority by requiring more research into the effects of various drugs on children. As the case proceeded on appeal, Schultz simultaneously lobbied for legislation. In 2003, Congress passed the Pediatric Research and Equity Act, which requires pediatric studies of certain drugs and biological products (the litigation was subsequently dropped).

More recently, Schultz was part of a team of lawyers representing the state of West Virginia in litigation against Purdue Pharma L.P. over the narcotic OxyContin. The state alleged that Purdue withheld information about the drug's addictiveness in an effort to boost sales. The case was settled for \$10 million in December 2004.

Schultz is now counseling the state of Illinois on its I-Save program, which facilitates the importation of less-expensive drugs from Canada and the United Kingdom into the United States.

Among his many generic-drug clients, Schultz counts the trade group Generic Pharmaceutical Association and the multinational

Alpharma Inc. In recent months he has represented Alpharma in high-profile cases involving 180-day exclusivity for the generics metformin and gabapentin, two big-selling drugs. Both cases were settled favorably after intense litigation.

Brendan Magrab, former vice president for intellectual property at Alpharma, praises Schultz for his "impeccable judgment," noting his success with "major FDA issues that were worth millions of dollars to the company."

Schultz received his J.D. from the University of Virginia in 1974. After a one-year clerkship with U.S. District Judge William Bryant of the District of Columbia, Schultz took a job with the Public Citizen Litigation Group.

The first case he was assigned—concerning liability limits for the nuclear power industry—wound up before the Supreme Court as *Duke Power Co. v. Carolina Environmental Study Group* (1978). At age 30, Schultz had his first high court argument. (He didn't win.)

He appeared before the justices again in *Young v. Community Nutrition Institute* (1986). The case challenged the FDA's decision to set limits on the food carcinogen aflatoxin without public notice and

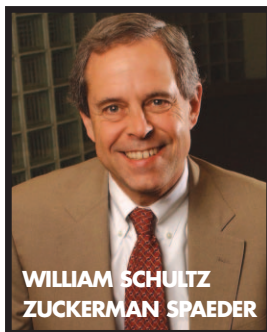
comment. In the end, his client won the case on remand before the U.S. Court of Appeals for the D.C. Circuit. Says Schultz: "It redefined when the FDA is required to issue regulations."

In 1990, Schultz took what he describes as "a great job" working for Rep. Henry Waxman (D-Calif.) as counsel to the House Commerce Subcommittee on Health and the Environment. During his five years on the Hill he worked on legislation such as the Safe Medical Devices Act, the Prescription Drug User Fee Act, and the Nutritional Labeling and Education Act.

In 1994, Schultz moved to the FDA as deputy commissioner for policy, a position in which he was involved in the agency's efforts to regulate tobacco. Other issues during his four years at the FDA included consumer labeling of over-the-counter drugs, food safety, and pediatric drug testing.

Next, he served as a deputy assistant attorney general in the Justice Department. Schultz supervised the Civil Division's appellate litigation as well as the department's lawsuit, still ongoing, against the tobacco industry for violations of the civil provisions of the Racketeer Influenced and Corrupt Organizations Act.

Schultz joined Zuckerman Spaeder in 2001 as the first food-and-drug specialist in its D.C. office.



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