William (Bill) McConagha

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Education

J.D., Georgetown University Law Center, 1993 (*cum laude*)

B.A., Carleton College, 1989 (*magna cum laude*)

Bar Admissions

District of Columbia

Maryland

Bill McConagha is a nationally recognized lawyer in FDA law who has a unique combination of experience in enforcement, regulatory and legislative matters. Mr. McConagha worked for more than 17 years at the Food and Drug Administration (FDA) in a variety of capacities, including an assistant commissioner, a senior attorney in the Office of Chief Counsel (OCC) and as a health policy adviser to the Senate Committee on Health, Education, Labor and Pensions (HELP).

While in the OCC, Mr. McConagha handled enforcement and defensive litigation, prosecuted criminal cases as a Special Assistant U.S. Attorney, advised the FDA's Office of Criminal Investigations, and provided regulatory counsel on a range of issues to the Center for Drug Evaluation and Research (CDER), the Office of Regulatory Affairs, the Office of Combination Products, the Office of Policy, and four FDA commissioners. As an assistant commissioner, Mr. McConagha managed the FDA's advisory committee process, helped resolve scientific and procedural disputes with stakeholders, and helped develop new scientific dispute resolution policies. At the HELP Committee, he played a key role in drafting and negotiating the Food Safety Modernization Act of 2011 and the FDA Safety and Innovation Act of 2012. He also counseled committee leadership on the FDA-related aspects of health care reform legislation.

Mr. McConagha assists clients in a wide range of matters, involving such issues as:

- compliance with FDA regulatory requirements such as current good manufacturing practice (GMP), quality system regulation (QSR), food safety preventive controls, adverse event reports, product recalls, radiological health issues, risk evaluation and mitigation strategies (REMS), pharmacy compounding and the new track-and-trace regulations for prescription drugs;
- responses to warning letters, Form 483s, import alerts, and FDA enforcement actions, whether civil or criminal;
- product development and the FDA's preapproval requirements;
- prescription drug advertising and promotion;
- internal investigations;
- congressional oversight and investigations regarding FDA-regulated products; and
- technical legal questions involving the Food, Drug and Cosmetic Act, the Public Health Service Act and the Administrative Procedure Act.

Recent representative matters include:

- helping a large, publicly traded medical device company respond to a warning letter and successfully defending a joint FDA-Department of Justice (DOJ) criminal investigation into the alleged sale of misbranded and adulterated products;
- helping a startup pharmaceutical company develop appropriate promotional materials, sample distribution programs and pharma-covigilance systems for a newly launched drug product;
- working with a team of outside lawyers as the lead FDA enforcement and government strategies counsel for a large device company confronted with two 483s, a related warning letter, two simultaneous congressional investigations, and simultaneous enforcement investigations by the FDA and DOJ;

- helping the U.S. subsidiary of a large international pharmaceutical company defend a REMS-related litigation and related dispute with the FDA;
- conducting internal investigations for several FDA-regulated companies, including a pet food manufacturer, a consumer products company and a large U.S.-based pharmaceutical company;
- helping a large, publicly traded drug company comply with the FDA's new track-and-trace pedigree requirements for prescription drugs; and
- helping a large, publicly traded medical products company develop procedures to comply with FDA's Post Market Safety Reporting Requirements for combination drug-device products.

In addition, Mr. McConagha has helped a number of other companies, including several *Fortune* 500 companies, enhance compliance with the FDA's manufacturing requirements (*i.e.*, GMP, QSR and preventive controls) for medical products, dietary supplements and foods. He has performed on-site diagnostics, helped sites prepare for regulatory inspections, coached subject matter experts during inspections by the FDA and Health Canada, and helped firms respond to over a dozen 483s and warning letters. He has worked on-site at manufacturing facilities located throughout the U.S. and in 15 other countries, including Germany, Ireland, Canada, Sweden, Italy, Hungary, Japan, Taiwan, Singapore and India.

Since entering private practice, Mr. McConagha has been recognized by *Best Lawyers in America* for FDA law and *Who's Who Legal* for life sciences. While at FDA, he received the following individual awards:

- Secretary's Award for Distinguished Service, Department of Health and Human Services
- Excellence in Legal Services, Office of the General Counsel, Department of Health and Human Services
- Commissioner's Special Recognition Award, FDA
- Commissioner's Special Citation, FDA
- Director's Award for Outstanding Service, FDA's Office of Criminal Investigations