Food & Drug Administration (“FDA”) Regulation

Williams & Connolly handles a broad range of Food & Drug Administration (“FDA”)-related issues involving pharmaceuticals and medical devices. These include advising on regulatory matters—e.g., citizen petitions, meetings with agency personnel, advisory committee meetings, general regulatory strategy—and compliance and enforcement—inspections, warning letters, disqualification and other administrative sanctions, injunction proceedings and criminal proceedings.

Firm lawyers have brought lawsuits against FDA, have represented clients intervening in lawsuits on the same side as FDA, and have represented executives of FDA-regulated companies at congressional hearings. They also successfully argued on behalf of the tobacco industry in the landmark Supreme Court decision invalidating the FDA's attempt to regulate tobacco.

Attorneys in our patent litigation practice routinely advise our brand clients on matters relating to Orange Book listings and ANDA filings with the FDA for our clients' NDA-approved drugs.