Clients find our regulatory knowledge and technical expertise invaluable when bringing new drugs, biologics, and medical devices to market. Fish & Richardson’s Drug and Medical Device practice combines regulatory know-how with the scientific expertise of our world-class intellectual property practice. One-stop shopping for patent and regulatory advice on drugs and medical devices means clients need not explain their technology and legal concerns to different sets of attorneys.

**Hatch-Waxman, Orphan Drugs, and Biosimilars**

One of Fish’s unique specialties is our understanding of the complex relationship between patent and drug laws to protect the exclusivity for pharmaceutical products worldwide. In the United States, we counsel clients on the scope and application of the Hatch-Waxman Act, including the 271(e)(1) “safe harbor,” Orange Book listing, patent term extensions, and ANDA litigation under 271(e)(2). We advise clients on the Hatch-Waxman marketing exclusivities available for brand and “first mover” generics, and on orphan drug and pediatric exclusivity rights. Our attorneys also follow closely the legal and regulatory developments related to biosimilar approvals under the 2009 Biologics Price Competition and Innovation Act (BPCIA).

We believe the collaboration among regulatory, patent, and litigation attorneys provides an integrated, team approach that gives our clients with a competitive edge to achieve their business and marketing objectives. Our regulatory attorneys work on interdisciplinary teams for a large number of Hatch-Waxman clients with a proven record of success. A representative list includes:

**ALPHAGAN® P**
Over the course of nearly a decade, Fish represented Allergan in multiple Hatch-Waxman litigations related to its ALPHAGAN, ALPHAGAN P 0.15%, and ALPHAGAN P 0.1% glaucoma medications.

**COMBIGAN®**
Represented Allergan in Hatch-Waxman litigation over its glaucoma drug COMBIGAN.

**AMRIX®**
Represented plaintiffs Eurand, Cephalon, and Anesta in Hatch-Waxman litigation related to the extended release muscle relaxant AMRIX.

**FENTORA®**
Represented Cephalon and CIMA Labs in litigations relating to FENTORA, a rapid-onset fentanyl tablet used in the treatment of opioid-tolerant patients suffering from breakthrough cancer pain.

**LUMIGAN®**
Represented Allergan in Hatch-Waxman litigation relating to its glaucoma drug LUMIGAN.

**RANEXA®**
Represented Gilead and Roche in Hatch-Waxman litigation over RANEXA, a treatment for chronic angina.

**SULAR®**
Represented plaintiffs in Hatch-Waxman litigation relating to Sciele Pharma’s blood-pressure drug, SULAR.

**XELODA®**
Represented Roche in Hatch-Waxman litigation involving XELODA, the first oral chemotherapy drug approved in the US for the treatment of breast and colorectal cancers and Dukes’ C Stage III colon cancer.
Medical Device Approvals and Compliance
Our medical device regulatory practice specializes in obtaining marketing authorization from the FDA, without which even the most innovative, lifesaving device cannot be legally marketed in the United States. We have assisted both domestic and foreign manufacturers through the FDA maze for a wide variety of devices, ranging from cutting-edge 3-D X-ray equipment to a cell phone-based medication reminder system (a precursor to smartphone medical apps) to collagen-based bone filling augmentation material. We regularly interact with FDA staff to ensure that clients meet all their regulatory requirements in the least burdensome manner possible.

Our experience also includes advising clients on medical device labeling, quality system compliance, imports and exports, establishment registration, device listing, recalls and other corrective actions, and a myriad of other FDA related issues. Outside of the United States, we routinely work directly with Health Canada to obtain medical device licenses for our clients.

A Sampling of Our Experience
- Preparing and filing 510(k) marketing applications with the FDA
- Assisting a university-affiliated hospital with the preparation of an investigational device exemption (IDE) application for use of a new device in treating depression
- Obtaining FDA designation of a novel product as a medical device and not a drug, thereby avoiding the burden and expense of filing a new drug application
- Convincing the FDA to exempt from 510(k) regulation a novel device that assists doctors in more accurately performing biopsies and other procedures while using medical imaging technology
- Consulting with FDA staff on when the use of wearable biosensors crosses the line from unregulated “health and wellness” applications to regulated medical device applications
- Advising a large international device manufacturer on improvements to its Medical Device Reporting protocols
- Negotiating with the FDA to allow continued marketing of modified devices while new 510(k) applications were prepared and filed

Medical Devices
We advise clients on a broad range of devices including:
- Medical telemetry and mobile medical applications
- Medical Device Data Systems
- Medical software
- Research and screening technologies
- Dental devices
- Implants
- Imaging agents
- Picture and communication system (PACS)
- Catheters
- Cardiovascular devices
- Microwave therapies
- Pressure monitors
- Oximeters
- Drug delivery technologies (drug/device combinations)

FCC and FDA Regulations for Digital Health
Fish helps medical device manufacturers, developers, and wireless medical technology companies navigate the still-evolving regulations of both the FDA and Federal Communications Commission (FCC). The FDA’s focus is on safety and effectiveness of devices. The FCC’s focus, on the other hand, is on preventing interference. Before wireless medical devices may be imported, marketed, or operated in the United States they must be cleared or approved by the FDA (unless exempt) and tested for compliance with the FCC’s technical standards. Authorization by one agency does not guarantee authorization by the other. As more medical devices are equipped with wireless functionality and as mobile medical applications blur the lines of what is and is not subject to medical device regulation, Fish helps developers understand all their regulatory obligations.