LIFE SCIENCES

Life science companies face complex hurdles on route to the marketplace and may need assistance navigating agency regulations and steering clear of enforcement action. Recent regulatory changes, increased scrutiny of marketing and pricing issues, and complex intellectual property issues require realistic and effective strategies to stay competitive.

Our multidisciplinary life sciences team is experienced in regulatory compliance, unfair competition, product liability risk control, intellectual property, and enforcement. We advise on traditional and special regulatory issues and can help you participate in agency rulemaking, respond to federal and state administrative enforcement actions, and handle civil and criminal litigation.

This team works closely with other Hodgson Russ attorneys to provide core interdisciplinary counsel to our life sciences clients. We have experienced attorneys for each stage of business development, including corporate attorneys specializing in mergers and acquisitions; finance attorneys with venture capital experience; business and regulatory attorneys capable of preparing appropriate licensing, distribution arrangements, and antitrust compliance advice; cross-border attorneys with extensive experience in international tax, import and export, and international business development; and real estate practitioners who can advise on leasing or real property investment.

When challenging issues arise, Hodgson Russ provides sophisticated counseling and advice to help protect clients' operations. Our attorneys have extensive experience representing clients before the FDA Consumer Product Safety Commission (CPSC), Drug Enforcement Agency (DEA), Environmental Protection Agency (EPA), Federal Trade Commission (FTC), and the U.S. Customs Service.

Our life sciences attorneys frequently lecture and write on topics in their specific areas of concentration, including health law, FDA regulatory law, fraud and abuse, health care reimbursement, intellectual property, HIPAA, international licensing, and technology, medical device, and biotechnology transactions.

We assist life science businesses with:

- Enforcement actions, including product liability, recalls, seizures, FDA warning letters, and other notices of alleged violation
- Facilities audits and FDA inspections
- Cross-border issues, including assisting Canadian companies with bringing their products to the United States

Contacts

Alfonzo Cutaia
716.848.1580
acutaia@hodgsonruss.com

John Lopinski Ph.D.
716.848.1430
jlopinsk@hodgsonruss.com

Professionals

Attorneys

Jane Bello Burke

John DiMaio Ph.D.

Sarah Grimaldi

John Lopinski Ph.D.

Ryan Lucinski

Paul Roman Jr. Ph.D.

Hugh Russ III

Christian Soller

Melissa Subjeck

Managing Partner

Benjamin Zuffranieri Jr.

- Cross-border and transfer tax issues
- Mergers and acquisitions
- Corporate financing
- Licensing and collaborative agreements
- Licensing, patent, or trademark protection for your product
- Regulatory and clinical research compliance
- Third-party, government, and health insurance reimbursement
- Recalls and corrective actions in conjunction with product liability
- Legislative and regulatory advocacy and policy development
- Compliance advice and white-collar criminal defense
- Compliance training and conduct audits
- Foreign Corrupt Practices Act (FCPA) compliance plans
- Analyzing permissible uses and disclosures of protected health information

Our attorneys have specific experience in medical device, drug, and biologics products and can help you navigate challenges including:

- Determining proper device classification
- Complying with cGMP (current good manufacturing practices)
- Obtaining investigational device exemptions (IDE)
- Advising on medical device reporting (MDR) strategy and compliance
- Advising on medical device pre-market applications, including 510(K) and PMAs
- Advising on drug advertising, labeling, and promotional material, including Web sites and direct-to-consumer advertising
- Addressing antitrust implications of bringing pharmaceuticals to market
- Obtaining new drug approvals, including filing veterinary applications
- Assisting in over-the-counter (OTC) drug manufacturer registration, product listing, and marketing compliance
- Food labeling
- Advising on importation of FDA-regulated products
- Advising on supplier agreements and other contracts in the regulated industry
- Advising on purchase and sale of businesses involving FDA-regulated products as assets, assignment, and transfer of FDA approvals and registrations

Experience

Hodgson Russ attorneys represented France-based Cegedim, a leading provider of databases and software solutions for the health care industry, in a deal reached in March to acquire Dendrite International, a former rival in the pharmaceutical marketing solutions sector. The $751 million deal was expected to result in a combined company with operations in more than 75 countries throughout Europe, North and South America and Asia Pacific, and with annual revenues of approximately $1.1 billion. Hodgson Russ assisted with all employment-related legal aspects of the transaction.

Hodgson Russ represented a publicly traded medical device company in the exchange of $118 million in existing convertible subordinated notes for new convertible subordinated notes and the sale of an additional $80 million of new convertible subordinated notes.

Mr. Gilbride served as lead counsel to the owner of the medical office building in conjunction with the formation of a commercial condominium and sale of an entire floor of the building to a nonprofit corporation affiliated with the State of New York.

Mr. Gilbride serves as counsel to Buffalo 2020 Development Corporation, a nonprofit joint venture between the University at Buffalo Foundation and the Research Foundation of the State University of the New York. This entity has been actively engaged in various capital projects in and around the Buffalo Niagara Medical Campus, including development of a $300-million clinical translational research facility and biosciences incubator for University at Buffalo. Through the utilization of a unique public-private partnership condominium structure, Buffalo 2020 Development Corporation was able to develop this facility by co-location with a working hospital, thereby maximizing operational efficiencies and substantially reducing duplicate costs for both facilities.

Mr. Gilbride represented a nonprofit affiliate of the University at Buffalo in conjunction with land acquisition for the development of the new School of Medicine and Biomedical Sciences facility in downtown Buffalo. This $450 million facility, which anchors the university's new downtown campus, represents the largest single construction project ever undertaken by the State University of New York and incorporates an operational subway station in the lobby. This feature necessitated negotiation of a first-of-its-kind long-term air rights lease agreement with the Niagara Frontier Transportation Authority.

Hodgson Russ represents a large life sciences manufacturer in multiple environmental and development matters, including wetlands work, real estate transactions, and project development, as the facility has expanded and provided jobs in Western New York. This work has included obtaining public assistance from state and local agencies such as the county industrial development agency and state development agency, and associated environmental reviews. Partner Paul D. Meosky played an instrumental role in the establishment of an Empire Zone to provide significant economic benefits to the facility.

Hodgson Russ attorneys are actively defending a pharmaceutical marketing company from claims of patent infringement. We initiated *inter partes* reexamination to invalidate the alleged patent. Based on our arguments, the U.S. Patent and Trademark Office held the alleged patent invalid. The USPTO decision is currently under appeal.

A team of Hodgson Russ attorneys represented a medical device manufacturer in connection with the formation of a division to develop new products, including the structure to allow incentive units for partner engineers and doctors.

Hodgson Russ attorneys routinely provide patent-related opinions, including patentability, non-infringement, and freedom-to-operate analysis. For one client, we provided significant guidance involving freedom-to-operate analysis, which resulted in the client engaging in new product development in the biotech area.

Hodgson Russ intellectual property attorneys manage a large and growing medical device patent portfolio for a designers and developer of medical products. The portfolio includes patents and patent applications in Europe, Asia, South America, and the Middle East.

Lead counsel for a publicly-traded medical products manufacturer in state and federal court litigation across the U.S., arising out of a Class I FDA recall of implantable medical devices. Ben obtained a successful resolution of claims through motion practice and mediations.

Hodgson Russ IP attorneys work closely with clients on building and maintaining robust patent portfolios. For a particular client, we provide advice related to patent portfolio management and protection on an ongoing basis and have been involved in evaluation of certain inventions related to devices and methods related to human health, which has resulted in an intricate patent filing strategy, both domestically and internationally.

Hodgson Russ acts as special U.S. tax counsel to U.S. shareholders of a large Swiss pharmaceutical company in connection with the acquisition of shares of that company. For this client, we provide U.S. tax planning services and assistance with U.S. tax filings by U.S. shareholders and foreign intermediary entities to avoid potential U.S. withholding taxes, including Form W-8IMY, Form W-8BEN, and Form W-8EXP filings.

Hodgson Russ lawyers represented a company that develops and manufactures medical device technologies for the cardiac, neuromodulation, vascular, and orthopaedic markets in connection with a merger agreement and tender offer for acquisition of a competing medical device manufacturing company.

In the News

Announcing the GatewayFDA Blog
September 14, 2011

Press Releases

Hodgson Russ Partner Hugh M. Russ, III Honored with Bar Association of Erie County's Award of Merit
September 26, 2022

Publications

Senate Bill Provides Path for Universities to Claim Micro-Entity Status
Intellectual Property & Technology Alert, March 13, 2015

Medical Device Excise Tax Liability of Foreign Manufacturers Selling Into the United States
July 2, 2013

Medical Device Excise Tax Liability of Foreign Manufacturers Selling Into the United States
July 2, 2013

Uncertainty in the Pharmaceutical Industry: FLSA Classification of Pharmaceutical Sales Representatives to Be Determined
The Voice, a publication of the DRI, March 16, 2012

Practicing Innovation: Special Device Commercialization for Innovators Who Continue Practicing
Business Law & Governance, July 11, 2011

Recall: Prevent, Manage, Mitigate, and Survive
February 2011

FDA Releases CDRH Action Plan for 510(k) and Science Initiatives
January 24, 2011

FDA's Medical Device Review Process: 510(k) Premarket Notification Process Scrutinized
November 5, 2010

A New Era in FDA Recall Authority
Medical Device and Diagnostic Industry, October 2010

FDA and CMS Announce Intention to Collaborate in Two Major Areas
October 6, 2010

Presentations & Events

Patenting of Protein Pharmaceuticals
University at Buffalo School of Pharmacy and Pharmaceutical Sciences, November 23, 2020