Buchanan Ingersoll·Rooney | LIFE SCIENCES

# Buchanan Life Sciences:

## *Helping Develop, Defend and Extend the Product Lifecycle at Every Step*

In today's world, every life sciences company is under the microscope, drawing intense scrutiny from government regulators, Congress, state attorneys general and plaintiffs' bar. At the same time, life sciences companies are facing fierce competition from business rivals, tackling formulary placement and taking on adversarial forces, such as pharmacy benefit managers and pharmacy and therapeutics committees. Now, the question becomes how can you protect, defend and optimize the lifecycle of your product in the face of these challenges? Buchanan Life Sciences has the answers.

We're a unique and seasoned legal and government relations group that makes your company, products and goals our central focus. Buchanan Life Sciences offers a rare mix of comprehensive legal services all delivered through one collaborative team including:

- FDA Regulatory
- Intellectual Property
- Corporate Finance
- Government Relations and Public Policy
- Pharmaceutical Reimbursement
- Healthcare
- Litigation
- Antitrust
- Labor and Employment
- Immigration

Our team is structured to advise, plan and execute a comprehensive strategy to tackle your complex legal, business and political issues and turn them into opportunities.

Our attorneys have decades of first-hand career experience with U.S. Congress and state legislatures, the Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), Centers for Medicare & Medicaid Services (CMS), U.S. Patent and Trademark Office (USPTO) and the Department of Justice (DOJ). We fully understand the competitive hurdles that must be cleared in order to fast track products through the maze of regulatory, marketing and political roadblocks. Our national and international clients include pharmaceutical and biotechnology companies, medical device companies, dietary and nutritional supplement companies, life sciences investors, financial institutions, public and private research institutes and more.

From multinational pharma giants to those just starting out, Buchanan Life Sciences can help you navigate current and emerging issues and anticipate growth opportunities down the road. We support your company at every stage of development, from idea conception to commercialization. Our only goals are to protect, defend and optimize your products, company and success.

## HOW WE CAN HELP:

### FDA: Bringing New Therapies to Market

When bringing new drugs or biologic therapies to market – and keeping them there – you can't separate the science from the law. That's why our FDA and Biotechnology team blends great depth in both the legal and scientific issues pharmaceutical and biotechnology companies face throughout the entire lifecycle of a drug, biologic, medical device or other life sciences product.

We provide you with a wide spectrum of services that help get you safely to your destination – FDA approval, marketing launch and strategic lifecycle management. Having represented both brand and generic pharmaceutical and biotechnology companies, we understand the roles that both science and law play in the success of your products.

Few firms can match the level of industry, science and FDA experience we offer. Our attorneys have diverse backgrounds that allow us to offer the unique perspectives that your development and marketing program requires. Our team includes a former FDA associate chief counsel, a former in-house counsel at a leading pharmaceutical company, a lawyer who worked in FDA's Office of Generic Drugs, and individuals with advanced degrees in life sciences and biomedical ethics. Our team also includes a founder and co-chair of the BioNJ Legal, Compliance and Regulatory Forum, which gives our clients access to networking opportunities and best-practice learnings from top companies within the New Jersey life sciences community. We are also well-connected with Biocom, BioFlorida and Life Sciences Pennsylvania. And that's just a start.

Our FDA services include the following and more:

**Regulatory assistance throughout the FDA regulatory process, from pre-IND meetings to postmarket requirement compliance • Addressing complex combination product issues Customized Drug Target Analysis to optimize new product launches and acquisition opportunities Clinical trial guidance • Review of pre- and post-approval of marketing communications Legal assessment of drug safety issues • Government and internal investigations Commercial contracts • Appearance before FDA in regulatory matters, including the Notice of Opportunity for Hearing (NOOH) process.**

### Finding Capital and Controlling Your Agreements

For many companies today, finding sound investments and securing capital can be a challenge. Due to high development and clinical trial costs, life sciences companies seek strategic alliances to share financial risks. Our clients benefit from Buchanan's relationships with financial institutions, established corporations, emerging companies, venture capitalists, private equity firms, healthcare organizations and universities, so you can get the guidance you need to structure the best deal. We span the gamut of helping you to obtain products from academic institutions to financing each stage of development.

We have the industry expertise to advise on:

- Asset Acquisition
- Mergers and Acquisitions
- Securities Offerings
- Private Placements
- Special Purpose Acquisition Companies (SPACs)
- Initial Public Offerings (IPOs)
- SEC Compliance
- Constructing and negotiating contractual agreements required during the product lifecycle, including clinical trial agreements, manufacturing and supply agreements, drug and device development agreements, and master services agreements with contract research organizations

## Protecting and Defending Innovations

Intellectual property (IP) procurement is the cornerstone of our full-service IP offering. We start by working with you to understand your goals and the challenges you face. Our teams will work closely with your technical and business leaders, as well as your internal legal staff, to manage your procurement strategy efficiently and effectively.

Our clients benefit from our extensive industry-specific knowledge and highly relevant and detailed legal counsel. We have worked to protect innovations in the fields of biotechnology, chemicals, electrical, medical devices, pharmaceuticals and many others.

Whether it's patent, trademark or copyright procurement, Buchanan IP can:

- Prepare, file and prosecute domestic and international patent applications
- Represent you in appeals before the Patent Trial and Appeal Board
- Manage global IP portfolios
- Provide comprehensive copyright and trademark coverage
- Prosecute and defend trademark oppositions and cancellations
- Represent you in appeals before the Trademark Trial and Appeal Board

We have especially deep experience defending and fighting pharmaceutical patent cases. Our lawyers have represented some of the world's most respected pharmaceutical companies. Our deep legal expertise enables us to help clients with a range of issues.

Early-Stage Advice:

- New and supplemental drug exclusivity
- Orphan drug exclusivity
- Pediatric exclusivity
- Patent term extension rights
- Patent listing issues

Advanced-Stage Advice:

- 180-day marketing exclusivity
- First applicant and forfeiture issues
- 30-month stays
- Follow-on molecules
- Authorized generics

When it comes to litigation, our lawyers have litigated complex cases with multiple defendants and jurisdictions for blockbuster drugs as well as niche drugs with smaller markets. We understand that each requires its own approach. Our lawyers are skilled courtroom advocates with experience litigating Paragraph IV patent certification (Hatch-Waxman) cases in key venues. Because members of our team have litigated in all major districts of the U.S. and are based in key locations – Delaware (Wilmington), New Jersey (Princeton and Newark), New York (New York City), and Virginia (Alexandria, home of the infamous "Rocket Docket") – the expense of local counsel is often minimized or avoided. We staff our teams in a manner that makes sense for the particular drug and dispute.

## Strategizing Your Commercialization

Our attorneys can create a business strategy to achieve FDA regulatory approvals, create private and public payor strategies, address drug pricing and reimbursement and develop a lawful, pre- and post-approval communication plan – all critical steps to achieve successful commercialization. With decades of first-hand career experience with the FDA, Congress, DEA and CMS, we are also here to help you navigate the political process.

Our Commercial Contracts group works vigorously to ensure that the regulatory aspects of the contracts are accurate, while working closely with clients to ensure their interests are protected. We have extensive experience drafting and negotiating commercial contracts for pharmaceutical companies, including:

- Supply Agreements
- Development Agreements
- Manufacturing Agreements
- Licensing Agreements
- Distribution Agreements
- Quality Agreements

We also counsel clients on the laws and industry standards that apply to the marketing and sale of pharmaceuticals, medical devices, biologics, dietary supplements and medical foods. We help clients with the review of marketing materials and guides, the set up and execution of physician speaker programs and share best practices for collaboration with patient support groups.

## On-the-Ground Government Relations Insight in Washington, D.C.

Buchanan's Federal Government Relations teams are staffed with professionals who understand the impacts of federal legislation and can help you get ahead of issues that are most important to you in an ever-changing political landscape.

In Washington, D.C., our bipartisan team of federal governmental relations professionals assists life sciences industry clients with decades of experience in public policy. The team, including former senior policy advisors to House and Senate members, a former chief of staff to a current high-ranking U.S. Senator, and a former 20-year veteran of federal healthcare lobbying, who also served as the head of federal lobbying for a hospital and healthcare association, have assisted life science companies in planning and executing government relations strategies to assist life sciences businesses at every stage of development.

Through our highly regarded Biotechnology and Food and Drug practices, Buchanan has partnered with a non-profit organization, The 505(b)(2) Platform, to help manufacturers better understand the 505(b)(2) commercialization process and the value of products developed using the regulatory pathway. Of recent concern is providing long-term vision/guidance for reimbursement of product lifecycle management in an era when the government is trying to trim the reimbursement for these products.

## Being Prepared for Litigation

Buchanan is a recognized leader in commercial litigation on behalf of life sciences clients. Our approach focuses on understanding the key legal, industry and scientific issues that are likely to be impactful in resolving or significantly narrowing litigation before trial. Coupled with our significant experience in the procedural aspects of multidistrict litigation, class actions, and other complex litigation, we have had significant success eliminating claims during pretrial proceedings.

Our litigators have long-standing, industry-specific experience in a wide range of matters, including Hatch-Waxman litigation, antitrust matters, consumer fraud litigation, and commercial and contract disputes. Our attorneys are well-versed in assisting clients through investigations by the U.S. Department of Justice, state attorneys general, and other government agencies.

### *Commercial Litigation*

We take great care in ensuring our clients' interests are proactively protected upfront. But if disputes arise, our Life Sciences litigation team is ready to defend your company, products and people. Our team has extensive experience representing life sciences clients in a wide range of contract issues, supplier disputes, manufacturing concerns, pricing issues, employment matters, consumer complaints, recalls and many more.

### *Product Liability*

Whether you are facing a single challenge to an allegedly defective product, a class action, or a coordinated series of filings throughout many jurisdictions, our Life Sciences product liability attorneys are able to swiftly marshal an experienced legal team appropriate to the challenge. We quickly learn about each product and engage with experts about the alleged product problems. In addition, we can work with your insurance carriers to defend products liability claims brought against you. And when an insurance carrier denies coverage for claims, we have experience litigating declaratory judgment actions to try to obtain coverage.

### *Government and Internal Investigations*

We're ready to help you comply with all regulatory requirements at every phase of your product's lifecycle, from development and manufacturing through marketing, distribution and beyond. And can help you establish compliance programs designed to reduce risk from the get-go. However, if a government investigation occurs, we are well prepared to guide you through it. We frequently represent clients before the FDA, DOJ, the Federal Trade Commission (FTC), state attorneys general and various other federal and state regulatory agencies. We help clients proceed efficiently and effectively through investigations, so they can carry on with business-as-usual. In the face of increasing regulations and government oversight, our clients have turned to us to help them overcome investigations dealing with deceptive marketing, labeling issues, data privacy, False Claims Act accusations, as well as state-specific issues like California's Proposition 65 requiring specific chemical exposure product warnings, for example. We can also assist your management team in preparing for congressional oversight investigations and hearings. And we can bring in PR partners to manage crisis situations that could cause irreparable harm to your product's future success and your company's reputation.

### *Antitrust*

The job of our antitrust and trade regulation attorneys is to help you achieve your business goals – period. We are prepared to represent you in all types of antitrust matters, from counseling and compliance, to M&A, to complex jury trials and everything in between. We are well positioned to handle both your antitrust transactional and litigation needs in the U.S. and abroad. Our clients include some of the country's best-known companies in the healthcare and pharmaceutical industries.

We provide comprehensive antitrust services for regulated and non-regulated industries by:

- Establishing antitrust compliance programs and providing ongoing counseling
- Facilitating merger and acquisition clearance and agency review
- Handling antitrust issues associated with licensing, joint technology agreements, settlements and IP contracts
- Providing antitrust counseling on distribution and pricing issues
- Negotiating with government agencies as part of investigative proceedings
- Handling civil antitrust litigation matters, including jury trials, the defense of class actions and opt-out lawsuits
- Representing corporate and individual clients in the defense of criminal antitrust investigations

Our antitrust lawyers are recognized by the American College of Trial Lawyers, the International Academy of Trial Lawyers, The Best Lawyers in America® and Chambers USA. We are often asked to serve as key speakers and panelists for competition law programs, and we frequently author articles and teach classes on competition-related issues.

## Leveraging Workforce Strategies

We take a highly proactive approach to preventing employment problems rather than simply waiting for them to appear. Our approach is designed to avoid or minimize liability and mitigate against costs, burdensome litigation and potential business interruption for employers. We provide assistance on every aspect of labor, employment, employee benefits and immigration matters. We work with human resources managers, senior vice presidents and in-house counsel on everything from regulatory compliance to labor relations, pre-litigation claims, litigation strategy, mediation and alternative dispute resolution and beyond.

The complexity of employment law, exposes employers to the risk of litigation every day, and particularly for life sciences companies. Of course prevention is the best approach, but we are well prepared for law suits, including class and collective action litigation, and ready to defend you before any agency or court. We bring our direct knowledge of the judges or court systems where the cases are filed to add significant value to our clients.

Today's life sciences companies often depend on the global mobility of their workforce. To facilitate your mobility and flexibility, we work with you to obtain and maintain temporary and permanent work visas for your foreign national employees. We also counsel you concerning transfers of employees to live and work in other countries and can assist with obtaining necessary work and residence permits.

## Driving Mergers & Acquisitions

Our M&A team helps you get deals done with a practical mix of deep experience across the life sciences industry and transaction management tools that maximize efficiency. We manage deals as your partner from start to finish, applying our resources across disciplines with a cost-effective approach that centers on increasing value and minimizing risk. We take a highly focused and customized approach to M&A, tailoring our legal team to your specific transaction. If you're a public company engaged in complex, sophisticated corporate transactions, a private equity-sponsored business or a closely held company, we have the breadth and depth scalable to meet your needs.

Over the course of working on thousands of business combinations over decades, we've developed efficient approaches to managing every phase of the process. We don't over-lawyer deals; we avoid needless duplication; and we use effective project management techniques – all designed to meet your goals.