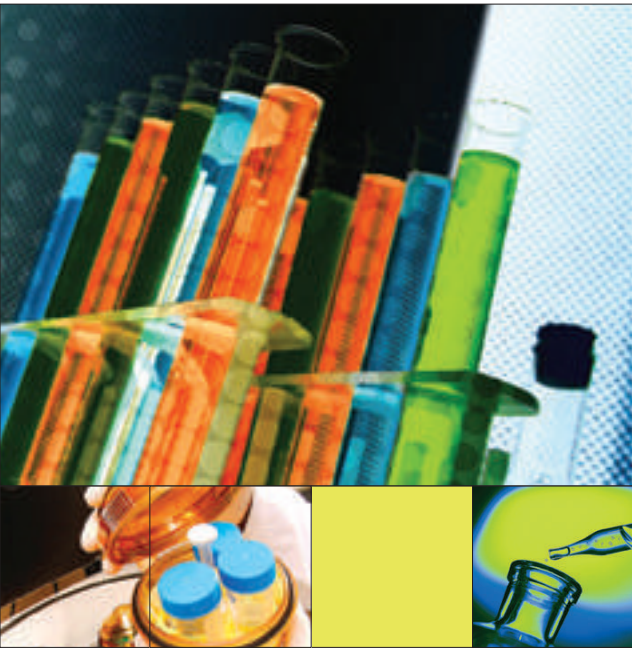


# THOMPSON HINE

Life Sciences Services





## About The Group

*Thompson Hine's Life Sciences group is focused on helping FDA-regulated industries translate their scientific advances to commercial success. A cascade of social, political, scientific, legal and regulatory factors combine to make the life sciences one of the most complex and dynamic business pursuits. Fostering the development of products that improve the condition of living beings also makes the life sciences one of the most rewarding endeavors.*

Our Life Sciences group recognizes that business success and the ultimate ability to positively impact public health depend on efficient, practical approaches. Our experienced professionals help pharmaceutical, OTC/consumer, medical device, biotechnology, food, medical research and other life science businesses successfully navigate the complex laws and regulations that govern them.

People who dedicate their business and professional lives to the life sciences need experienced professionals to assist in the practical interpretation of the laws and regulations that establish their operational framework. These decision-makers also need lawyers with the experience to protect and defend their businesses.

# *L a w y e r s* from our regulatory & corporate *p r a c t i c e* groups . . .



Thompson Hine's Life Sciences practice draws upon experienced professionals with science and industry backgrounds to develop practical, efficient solutions to the challenges faced in the life sciences. The Life Sciences practice comprises a team of professionals that includes:

- Regulatory and corporate lawyers experienced in the areas of research and development, manufacturing and marketing of new products, including clinical trial structuring, investigational and marketed product applications, labeling development, risk management and assessment, and corporate compliance issues.
- Corporate lawyers who have successfully negotiated co-development, co-marketing, cost sharing and risk allocation agreements on both national and international levels.
- Litigators who defend companies in criminal and civil investigations and enforcement actions, including extensive experience with the Food and Drug Administration, the Department of Justice, the Office of Inspector General and state attorneys general.
- Litigators with experience in complex multijurisdictional tort and contract litigation involving efficacy, labeling and safety claims with respect to pharmaceutical, medical device and biologic products.
- Lawyers with experience in food safety regulation.
- Lawyers experienced with the creation and preservation of intellectual property and the unique challenges of life-cycle management in pharmaceutical, medical device and biotechnology businesses.
- Lawyers who provide practical advice to comply with state, federal and global laws that affect life sciences, such as the Federal Food, Drug, and Cosmetic Act; the Prescription Drug Marketing Act; the Food and Drug Administration Modernization Act; the Prescription Drug User Fee Act; the Medical Device User Fee and Modernization Act; the Controlled Substances Act; the Controlled Substances Import and Export Act; the Medicare Modernization Act; the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the False Claims Act; Hatch-Waxman and the Anti-Kickback Act and applicable EU directives.
- Lawyers with experience in animal health regulation.
- Lawyers with experience in planning, implementing and monitoring clinical trials; preparation and defense of investigational and marketing applications and advisory committee presentations; and in all other facets of drug and medical device labeling, packaging, CMC development, cGMP issues, hearings and negotiations within the reviewing divisions of FDA, including CDER, CBER and CDRH.
- Lawyers with extensive government contacts and experience in policy development and lobbying with respect to state and federal legislative and administrative initiatives impacting the life sciences (including tort reform, importation, trade regulation, controlled substance restrictions, Medicare reform, Medicaid reform, and other access, reimbursement and operational hurdles).
- Lawyers with practical real-world experience with bioterrorism issues.

Lawyers in our Life Sciences group are experienced with the business impact brought by the interplay of state and federal laws, regulations and policies that act upon the life sciences. That's why we do more than just identify risk in business practices. We work with clients to understand their businesses and bring our experience to assist them in implementing innovative solutions that allow them to do what they do best – deliver products and services that improve the health and well-being of living beings.



## Representative Clients

Our clients include the following life science providers:

- Pharmaceutical companies engaged in branded, consumer and generic pharmaceuticals
- Biotechnology innovators creating the next generation of medicines
- Medical device companies
- Animal health companies
- Contract research organizations
- Institutions responsible for medical research and development
- Health-related e-businesses
- Physicians, health plans and hospitals
- Companies engaged in the development of bioterrorism protection



## Representative Matters

Thompson Hine's Life Sciences group draws from a diverse range of experience. Whether your business requires regulatory representation before governing agencies for the approval of a key product, the development of a comprehensive compliance program to prevent and defend against claims of off-label promotion, the optimization of a tax strategy in a global co-development agreement or defense of your products from product liability claims, our lawyers have the ability and experience to meet your needs. Following is a list of some of the projects our Life Sciences lawyers have undertaken recently:

- Provided regulatory guidance and representation on investigational and marketed product matters brought before global regulatory bodies including FDA, EMEA and MHRA.
- Counseled life sciences clients in all phases of global product launch, including clinical trial development, risk management and assessment both pre- and post-product launch, publication plans, FDA dialogue, product and disease state education, training and promotional strategy.
- Provided advice on issues pertaining to the import and export of controlled substances and raw materials.
- Advised life sciences clients in the application of FDA regulations to product labeling, advertising and promotional and educational activities, as well as provided advice on limiting liability exposure relating to those communications (including product liability, intellectual property, competition laws, and fraud and abuse laws).
- Represented a pharmaceutical company in the resolution of a corporate compliance concern.
- Counseled biotechnology and pharmaceutical clients on the use of accelerated and special review opportunities including special protocol review processes, orphan drug designation, combination drug/device products and individualized patient therapy.

*P r o v i d i n g* o u r c l i e n t s  
w i t h w i d e - r a n g i n g  
*g u i d a n c e . . .*



- Represented a pharmaceutical client in multidistrict product liability litigation.
- Represented a life sciences client on a variety of international transactions including an international licensing arrangement for a controlled substance, cost allocation for new product development and profit sharing arrangements.
- Provided advice on the informed consent process, clinical trial recruitment strategy and related advertising and education.
- Provided advice on the use of coupons and vouchers for prescription drugs.
- Advised a pharmaceutical client on the structure and operation of patient assistance programs.
- Provided advice on DEA, PDMA and licensing restrictions pertaining to prescription drug sampling.
- Advised a life sciences client in the establishment of a compliance program, including structural formation, policy and procedure development, training and advice.
- Established educational and research grant review process for FDA-regulated client.
- Provided advice on issues relating to orphan drug and compassionate use programs.
- Represented medical device, biotech, pharmaceutical clients, and institutional clients on acquisitions and asset transfer arrangements.
- Advised life sciences client regarding the appropriate role of the client in medical communications and the publication of clinical trial results.
- Advised a pharmaceutical client on structuring sales contracts, formulary support activities and “value added” initiatives to support its managed care customers.
- Developed and delivered numerous training sessions on life sciences compliance matters and legal and government trends to private and public audiences ranging from sales representatives to legal and regulatory professionals.
- Developed public comment process and composed *Federal Register* responses for a pharmaceutical client regarding FDA and OIG initiatives.
- Represented and advised a pharmaceutical manufacturer on state and federal legislative and administrative initiatives including those related to tort reform, importation, Medicare, Medicaid, controlled substances, and fraud and abuse.
- Structured a global clinical trial site and investigator programs for medical device and pharmaceutical clients.
- Advised early stage biotechnology venture in licensing deal.
- Negotiated and drafted sponsored research agreements and technology/intellectual property license agreements between for-profit corporations and not-for-profit institutions.

# OUR CLIENT SERVICE PLEDGE

## What Our Clients Can Expect From Us . . .

### 1. We will know your business.

We make it our business to understand your business. We will invest our time and resources to develop and maintain knowledge of the dynamics that impact both your industry and your organization. Understanding your business will help us provide better counsel to you.

### 2. We will plan our engagements with you.

We know that clients differ in their goals, risk tolerance and a variety of other factors that must be taken into consideration before work can begin on any matter. At the beginning of every significant matter, we will work with you to develop a plan to meet your strategic goals. By agreeing on a plan at the beginning—and adjusting it as needed—we will stay focused on what is most important to you.

### 3. We will manage your work as if we were the client.

We will work with you to manage your costs. We will staff every matter with the right resources, and we will manage the work as if we were the client—delivering the highest quality of service on time and in the most cost-effective manner.

### 4. We will be available when you need us.

We recognize that you often need to make swift decisions and act quickly. We will be ready to act for you when you need us, and we will make ourselves available wherever and whenever necessary.

### 5. We will communicate often.

Our goal is that you will never be surprised about developments in anything we are handling. We will provide regular updates on the progress of your matters, including all significant developments and changes to scope, timeline or budget.

### 6. We will provide the highest-quality counsel.

Above all else, we stand for the highest quality. Our lawyers, paralegals and staff take pride in the work they do. From the boardroom to the courtroom, you can count on Thompson Hine for the highest-quality service.

## What Our Clients Can Do To Help . . .

### 1. We ask you to share your goals.

The more we know about your goals, the better we can manage our services to help you attain them. If your goals change as a matter progresses, we ask that you tell us, so we can adjust our approach to meet your expectations.

### 2. We want to know your preferences for working with us.

We ask you to tell us your preferred methods of communication, invoice and billing procedures, and anything else that is important to you, so that we can deliver our service the way you want it.

### 3. We need your feedback.

We want your feedback on our performance so that we can continue to meet and exceed your expectations.

## About Thompson Hine

Established in 1911, Thompson Hine is a business law firm dedicated to providing superior client service. The firm has been recognized as one of the Best Corporate Law Firms in America in an annual survey of corporate directors conducted by *Corporate Board Member* magazine. With approximately 400 lawyers in offices in **ATLANTA, CINCINNATI, COLUMBUS, CLEVELAND, DAYTON, NEW YORK** and **WASHINGTON, D.C.**, Thompson Hine serves premier businesses worldwide, including:

AKZO NOBEL INC.

AMERICAN CHEMISTRY COUNCIL, INC.

AMERICAN STEAMSHIP COMPANY

AVERY DENNISON CORPORATION

BUCKEYE POWER, INC.

CENTRAL GULF LINES, INC.

CENTRAL HUDSON GAS &

ELECTRIC CORPORATION

CH ENERGY GROUP, INC.

CHIQUITA BRANDS INTERNATIONAL, INC.

COLUMBUS ZOO AND

AQUARIUM/ZOOMBEZI BAY

CROWN EQUIPMENT CORPORATION

THE DAVEY TREE EXPERT COMPANY

DEVELOPERS DIVERSIFIED

REALTY CORPORATION

EATON CORPORATION

ENERGIZER/EVEREADY

EXXON MOBIL CORPORATION

FIFTH THIRD BANK

FORD MOTOR COMPANY

FORMICA CORPORATION

GOODRICH CORPORATION

THE GOODYEAR TIRE &

RUBBER COMPANY

THE HARTFORD

JO-ANN STORES, INC.

KEYCORP/KEYBANK

LEXISNEXIS

LIMITED BRANDS

THE LUBRIZOL CORPORATION

MEADWESTVACO CORPORATION

MILACRON INC.

MISSION ESSENTIAL PERSONNEL LLC

MORGAN STANLEY

NATIONWIDE MUTUAL

INSURANCE COMPANY

NETJETS INC.

NEWELL RUBBERMAID INC.

NORDSON CORPORATION

OFFICE DEPOT, INC.

PARKER HANNIFIN CORPORATION

POLYONE CORPORATION

PPG INDUSTRIES

THE PROCTER & GAMBLE COMPANY

R+L CARRIERS, INC.

S.C. JOHNSON & SON, INC.

SHELL OIL COMPANY

THE SHERWIN-WILLIAMS COMPANY

SOLVAY S.A.

STERIS CORPORATION

THE TORO COMPANY

VERIZON

WELLPOINT, INC.

WHIRLPOOL CORPORATION



2002 • 2005 • 2006 • 2007  
2008 • RECIPIENT



Ranked as a Leading Firm  
by Chambers USA • 2003 - 2010



Ranked as a Top 25 Firm for  
Client Service • 2008 • 2009 • 2010

## For More Information

For more information, send an email to [AskUs@ThompsonHine.com](mailto:AskUs@ThompsonHine.com) or visit our website at [www.ThompsonHine.com](http://www.ThompsonHine.com)

**THOMPSON  
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ATTORNEYS AT LAW

THOMPSON HINE LLP

[WWW.THOMPSONHINE.COM](http://WWW.THOMPSONHINE.COM)

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