

CONFIDENTIAL

May 2024

Life Sciences

COVINGTON

BEIJING BOSTON BRUSSELS DUBAI FRANKFURT
JOHANNESBURG LONDON LOS ANGELES NEW YORK
PALO ALTO SAN FRANCISCO SEOUL SHANGHAI WASHINGTON

Firm Overview

CORPORATE

- 550+ M&A deals valued at \$750+ billion in the past five years
- 300+ transactional lawyers in New York, Boston, Washington, California, London, Frankfurt, Beijing, Shanghai, Seoul, Dubai, and Johannesburg, including lawyers focused on Latin America, India, Japan and Israel
- 350+ capital markets deals valued at \$115+ billion in past five years
- Combination of regulatory and industry expertise along with transactional practice—optimizes effectiveness and efficiency

LITIGATION

- 45 trials to verdict in the last five years
- Eight members of American College of Trial Lawyers
- 140+ patent litigators; 90 ITC Section 337 cases over 30 years
- String of recent products/mass torts trial wins
- \$20+ billion in insurance recoveries secured for policyholders
- 50 international arbitration lawyers

REGULATORY AND PUBLIC POLICY

- Leading practices in broad array of regulated sectors
- Senior officials from the Food and Drug Administration, U.S. Departments of Commerce, Defense, Energy, Health and Human Services, Homeland Security, Justice, Treasury, and State, as well as EPA, CFTC, SEC, OCC, ITC, and FTC
- Many former congressional staff
- A number of former diplomats and other senior U.S., UK, EU, and Asian government officials

WHITE COLLAR AND INVESTIGATIONS

- Team of former prosecutors in Washington, New York, and California
- Significant investigations capabilities in EU, China, U.S., and UK
- Alumni of 30 investigating agencies in U.S. and EU
- 65+ countries where we have handled investigation matters in the past two years
- 30+ government declinations since 2017

Practices in Key Substantive and Regulatory Areas

- Anti-corruption
- Antitrust and Competition
- CFIUS
- Communications, Media, and Entertainment
- Data Security and Cybersecurity
- Election and Political Law
- Energy and Environment
- ERISA, Benefits, and Pension De-risking
- Export Controls and Economic Sanctions
- Financial Services
- Food, Drug, and Device
- Global Mobility and International Employment Compliance
- Government Contracts
- Health Care and Market Access
- Insurance Recovery
- Intellectual Property
- International Tax and Transfer Pricing
- International Trade Controls
- Life Sciences
- Public Policy
- Securities

1,300 +

Lawyers and
Advisors Worldwide

50 +

Languages Spoken

120 +

Former Government Officials and
Diplomats

17

Times named to The American
Lawyer's "A-List"

245,000 +

Pro Bono Hours
Provided in 2022

1919

Year Founded in Washington

Integrated, Full Service, Multi-disciplinary Life Sciences Practice Capabilities

Our lawyers understand the life sciences, food, and technology industries, and are adept at seamlessly integrating the firm's extensive sector-specific expertise to meet the specialized needs of companies around the world.

Our sector-specific focus enables us to provide nuanced regulatory advice and comprehensive, practical solutions for clients in the wide range of life sciences sectors.

We offer unsurpassed diligence capabilities across the full range of key areas to support transactions.

Clients consistently commend our ability to translate diligence findings into the drafting and negotiating process.

“The deepest bench of attorneys and a level of industry specific expertise that no other firm can match.”

LMG Life Sciences

FDA, CMS, FTC,
EMA, MHRA
Regulation

Data Privacy &
Cybersecurity

Intellectual
Property

Advertising &
Consumer
Protection

M&A, VC,
Finance, ECM

Collaborations,
Licenses,
Commercial
Agreements

Technology
Transactions

Tax

Antitrust/
Competition

Product Liability
& Mass Torts

Commercial
Litigation

Class Actions

White Collar
Defense &
Investigations

ESG/Business &
Human Rights

Anti-Corruption/
FCPA

US, UK, EU
Public Policy

Full Life Sciences Life Cycle Support

Covington’s Life Sciences Industry Group integrates the firm’s extensive transactional, regulatory, litigation, and intellectual property experience across multiple offices to meet the specialized needs of life sciences companies

“They have expertise that is unmatched, they’re responsive and the work product we get is what we ask for, better in fact...”

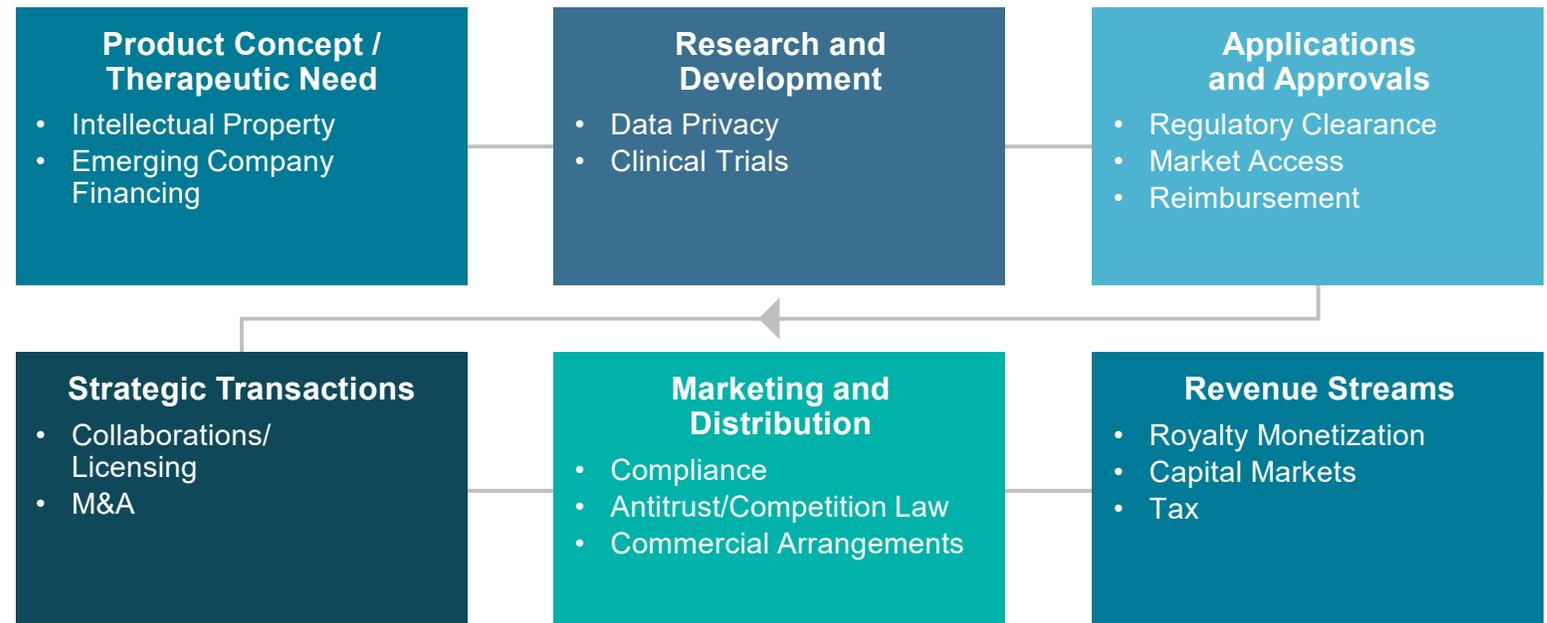
Chambers USA

“We like the way they bring together people from different practice areas to provide strategic help.”

Chambers UK

“The deepest bench of attorneys and a level of industry specific expertise that no other firm can match.”

LMG Life Sciences



Representative Life Sciences Clients



Representative Food and Agri-Business Clients



Covington's Israel Initiative

Drawing on the deep expertise of our regulatory, corporate, litigation, and investigations lawyers and advisors, we have the exceptional ability to help Israeli clients achieve their critical business goals and navigate their most complex legal problems, deals, and disputes.

Our experience and understanding of the Israeli business environment, coupled with the relationships we have developed on the ground in Israel, enable us to provide timely, practical, and effective advice on Israel-related matters for all of our clients.

COMPREHENSIVE APPROACH TO MATTERS

The Covington team handles a broad range of Israel-related matters by working seamlessly across our firm's practices, initiatives, and industry groups to advance our clients' business priorities and provide substantive and comprehensive services tailored to our clients' specific needs.

Using this multidisciplinary approach, Covington's Israel Initiative provides legal, regulatory, and policy advice to Israeli individuals and companies—from multinationals to medium- and small-sized businesses, including unicorns and startup ventures—to help them achieve their business goals across the globe.

GEOGRAPHIC REACH AND GLOBAL RESOURCES

With offices in the U.S., Europe, Middle East, Africa, and Asia, and a network of expert local partners, we use our extensive insights into the workings of governments around the world to provide practical business advice. Covington's professionals include more than 120 former government regulators, enforcers, diplomats, lawmakers, and professionals with a breadth of experience advising companies around the world. Notably, our Dubai colleagues are exceptionally well-positioned to help Israeli companies seize opportunities presented by the Abraham Accords.

Our Israel Initiative is supported by skilled advisors on the ground in Israel and by in-house, Hebrew-speaking teams that leverage the full breadth of Covington's international expertise. We also regularly collaborate with Israeli law firms and other consultancies to provide integrated and strategic approaches to time-sensitive legal and policy-driven challenges and opportunities.

70⁺

lawyers firm wide recognized
by *Chambers Global*

Ranked among the leading
corporate practices by
Corporate Board Member,
Chambers, and *Legal 500*

Recognized as a leading food,
drug and device regulatory firm
by *Chambers*, *Legal 500*,
Law360, and *LMG Life
Sciences*

Food, Drug, and Device Regulatory

Covington has one of the largest and most established food, drug, and device regulatory practices in the world representing leading companies and trade associations globally in key sectors, including:

- Pharmaceutical
- Medical device
- Technology (digital health)
- Food
- Dietary supplements
- Animal food and drug
- Cosmetics

DEEP BENCH OF LAWYERS WITH REGULATORY EXPERIENCE

- We cover every facet of U.S. food and drug regulatory law, including all matters within the regulatory purview of the FDA, federal and state fraud and abuse issues, Medicare, Medicaid, and related reimbursement areas.
- 14 former U.S. Food and Drug Administration (FDA) officials, including 2 former Chief Counsels and a former Chief of Staff to the FDA Commissioner.
- Deeply-rooted experience in matters relating to drug and device approvals, clinical trials, advertising and promotion, good manufacturing practices (GMP) and quality system compliance, and various enforcement and rulemaking proceedings.
- Representation before the FDA, FTC, and USDA, and litigation at all levels in the federal courts.
- Uniquely suited to assist companies seeking to establish themselves in other jurisdictions.

FOOD AND DRUG LAW COUNSELING

- Advertising, Labelling, and Promotion
- Manufacturing, Product Quality, and Inspections
- Market Access and Drug Pricing
- Medicare and Medicaid
- Trade Associations
- Crisis Management and Litigation
- Legislation

MULTIJURISDICTIONAL COVERAGE

- More than 30 lawyers in London and Brussels qualified in various EU Member States, and have actively participated in the development of key pharmaceutical legislation in the UK and Europe.
- Decades of experience in China and throughout Asia region, frequently serving as advisors or advocates on projects and transactions of pan-Asian importance.

Band 1

for Life Sciences across *Chambers'* U.S., UK, Europe, China, and Global surveys

250⁺

Life Sciences Industry Lawyers

80⁺

Food, Drug, and Device Regulatory Lawyers

Mergers & Acquisitions

Our M&A team represents biotech, biopharmaceutical, biotech, medical device companies, and life sciences investors in public and private acquisitions globally. We provide thorough and sophisticated analysis of the agreements, regulatory issues and IP rights that are central to M&A transactions in the life sciences industry.

Of Covington's M&A team

"The firm has a strong M&A practice."

"...very dedicated, very customer-oriented and very practical."

Chambers USA

550⁺

550 M&A deals valued at over \$750B in the last 5 years



Chambers USA 2023

Corporate/M&A: Highly Regarded



Chambers UK 2023

Corporate M&A: Mid-Market (London firms)

300⁺

transactional lawyers firmwide in financial centres around the globe

PUBLIC AND PRIVATE M&A

- Acquisitions and dispositions of companies, discrete content, products, rights and/or technologies
- Hostile and friendly transactions
- Spin-offs and split-offs
- Pre- and post-M&A reorganization matters

STRUCTURED TRANSACTIONS

- Deals with contingent value rights or deferred consideration mechanics
- Continued management equity participation
- Buy-back options/asset reversion rights
- Joint ventures and other strategic alliances

MULTI-DISCIPLINARY EXPERTISE

- We draw on Covington's multi-disciplinary expertise in technology to ensure that transactions work from commercial, regulatory, and IP perspectives

VERSATILITY

- Our team has the ability to shift fluidly from one form of transaction to another as our clients' business goals evolve

Strategic Collaborations & Licensing Transactions

With 30+ lawyers focused on life sciences collaborations and transactions, Covington is an industry leader in structuring, drafting and negotiating highly complex global alliances, strategic collaborations, joint ventures, licenses and other technology-focused agreements.

The Life Sciences Transactions practice has recruited, developed, and promoted an outstanding and diverse pool of talented lawyers – our team is 66% women, 37% people of color, and 13% LGBTQ+.

We represent both innovators and acquirers of technology and have specialized expertise in late-stage, marketed, and combination product arrangements as well as experience with products at all stages of R&D and across the product life cycle.

R&D /
Discovery
Agreements

CRO/CMO
Agreements

Clinical Trial
Agreements

Technology In-
Licensing
Agreements

Companion
Diagnostic
Agreements

Option
Agreements

(Co)
Promotion
Agreements

Strategic
Collaboration
Agreements

Distribution
Agreements

“Covington & Burling LLP is renowned for ... expertise in strategic partnerships, collaboration agreements and licensing deals... The group has impressive knowledge of all disciplines within life sciences, including cutting-edge technologies such as digital health and regenerative medicine.”

Chambers USA

Global Food Regulatory

Covington’s Global Food Industry Group advises leading food, beverage, and dietary supplement companies and trade associations on the broad range of issues that may arise from product development, safety, labeling, and promotion, as well as overarching nutrition and public health policy considerations, in the United States, Europe, China, and elsewhere across the globe.

Our lawyers have extensive experience assisting in developing and executing “multi-branch” strategies and regulatory solutions to address legislative and regulatory risks and opportunities.

“Covington occupies a powerful position within the food and beverage space. Provides comprehensive regulatory compliance advice thanks to the presence of lawyers with significant FDA experience.”

Chambers and Partners

Unmatched history

Involved in every major piece of food-related legislation and regulation for more than a century

Band 1

Chambers USA, Nationwide: Food & Beverage Regulatory and Litigation

Unparalleled record of involvement

In the most important legislative developments in the food arena, including the FDA Food Safety Modernization Act of 2011 (FSMA).

Full Spectrum of Services Devoted to Food and Beverage

- Covington provides services to assist clients in all aspects of food and beverage product development and marketing, including:
 - Regulatory compliance with FDA, FTC, USDA, and global regulatory bodies
 - Labeling, advertising, sustainability, and marketing
 - Product development, supply, distribution, import/export
 - Ingredient and sourcing considerations
 - Nutrition and public health policy
 - Food safety and Good Manufacturing Practices
 - Mergers & Acquisitions
 - Commercial and class action litigation
- We serve as outside counsel to over 20 major food and beverage trade associations, including the Consumer Brands Association and the American Bakers Association, as well as leading food and beverage companies, addressing individual company issues as well as broad industry interests and concerns.

China/APAC Drug Regulatory

Our Drug Regulatory team has experts in the U.S. and China, with a reach and resources to assist companies with a wide range of pharmaceutical and biotechnology matters as they do business in the Asia Pacific region.

Covington's unparalleled record of advising clients on pharmaceutical and biotechnology regulatory matters for over a century enables us to assist our clients to achieve their global business goals while managing regulatory and litigation risks.

We have decades of experience in China and throughout the Asia region, and frequently serve companies and trade associations as advisors or advocates on drug regulatory projects and transactions presenting novel and complex issues of pan-Asian scope and importance. With our drug regulatory team based in China and the United States, we are able to seamlessly advise our clients on their regulatory questions regardless of where they are based

Business Law Awards - Government and Public Policy

China Law Business Journal 2022

***“Covington & Burling
has a real breadth of
life sciences capabilities
in the area.”***

Chambers and Partners

Recognized by Chambers as a “Band 1” firm for Life Sciences China and Global surveys

Our Capabilities

- Our drug regulatory team has extensive experience advising clients on numerous aspects of the drug regulatory process before the National Medical Products Administration (NMPA).
- We have advised clients on various NMPA matters, including pre-clinical and clinical development, registration strategies, intellectual property (IP) issues, pharmacovigilance, GxP inspections, and other post-market compliance issues.
- Our team has extensive experience with small molecule drugs and biologics, including vaccines, gene therapy products, and radiopharmaceuticals.
- Our teams are built on a strong foundation of Chinese nationals trained both in the United States and China as well as lawyers and advisors from the United States with deep China experience.
- Our lead partner, John Balzano, has over 18 years of experience in this area and speaks and reads both Mandarin and Japanese.

Regulatory Due Diligence Private Equity Funds

With more than 250 lawyers practicing across the U.S., Europe and Asia, together with a network of specialist life sciences firms in key jurisdictions, Covington's market leading Life Sciences practice advises private equity firms and their portfolio companies on complex regulatory risks from a global perspective.

We provide unsurpassed regulatory support for transactions in all areas including:

- Drugs
- Biologics
- Medical Devices
- Food, Beverage, and Dietary Supplements
- Cosmetics
- Animal health

Unsurpassed Capabilities

- Unsurpassed diligence capabilities across full range of key areas to support all manner of transactions
- Use industry knowledge to provide sophisticated, in-depth analysis
- Identify relevant (but not always obvious) issues and proposing practical solutions is our hallmark
- Clients consistently commend our ability to translate diligence findings into drafting and negotiation process

“Experts in this field. Very willing to listen to a company’s business needs and strategies, also taking into account different companies’ risk profiles and tailoring their advice....”

Chambers and Partners

Regulatory Know-How

- Our exceptional due diligence can uncover regulatory risks and potential obstacles across a wide range of areas relevant to life sciences transactions, including:
 - Product Approval/Clearance
 - Clinical Trials and other R&D Issues
 - Advertising and Promotion Risk
 - GxP, Inspections, and Recalls
 - Anti-Kick Back/Corruption Risks
 - Privacy, HIPAA, GDPR, and Data Security
 - Price Reporting/Sunshine Act
 - Government Enforcement Actions

Unmatched work

- We are often engaged as co-counsel to colleagues at other law firms and we have strong relationships with M&A lawyers at many peer firms.

Digital Health

Covington's market-leading global Digital Health team has unmatched breadth and depth of experience providing clients with solutions to navigate the legal, regulatory and policy issues that affect their digital health products and services.

We represent a variety of key players throughout the digital health ecosystem, including:

- Pharmaceutical companies
- Medtech companies
- Technology companies
- Emerging digital health companies
- Health data storage and analytics platforms
- AI platform providers
- Investors
- Trade associations

AT THE FOREFRONT OF THE DIGITAL HEALTH ENVIRONMENT

- We help clients with a myriad of regulatory issues posed by AI and digital health technologies and services, including regulatory classification of software, devices, and combination products; drug regulatory issues implicated by digital health products that are associated with pharmaceuticals or developed by or in collaboration with drug manufacturers; the application of market access rules; the regulation of healthcare and e-commerce services; wireless device regulation; and pricing and reimbursement.
- We bridge the gap between pharma and device clients operating in highly regulated environments and tech clients operating in relatively less regulated environments understand each other to create balanced and workable deal structures.
- With exceptional service, we are uniquely positioned to help clients respond to these challenges anywhere in the world at any given moment.

30⁺

Individual Attorneys Recognized for excellence in life sciences by the leading legal industry surveys

EXPERTISE ACROSS RELEVANT SUBJECT AREAS

- Regulatory and Public Policy
- Privacy and Data Security
- Commercial
- Market Access and Reimbursement
- M&A and Corporate
- Liability Considerations
- Government Contracting
- Antitrust and Competition
- Health Care Compliance
- Artificial Intelligence
- ESG
- Intellectual Property

Global Practice

Spanning the United States, Europe, Asia, the Middle East and Africa

Covington Digital Health Blog

Developments and Trends in Digital Health, eHealth and Health IT

Health Care

Covington is at the forefront of helping leading life sciences companies navigate the regulatory complexities and compliance challenges related to medical and health law.

We advise on advertising and promotion issues; market access strategies; health technology assessments; coverage, coding and payment; compliance with fraud and abuse laws; protection of health information; price reporting; interactions with health care professionals; and a host of other health care regulatory issues.

We have also worked extensively on emerging strategic issues under the U.S. Inflation Reduction Act. The Covington team is skilled at providing legal and strategic advice—we know how to help clients navigate gray areas and maximize opportunities.

Our Expertise

- Affordable Care Act
- Anti-Kickback, Stark self-referral prohibitions and related state laws
- Common rule on protections for human research subjects
- DRGs and reimbursement of hospital treatments
- eHealth, mHealth and telemedicine
- Electronic health records and meaningful use
- False Claims Act
- Graduate medical education
- Health Insurance Exchanges and Qualified Health Plans
- Health privacy and data protection, HIPAA, HITECH
- Home and community-based supports and services
- Marketing rules and restrictions
- Medicaid drug pricing and rebates
- Medicare Part D
- Out-of-network reimbursement
- Regulation of interactions with health care professionals
- Reimbursement for services, medical devices and drugs, Medicare coverage, and coding
- State Medicaid programs and State Demonstration Programs
- State licensing and scope of practice
- Sunshine Act and international transparency rules
- UK NICE Pharmaceutical Price Regulation Scheme (PPRS)
- Wellness programs
- 340B drug pricing and reporting

Covington's Market Access Treatise

Market Access, Pricing, and Reimbursement of Drugs and Devices: Legal Principles and Practice

Published Spring 2023

White Collar Investigations & Compliance

With decades of experience with the regulators and enforcement authorities with whom our Life Sciences clients interact, we leverage our expertise and credibility to provide comprehensive, cross-border representation.

- One of largest collections of former prosecutors in private practice.
- Alumni of 30 of the most active investigating agencies in U.S. and EU, who deliver unmatched credibility with government enforcement officials.
- Team includes Eric Holder, former U.S. Attorney General, and 2 former Heads of U.S. Department of Justice Criminal Division.

130⁺

Former government prosecutors

20⁺

declinations since 2019

Broad experience in the Americas, Africa, Europe, and Asia

Our Capabilities

Government Enforcement Actions

Internal Investigations

Compliance Advice and Program Evaluations

Risk Assessments

Transactional Due Diligence & Post-Closing Integration

Qui Tam Litigation

Chambers
AND PARTNERS
Highly ranked



Compliance Practice Group of the Year Since Inaugural Year



Top 10 Investigations Practice Since 2019

CFIUS/FDI

We offer dedicated CFIUS/FDI teams in the U.S., UK, Germany, and capabilities in the Middle East, Africa, and Asia to identify, and help clients navigate, global investment regulatory barriers at an early stage and provide long-term strategic advice.

We have significant perspective on the broader U.S., Asia, EU, and UK investment policy landscape and strong relationships with government officials in the U.S., UK, EU Member States, and the EU Commission.

DEEPEST CFIUS/FDI TEAM OF ANY FIRM IN THE WORLD, WIDELY RECOGNIZED FOR OUR LEADING CFIUS PRACTICE

- Twice named “Dealmakers of the Year” by The American Lawyer: 2016 (CFIUS approval for GLOBALFOUNDRIES’ \$1.5 billion acquisition of IBM’s semiconductor unit) and 2019 (CFIUS-based defense of Qualcomm against the hostile takeover bid by Broadcom).
- Team includes former Cabinet and sub-Cabinet level officials from virtually every CFIUS member agency, including Treasury, State, Commerce, Energy, Homeland Security, Defense, Justice, and USTR.
- Significant perspective on the broader EU and UK investment policy landscape and strong relationships with government officials in EU Member States, the EU Commission, and the German and UK governments.

\$500B+

In transactions for the world’s most sophisticated investors and transaction parties

Chambers USA 2023

CFIUS (Nationwide) – Band 1.
The only firm with two CFIUS partners ranked in top tier of *Chambers USA*

ADVISE CLIENTS IN CONNECTION WITH M&A AND OTHER TRANSACTIONS

- Unrivaled deal list for transactions across industry sectors, as well as transactions involving life sciences.
- Clients routinely turn to us for bet-the-company matters, as evidenced by the defense of Qualcomm in the proposed acquisition by Broadcom and GLOBALFOUNDRIES’ acquisition of IBM’s Microelectronics Division.
- We work closely with Covington’s premier International Trade Controls practice to plan and execute transactions that involve sensitive technologies.

Described as “field leading”

Covington “lawyers combine technical skills with political judgments that are unparalleled”

Global Antitrust and Competition

Global Reach: Our global team is fully integrated, and works closely with colleagues in the U.S., Asia and Europe

Regulatory Capabilities: Our team is unparalleled in its ability to assist multi-national companies, drawing on Covington's deep regulatory capabilities and understanding of regulated industries

Regulator Insight: The team has extensive relationships with the competition law enforcement authorities in the U.S., Europe, the UK, China, and elsewhere. With multiple former regulators and enforcement officials among our ranks, we can offer clients first-hand knowledge of how matters are handled on the side of the regulator

“Powerhouse international practice”

Global Competition Review

80 +

Global Antitrust Litigation Lawyers strategically located in the U.S., Europe, and Asia

14

Former Senior Enforcers are senior lawyers in our Antitrust Practice

Consistently honored as one of the leading antitrust practices by *Chambers, GCR, Legal 500, and Law360.*

Our Expertise

- Covington particularly excels at advising life sciences companies on issues at the intersection of antitrust and patent law. Our team, strategically located in the U.S., Europe, and Asia, collaborates closely to identify potential competition law issues in jurisdictions around the world. Covington is truly a one-stop shop for global competition concerns for our life sciences clients.
- Our deep experience in the industry enables us to issue spot for regular antitrust counseling and provide business-friendly advice on the most cutting edge competition issues.
- Covington regularly handles cutting-edge litigation for life sciences companies covering the full range of competition-related disputes, including individual and class action litigation and monopolization claims.

Our Value-Add

- With multiple former regulators and enforcement officials among our ranks, we are powerfully equipped to help clients anticipate potential issues, navigate merger reviews efficiently, respond to investigations and enforcement actions effectively, litigate on behalf of our clients, and develop practical compliance programs to reduce risks proactively.

Product Liability

For decades, Covington has litigated a wide range of high stakes, high profile mass torts for clients across industries. We understand the significant risks that product liability and tort litigation can pose to our clients' businesses.

We develop thoughtful, effective strategies to manage not only the financial risk presented by plaintiffs, but also the political and reputational risks that are often so intertwined in tort litigation.

16

Trials to verdict

Band 1

Chambers USA, Nationwide:
Product Liability & Mass Torts

Historic Wins

NJ Supreme Court, reshaping law on experts and warning adequacy

Our Expertise

We have extensive experience with the range of federal agencies, such as the Food and Drug Administration, Consumer Product Safety Commission, and the Environmental Protection Agency, and others, and can assist with compliance to existing regulations and navigation of the investigatory processes. We advise on:

- Impact of manufacturing deficiencies
- Product recalls
- Liability of component part manufacturers

We help clients at every stage of:

- Conducting Product Risk Assessments
- Strategizing Responses to Consumer Complaints
- Managing Product Liability Cases
- Steering Multidistrict Litigation
- Handling Case Appeals

Our Value-Add

- The team's success relies on Covington's core strengths some of the top trial lawyers in the country; keen strategic judgment; the experience and resources to manage sprawling multi-jurisdictional litigation; access to world-class regulatory and investigative expertise; and exceptional oral and written advocacy.

Patent Litigation

- Skilled at managing every stage of case from pre-litigation assessment and planning through trial and appeal
- Successfully litigated cases in every significant U.S. patent jurisdiction
- Practice includes two former PTAB Judges
- Frequently take cases to trial, as both plaintiffs and defendants, in federal district court, the U.S. International Trade Commission, and the Patent Trial and Appeal Board
- Longstanding, highly successful appellate practice
- Experience with wide range of technologies, including pharmaceuticals, biotechnology, and medical devices

110⁺

Lawyers in the Practice

1

Largest Civil Litigation Practice at Covington

150⁺

PTAB Wins

70⁺

Lawyers with Technical Degrees

2

Fellows of the American College of Trial Lawyers

9

Trials Since the Pandemic

700⁺

Cases Litigated

50⁺

Former Clerks

Patent Trial and Appeal Board

Stand Out Practice

Handled more than 200 Patent Trial and Appeal Board (PTAB) proceedings for petitioners and patent owners, many through final written decision, in all fields of technology

Experienced Litigators and Seasoned PTAB

InsidersTeam includes two former PTAB Administrative Patent Judges (APJs), including **Scott Weidenfeller**, a former Vice Chief APJ who also previously served in the Solicitor's Office of the USPTO, and **Peter Chen**, a former Lead APJ

Combination of insider knowledge and deep bench of litigation talent enables clients to bring and respond to challenges successfully, while effectively managing parallel litigation

122 cases representing patent challengers; 99 cases representing patentees

12 Covington lawyers have argued at a PTAB oral hearing

Results in AIA Trial Proceedings with Final Written Decisions:

57

total cases

49

wins

4

mixed results

Representative clients include:

 Boston Scientific

 LifeCell®

 Bristol Myers Squibb

 Lilly

 AstraZeneca

Appellate & Supreme Court Litigation

60+ lawyers, including 2 former Assistants to the Solicitor General, 15+ Supreme Court clerks, and former law clerks from every federal court of appeals

Represent appellants and appellees at both the Circuit Court and Supreme Court levels

75+ Federal Circuit appeals in patent cases in the last five years

50+ Supreme Court cases including a landmark patent case *Return Mail v. U.S. Postal Service* (U.S. 2019)

Representative Clients



Insurance Coverage

The preeminent, and largest practice in the U.S., representing policyholders in major litigated and non-litigated coverage disputes.

Well-known and respected by all top insurers for our long history of litigation victories allowing us to settle many claims for fair value without litigation.

\$20B +

In recoveries

“Gold Standard”

“The Strongest Policyholder practice in the field.”
Chambers USA

100 +

Coverage lawyers working across the United States and Europe

Our Expertise

Expertise in numerous lines of coverage and types of underlying claims:

- Mass and other torts
- Management and other professional liabilities
- Business interruption and property loss
- Cyber breach losses
- Financial fraud
- D&O, E&O, Professional Liability
- Employee claims
- CGL
- First-party property
- BPL, Fidelity/Crime Guard
- EPL

Our Value-Add

- We substantially improve insurance recovery on disputed claims due to decades of collective experience advising, litigating, and settling disputes.

Government Contracts

“Their real strength is that they have a multidisciplinary team to address any issue beyond everyday government contracts work. They are always able to bring the right people to be able to help navigate any novel or really complex situation.”

Chambers USA

50⁺

Lawyers dedicated to Government Contracts

Band 1

Chambers USA, Nationwide:
Government Contracts

Leading investors and government contractors routinely turn to us for advice

Our Expertise

- We advise on the development, production, and supply to the government of vaccines and other medical countermeasures addressing threats such as COVID-19, Ebola, Zika, MERS-CoV, Smallpox, seasonal and pandemic influenza, tropical diseases, botulinum toxin, nerve agents, and radiation events.
- We help clients navigate Federal Supply Schedule contracts, including the complex pricing requirements imposed on products under the Veterans Health Care Act, as well as on the obligations imposed by participation in the 340B Drug Pricing program.
- Our substantive healthcare, FDA, government contracts, and other regulatory expertise provides a distinct advantage for clients in FCA-related litigation.

Our Value-Add

- We have a unique capability to advise on transactions involving government contractors holding US government classified contracts or performing other sensitive national security work.

DEI Strategic Actions

Incorporate

diversity, equity, and inclusion into firm leadership and practice group priorities.

Collaborate

with clients through diversity, equity, and inclusion initiatives to increase diversity in the profession

Develop, Promote, and Retain

a diverse lawyer population at all levels and across all offices.

A Leader in Diversity, Equity & Inclusion

At Covington, we believe that excellence in the practice of law knows no boundaries with regard to race, ethnicity, gender, religion, sexual orientation, gender identity, or physical ability.

Covington is proud to be recognized for our diversity, equity, and inclusion efforts.



Shared Covington’s commitments to furthering diversity, equity, and inclusion through LCLD’s **Leaders at the Front** initiative.



One of 4 Firms to achieve both US and UK **“Gold Standard Certification”** in 2022 by the Women in Law Empowerment Forum (WILEF).



Ranked **4th for minority partners** and **6th for women partners** for firms with more than 600 lawyers.



Certified by Diversity Lab **every year since 2018**.



Ranked among The American Lawyer’s 2022 **A-List of 20 elite US law firms** based on financial performance, pro bono activity, associate satisfaction, and diversity.



Achieved a perfect score of 100 on the **“Corporate Equality Index Survey”** in each of the last 14 years.



Named as one of the **Top 50 “Best Law Firms for Women”** for implementing best practices in recruiting, retaining, promoting, and developing women lawyers.



Recognized as **Outstanding Veterans Program** for efforts to remove barriers for, and increase representation of, military personnel in the workplace.

What Clients Say About Us

Expertise in a Highly Regulated World

There's a lot of overlap between our deal work and regulatory issues. Knowledge of the industry as a whole is very helpful.

Collaborative Culture

They are very collaborative—within themselves, with in-house lawyers, and with other firms. There's no 'my clients vs. your client,' no battles over credit.

Multi-disciplinary Strength

They are a highly skilled, integrated law firm that really is able to provide the full spectrum of services that we need both locally and globally.

Combining Quality with Commercial Acumen

A rare combination of analytical thinking and practical advice.

Cracking the Toughest Problems

Covington are the only people we call for problems we can't fix ourselves. We can solve most of it—Covington are unique in that they are the only ones who can solve what we cannot.

Covington Team

**Miriam Guggenheim**

Partner
FDA Regulatory

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Miriam, co-chair of Covington's Food, Drug and Device Practice Group, the Food Industry Group and is Chair of the Firm's Israel Initiative, assists a broad range of major food and dietary supplement companies in achieving their marketing goals while minimizing regulatory and litigation risks. She also helps clients successfully navigate crises such as recalls and unwanted Congressional or regulatory attention. In addition to her work for individual clients, Miriam serves as outside counsel to a number of key trade associations, helping them accomplish broad industry objectives by engaging with the FDA, FTC, and Congress. Miriam is at the forefront of legislative and regulatory changes and food policy and litigation trends. She draws on this deep knowledge and insight to advise clients on all aspects of food development and marketing, from product ingredient sourcing and manufacturing considerations to food labeling and marketing. She also advises clients regarding the most advantageous regulatory categories for the marketing of their products. Partnering with Covington colleagues in international offices, Miriam helps clients solve regulatory problems across the globe.

**Kristin Davenport**

Partner
FDA Regulatory

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Kristin Davenport advises medical device companies regarding premarket strategies and pathways, the premarket submission process, advertising and promotion, compliance and enforcement matters, and import/export issues. She has extensive experience with 510(k) premarket notifications, de novo petitions, premarket approval applications, investigational device exemptions, device modifications, 513(g) Requests for Information, MDR reporting, device recalls, and Part 806 reports. Kristin regularly prepares 513(g) Requests for Information to obtain FDA's views regarding the classification and applicable regulatory requirements for novel devices, such as mobile medical applications. She develops successful premarket strategies for clients, and frequently participates in pre-submission meetings with CDRH. Kristin navigates issues that arise during the premarket review process, and has successfully represented device companies in administrative appeals.

**David Wildman**

Partner
Technology Transactions

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David Wildman specializes in complex transactions involving technology, intellectual property, and data. In this role, he regularly advises clients on issues relating to data commercialization, IP licensing, software development, and information technology services (such as cloud services, IT procurement, and outsourcing). David, who is a registered Patent Attorney and former electrical engineer, also advises on the intellectual property aspects of mergers, acquisitions, and strategic investments. David represents clients in a wide array of industries, including health technology, travel, and finance. In addition to his broader practice, David is a member of Covington's Digital Health Initiative. In that capacity, he counsels pharmaceutical, medical device, and technology companies on the complex commercial and intellectual property considerations that arise at the intersection of information technology, life sciences, and healthcare.

Counsel of Choice



Covington & Burling LLP



Covington & Burling LLP



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