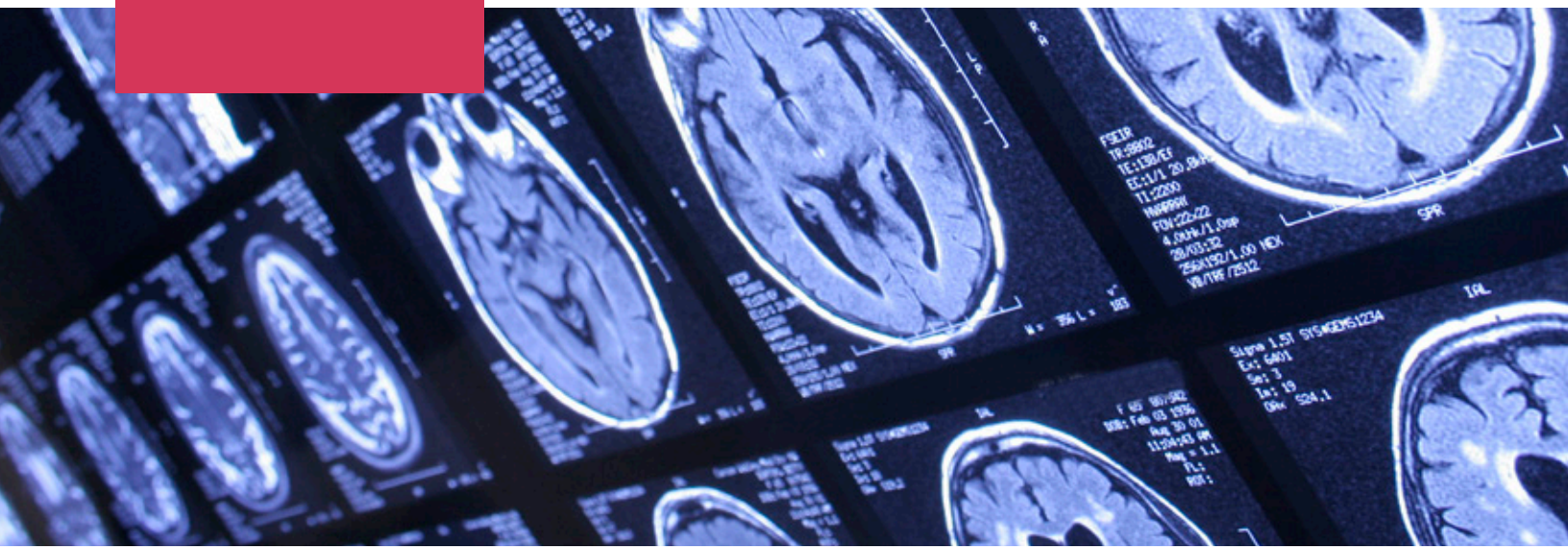
K&L GATES

GLOBAL FOOD, DRUG, AND MEDICAL DEVICE PRACTICE



With offices in key markets in the United States, Europe, Australia and Asia, K&L Gates' Global Food, Drug, and Medical Device Practice is positioned to provide comprehensive and integrated global, regulatory, and transactional support. We offer a broad global platform with on-the-ground local capability, equipping us to meet our clients' needs—no matter the issue or location.

Drawing on our deep knowledge of the local markets in which we practice, our worldwide resources allow our team to offer international and multinational companies 24/7 availability and a unique advantage based on our cross-office and cross-continent ability to advise on research, approval, registration, import, export, adverse events, and recall matters involving food, drug and medical device issues on both the East and West coasts of the U.S., as well as throughout Europe, Australia, China, Japan and the Pacific Rim, Latin America, and other markets.

Across our global platform we advise manufacturers and distributors of food, dietary supplements, nutritional and pharmaceutical products, biological and medical devices, tobacco, personal care, and cosmetic products, as well as trade associations, individuals, and institutions involved in preclinical and clinical research of regulated products.

We Understand the Science

Our Global Food, Drug, and Medical Device Practice has not only significant legal and regulatory experience, but many of us have scientific degrees in areas such as biology, molecular biology, neuroscience, and engineering, as well as first hand experience with biomedical research. As the scientific landscape continues to evolve, we have the knowledge necessary to assist clients with the regulatory challenges affecting new drugs, monograph drugs, alternative medicines and therapies, medical devices, radiological products, food, nutraceuticals, dietary supplements, medical food, cosmetics and other personal care and "combination" products. Additionally, we are familiar with emerging issues including those related to biotechnology, food safety, GMOs, nanotech, stem cell, organic/natural foods, software, telemedicine, and tele-pharmacy.

Our Practice in the United States

K&L Gates' U.S. practice advises on all areas regulated by the U.S. Food and Drug Administration ("FDA")—food, drug, medical device, combination drug/device, cosmetic and personal care, dietary supplement, veterinary, biologic and tobacco products. Our team is experienced and integrated with a proven track record on regulatory, compliance, and enforcement issues. We help clients navigate the regulatory process throughout the life cycle of their products—from planning and development, to approval and marketing, to enforcement and ongoing compliance.

In addition to addressing regulatory issues before and after companies have funding and patents in hand, we closely follow legislative and regulatory initiatives that impact FDA-regulated industries and help clients develop comments and positions based on them. We provide executive training and, as part of our transactional practice, conduct regulatory due diligence and draft and negotiate manufacturer, supplier, distributor, and clinical research agreements. When problems arise, our lawyers also have

"Our team is experienced and integrated with a proven track record on regulatory, compliance, and enforcement issues."

significant experience assisting clients with recalls, import detentions, enforcement actions, administrative hearings, public health emergencies, and criminal and civil investigations. Our clients include domestic and international manufacturers, distributors and investors, as well as trade associations, individuals, and institutions involved in preclinical and clinical research of FDA-regulated products.

We offer clients multidisciplinary, global, regulatory, and transactional advice to help address FDA, Federal Trade Commission (FTC), Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC), and other agency hurdles. We have excellent working relationships across the government agencies that regulate life science companies and are recognized thought leaders in FDA law.

Representative U.S. Practice Matters Include:

- Advising clients on regulatory and legal issues related to the development and launch of conventional food products, functional food, medical food, and dietary supplement products, including review of labels, labeling, advertising, and other marketing material to ensure compliance with all applicable FDA, USDA, and FTC requirements.
- Counseling clients on food packaging, food contact notifications and secondary direct food additives, and GRAS assessments; organic/natural products and labeling; nutrition information, nutrient content claims, structure/function claims, and health claims; and the safety evaluation of food ingredients.
- Advising clients in the drug and biologics industry on all aspects of FDA compliance and enforcement; assist with IND, NDA, ANDA, NADA, ANADA, BLA, and Biosimilar approval and orphan designation processes; and advise on strategic life-cycle management decisions including Hatch Waxman patent challenges.
- Advising established and emerging medical device companies involved in a wide range of technologies including in vitro diagnostics, medical equipment, eHealth/mHealth/medical software, combination products, and biotechnology on issues throughout the product life cycle.
- Providing customized strategic advice on matters including market entry strategies, premarket submissions (510(k), PMA, and IDE), product development plans, and clinical research.
- Assisting with device submissions and advising on labeling and promotional activities, modifications to devices, competitor challenges, adverse event reporting, global regulatory remediation strategies, recalls and enforcement defense.
- Conducting regulatory due diligence investigations for corporate transactions across the FDA-regulated space; assisting with the preparation of reports and disclosures to the SEC; drafting supplier, manufacturer and distributor agreements, and drafting and negotiating clinical research agreements.
- Counseling clients across the cosmetics and personal care industry on safety, intended uses, and labeling compliance.
- Advising on all aspects of veterinary product development, testing, manufacturing, approval, and marketing, including FDA regulation of veterinary pharmaceuticals and biological products, animal feed, and pet food.
- Providing advice to clients in the tobacco industry with regard to labeling, substantial equivalence submissions, listings and registration, and dissolvable tobacco products.
- Advising on all aspects of preclinical and clinical research; providing integrated advice on compliance with IND/IDE and GLP/GCP requirements, clinical trial billing and reimbursement, tissue repositories, stem cell research, HIPAA and privacy, research misconduct, and human subject protection program accreditation.
- Advising clients in all FDA-regulated sectors on product claims, substantiation, and testing; facility inspections and audits; product recalls; and meeting related state, federal and international requirements.
- Conducting compliance audits and assisting clients across industries in responding to government enforcement activities, internal investigations, warning letters, inspectional observations, competitor challenges before the National Advertising Division of the Better Business Bureaus (NAD), as well as criminal investigations by the FDA and FTC.

We closely follow legislative and regulatory initiatives that impact FDA-regulated industries and help clients develop comments and positions based on them.

Our Practice in Europe

Members of our Global Food, Drug and Medical Device Practice in the EU have experience in a wide range of areas including EU regulatory law and policy (free movement of goods), product labeling (food labeling and labeling of medical devices) and advertising issues (health and nutrition claims), product registration (novel foods, food supplements, food for special medical purposes, medical devices and cosmetics, etc.), licensing and product liability (withdrawals, recalls), among others, with particular focus on innovative foods and drinks. We also draw on our close relationships with local counsel outside the EU to provide advice on related European matters.

For clients that are seeking to expand the marketing of products into the EU, we help navigate them through all aspects of the EU regulatory process, including classification procedures and distinguishing between medical devices and cosmetics; clinical trials procedure; EU marketing authorization; and CE marking. Team members are also experienced in high technology, contracts, tax, and licensing. We provide global clients with legal advice, creative solutions, and specific strategies for products being imported or marketed into Europe.

K&L Gates lawyers are highly regarded in this field and are regularly invited to speak at food and nutrition law and medical device seminars and conferences globally. We have experience at the Court of Justice of the EU where we have worked on 100s of cases, including numerous food law matters, and also have extensive experience in lobbying EU institutions.

Representative European Practice Matters Include:

- Advising an international manufacturer of medical implants on interaction with national health supervisory authorities in Asia and Europe, product liability issues and contractual advice regarding distribution companies and end customers.
- Advising a multinational pharmaceutical company on white collar criminal matters in connection with its cytostatic drugs business, and conducting an internal investigation.
- Advising an international foundation during the contract negotiations between the foundation, the Kingdom of Norway and an international pharmaceutical group regarding the manufacture and the supply of developing countries with contraceptives.
- Representing the offeror in several procurement processes regarding implantable defibrillators and cardiac pacemakers and advising on public procurement and antitrust law regarding the supply of private clinics.
- Acting as lead counsel in the acquisition of 100% of the shares in an international health joint stock corporation.
- Advising on the introduction of a healthcare product in the European market.
- Advising an international device development company during conduct of clinical trials, in particular as to negotiations and drafting of agreements with Scottish and German university hospitals and an international consultant offering services as its authorized representative under the Medical Devices directive.
- Advising on the requirement for a medical device manufacturer to be established in a Member State.
- Advising on the authorization of generic drugs in Germany, the UK, Poland France, Italy, and the EU.
- Representing the Spanish food supplement industry in the seminal case C-88/07 Commission v Spain whereby the Court of Justice of the EU condemned the Spanish authorities for not implementing the mutual recognition principle with regard to herbal food supplements legally marketed in other Member States.
- Acting before the European Commission whereby Spain dropped the maximum limits of vitamins and minerals present in food supplements.
- Advising a producers group on reforms in food and drug legislation.
- Preparing various applications for substantial equivalence under Regulation 258/97.
- Registering more than 1,500 nutritional supplements and functional foods across various jurisdictions in the EU.
- Representing a U.S. cosmetics firm before the European Commission for the amendment of the relevant EU guidelines on cosmetic products to include language suitable for our client's products.
- Advising a waters industry association on several issues in connection with health claims.
- Representing a leading sport nutrition multinational in a product recall and a commercial dispute in several EU countries.
- Representing a probiotic industry association on the legality of the use of the term "probiotic" in the labeling and advertising of food stuffs.
- Representing an importer of raw materials for nutritional supplements as to customs classification and tariffs.
- Advising a US food supplements producer on EU regulation regarding product safety and liability and country of origin marking.
- Representing a US producer of energy drinks in a challenge to Belgian rules on caffeine content.
- Drafting legal opinions on the compliance status of food supplements, foods for special nutritional purposes, botanical extracts, novel foods and ingredients, functional foods, organic products, cosmetics, borderline products and regular foods for a variety of companies.

Our Practice in Australia

Our Global Food, Drug, and Medical Device Practice in Australia has extensive experience in advising clients in the therapeutic good (including medical device), biotechnology, food and cosmetics industries. Many members of our Australian Practice have health or science qualifications in addition to legal qualifications with the result that they understand both the science and the law relevant to clients' needs.

The Australian Practice specializes in providing advice in relation to regulatory compliance (including privacy), contracting, structuring and mergers and acquisitions. We have the capability to assist with all areas that impact therapeutic goods or food including product development, registration and licensing, manufacture and distribution, marketing and advertising, labeling, recalls and liaising with regulators. We also have the transactional experience to assist with any transactions involving therapeutic goods or foods.

Representative Australian Practice matters include:

- Advising on compliance with legislation, policy and codes of practice, in particular advertising restrictions and labeling regulations.
- Drafting commercial agreements such as contract manufacturing, research, marketing and distribution, appointment to advisory boards, sponsorship and speaker agreements.
- Providing counsel with respect to clinical trials, including clinical trial agreements, compliance with TGA and NHMRC Guidelines, informed consent and ethics approvals.

"We also have the transactional experience to assist with any transactions involving therapeutic goods or foods."

- Advising on the registration and listing of therapeutic goods and the licensing of pharmaceutical and medical device manufacturers.
- PBS listing of pharmaceutical products, including risk sharing agreements with the Commonwealth and compliance with price disclosure requirements.
- Advising on compliance with Food Product Standards, Food Safety Standards that are applicable to all food businesses in Australia, and Primary Production Standards, such as production and processing requirements for producers in the dairy, meat and seafood industries.
- Advising on compliance with the Australia New Zealand Food Standards Code, industry-specific laws that apply to primary industry food producers, licensing or other approval requirements, and other requirements under Commonwealth or State/Territory laws that are typically relevant to the food and beverage industry.
- Providing counsel on recalls and adverse event reporting.
- Counseling on privacy, privacy audits and the preparation of standard operating procedures generally.
- Advising on compliance with Australian Competition and Consumer Law, including acting for a client in proceedings before the Australian Competition Tribunal relevant to the authorization of Edition 15 of the Medicines Australia Code of Conduct by the Australian Competition and Consumer Commission.
- Providing counsel on regulatory issues in the context of therapeutic good and food mergers and acquisitions.

Members of our Australian Practice have worked with a number of key players in the pharmaceutical sector including:

- Advising Mayne Group Limited in relation to its takeover of FH Faulding – an acquisition valued at AUD2.64 billion as well as on the demerger of Mayne Group Limited into Symbion Health Limited and Mayne Pharma Limited.
- Acting as key regulatory advisers to Australian private equity firms Archer Capital Pty Ltd and Ironbridge Capital Pty Ltd in their acquisition of the 3M branded pharmaceuticals business in Australia, New Zealand, Asia Pacific and South Africa.
- Advising Symbion Pharmacy Services in relation to general contractual and regulatory advice including in relation to product recalls. In addition, a team member was seconded to Symbion Pharmacy Services (as well as other divisions of Symbion Health Limited).
- Advising AstraZeneca, Gilead Sciences, Biogen Idec, FH Faulding, Mayne Pharma, Hospira, Genzyme/Verigen, Sandoz, Ranbaxy and iNova in relation to general contractual and regulatory advice (including privacy, MA Code/GMiA Code/MTAA Code compliance and TGA/PBS issues).

Our Practice in Asia

Members of our Global Food, Drug, and Medical Device team in Asia regularly advise clients on regulatory issues surrounding commercial transactions, crisis management in recall situations, and counsel on ingredient, labeling, and advertising matters. We devise regulatory strategies for conventional food, functional food, dietary supplements, and medical food and compliance with dietary supplement GMPs. Our team represents clients in enforcement proceedings and a comprehensive range of other services.

Representative Asia Practice Matters Include:

- Assisting a general nutrition company with health food registration and IP investigation and protection in China, which involves negotiating approvals from the Ministry of Health and the State Food and Drug Administration.
- Representing a wholesale seafood company in connection with issues in China including IP, immigration and other operational matters.
- Advising a world-famous confectionary brand on a range of food regulatory issues, including labeling, recall, consumer protection, associated PRC enforcement actions, and food regulatory diligence in the M&A context.
- Advising a Fortune 200 diversified healthcare provider on its food incident reporting system and practice in China.
- Advising a leading California-headquartered food supplier to the hotel and restaurant industries in setting up a representative office in China to promote the import of products for the Olympic Games held in Beijing.
- Advising several U.S.-based companies on the regulatory status of one or more food ingredients in China and whether food products containing such ingredients can be sold in China;
- Advising a European private equity fund on its acquisition (including regulatory aspects) of a global health and nutrition manufacturer based in Japan.
- Advising a European private equity fund on its acquisition of a diagnostic medicine manufacturer from a U.S. pharmaceutical company.
- Advising an Asian medical corporation on the potential restructuring of a Japanese medical corporation.
- Advising device manufacturers on Japanese import regulations of medical device and approval and license procedures under Japanese law.
- Advising a global food company on labeling and description requirements under Japanese regulations.
- Advising a global testing institute on the implication of Japanese doctors and medical corporation laws.
- Advising clients on compliance and consent requirements in the capacity as a member of an Internal Clinical Trial Board and R&D Ethical Review Board of Japanese subsidiaries of global healthcare companies.

"Our team represents clients in enforcement proceedings and a comprehensive range of other services."

Global Regulatory Agency Experience

Our global team has worked with many major regulatory authorities around the world and have excellent working relationships with government agencies, government related associations, and federal and state legislatures.

Illustrative Government Agencies Include:

- Food and Drug Administration
- Federal Trade Commission
- Drug Enforcement Administration
- Consumer Product Safety Commission
- U.S. Department of Agriculture
- Environmental Protection Agency
- Alcohol, Tobacco Tax & Trade Bureau (formerly Bureau of Alcohol, Tobacco, and Firearms)
- National Advertising Division of the Better Business Bureaus
- State Boards of Pharmacy
- Therapeutic Goods Administration
- Pharmaceutical Evaluation Branch / Pharmaceutical Benefits Division of the Federal Department of Health and Ageing
- Drugs and Poisons Units of State and Territory Departments of Health
- Federal Department of Health and Ageing
- Australian Competition and Consumer Commission
- Australian Radiation Protection and Nuclear Safety Agency (as well as State and Territory based Departments of Health)
- Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte ("BfArM"))
- Medicines and Healthcare products Regulatory Agency ("MHRA")
- European Medicines Agency
- UK Medicines and Healthcare Products Regulatory Agency
- DG SANCO (European Commission Directorate General for Health & Consumers)
- China Ministry of Health and State Food and Drug Administration
- Tokyo Metropolitan Governmental Office

Additionally, in jurisdictions where we do not have a K&L Gates lawyer who is licensed to perform the work, we have a very strong network of pre-qualified local firms.

More than a Global Food, Drug, and Medical Device Practice

Our clients typically face complex issues that cross practice areas. In addition to the far-reaching expertise our Global Food, Drug, and Medical Device Practice provides, the availability of over 2,000 lawyers across the K&L Gates global platform allows for efficient and seamless interface across offices and Practices including the following:

- Life Sciences
- Health Care
- Consumer Product Safety
- Patents, Trademarks, and Copyrights
- IP Technology Transactions and eMerging Commerce
- Corporate
- Commercial Disputes
- White Collar Crime/Criminal Defense
- International Trade
- Insurance Coverage
- Environmental, Land, and Natural Resources
- Public Policy and Law

Learn more about our Global Food, Drug, and Medical Device practice at klgates.com.

K&L GATES

Anchorage Austin Beijing Berlin Boston Brisbane Brussels Charleston Charlotte Chicago Dallas Doha Dubai Fort Worth Frankfurt Harrisburg Hong Kong Houston London Los Angeles Melbourne Miami Milan Moscow Newark New York Orange County Palo Alto Paris Perth Pittsburgh Portland Raleigh Research Triangle Park San Diego San Francisco São Paulo Seattle Seoul Shanghai Singapore Spokane Sydney Taipei Tokyo Warsaw Washington, D.C. Wilmington

K&L Gates practices out of 48 fully integrated offices located in the United States, Asia, Australia, Europe, the Middle East and South America and represents leading global corporations, growth and middle-market companies, capital markets participants and entrepreneurs in every major industry group as well as public sector entities, educational institutions, philanthropic organizations and individuals. For more information about K&L Gates or its locations, practices and registrations, visit www.klgates.com.