Tucker Ellis LLP

Regulatory Issues

Overview

Today's businesses face rising pressure to comply with strict and seemingly ever-changing government regulatory requirements. Compliance is both costly and complicated to navigate, and penalties for noncompliance can be onerous. Well-acquainted with regulated industries, Tucker Ellis appreciates these issues faced by our clients. We help our clients ensure compliance through our understanding of the regulations and mandates promulgated by a variety of government agencies, including those under federal acts requiring sourcing, compliance registration, testing, labeling, and reporting.

We approach regulatory issues using expertise from both our corporate lawyers and litigators. Our multidisciplinary team is experienced in providing compliance advice on a wide range of risks and hazards involved with these regulated entities, including the formation and maintenance of compliance programs.

When the situation calls for it, our well-connected team has ready access to a variety of subject matter experts to strengthen and develop our strategies for the best possible outcomes.

Members of our experienced team are often invited to share their insights at eminent industry events throughout the United States and abroad and are frequently published in industry publications.

AREAS OF EMPHASIS

- Automatic Renewal Laws
- California Green Chemistry Initiative
- California Organic Products Act
- California Proposition 65
- California Safe Cosmetics Act
- California Transparency in Supply Chains Act
- Child Safety Protection Act
- Consumer Product Safety Commission
- Consumer Product Safety Improvement Act
- Consumer protection investigations by state attorneys general and local district attorneys
- Country of Origin labeling
- Department of Transportation
- Environmental Protection Agency
- Fair Packaging and Labeling Act

- Federal Drug Administration and enforcement actions
- Federal Hazardous Substances Act
- Federal Trade Commission and enforcement actions
- Flammable Fabrics Act
- ISO/ANSI/ASTM standards
- Mislabeling claims
- NAFTA
- Occupational Safety and Health Administration
- Poison Prevention Packaging Act
- Privacy and consumer information protection
- Product recalls
- S. Coast Guard
- S. Customs and Border Protection

Regulated Industry Services

Consumer Products

As the number of consumer product safety regulations continues to escalate in the United States and throughout the world, we assist our clients in navigating the resulting legal and business implications. Our interdisciplinary team of attorneys partners with manufacturers, private labelers, distributors, and retailers of consumer products to address a wide range of consumer product safety issues.

We work proactively with our clients to identify potential product hazards and defects to help them avoid costly litigation and regulatory fines. We work with standards organizations such as the American Society for Testing and Materials (ASTM) and the International Organization for Standardization (ISO) in developing and modifying product standards based on our clients' needs.

Our consumer products areas of emphasis include:

- Off-road vehicles
- Household and kitchen appliances
- HVAC units, as well as air purifiers and humidifiers
- Security/alarm system controls
- Fire extinguishers
- Sporting goods
- Electronic products
- Drugs and nutritional supplements (including child-resistant packaging)
- Children's products, including books, clothing, and toys

- Paint
- Beauty products

Employment and Employee Benefits

Our Labor & Employment Group provides advice and representation to employers in all areas of labor and employment law, including counseling and litigation involving ERISA, employment discrimination, employment-at-will, wrongful discharge, workplace harassment, whistleblower, work-related tort claims, FLSA and state wage and hour laws, FMLA, and workplace accommodations. Our Employee Benefits Group provides a full range of services related to retirement plan, executive, incentive and equity compensation plans, and health and welfare plans. We counsel clients regarding plan design, documentation and legal compliance, administration and corrections, termination, and any issues or complications that arise along the way, including Internal Revenue Service (IRS) audits and Department of Labor (DOL) investigations. We have substantial experience with IRS and DOL document requirements, reporting and disclosure requirements, and regulated and voluntary correction programs.

Our employment and employee benefits areas of emphasis include:

- FLSA/wage and hour audits
- Counseling regarding compliance with FMLA, ADA, Title VII and other federal, state and local employment laws and regulations
- Defense of employment litigation in federal and state courts and before administrative agencies
- Qualified retirement plans, including 401(k) plans, age/service-weighted profit sharing plans, cash balance and traditional pension plans, and ESOPs
- 403(b) and 457(b) plans for tax-exempt and governmental employers
- 409A and 457(f) nonqualified deferred compensation plans
- 421 – 424 equity-based compensation arrangements, including incentive stock option plans and employee stock purchase plans, among others
- Health and welfare plans, including self-insured medical plans, insured welfare benefits, ERISA “wrap” plans, and 125/cafeteria and other fringe benefit plans

Environmental

Effective representation of our clients in the area of environmental regulation requires Tucker Ellis attorneys to have a thorough understanding of applicable regulations, as well as knowledge of the science behind them. Strong advocacy requires a combination of trial and litigation skills, which allows us to effectively communicate and interact with government regulators.

Tucker Ellis LLP

Our attorneys have more than 50 years of collective experience representing clients in all aspects of environmental regulation and litigation. We have a superior level of understanding regarding the science behind environmental regulation, with technical expertise in groundwater modeling, hydrogeology, and toxicology, as well as remediation methods. Our unique governmental and prosecutorial experience translates to more effective and efficient representation of our clients. Our environmental areas of emphasis include:

- Clean Air Act, Clean Water Act, RCRA, TSCA, CERCLA, and FIFRA
- Brownfield redevelopment and cleanup
- Superfund enforcement and cost recovery actions
- Air, water, wetland, and solid waste permitting

Food, Cosmetics & Dietary Supplements

Our lawyers work with clients ranging from start-ups to well-established global companies and everyone in between to develop and implement litigation avoidance strategies to reduce the risk of exposure to FDA and FTC regulatory actions and consumer class actions. In addition to representing brands across the spectrum, we work with clients all along the supply chain: product formulators, contract manufacturers, logistics companies, on-line and brick-and-mortar stores, investors, consumer testing companies, and industry organizations. Our international client geographic base includes representing companies from UK, France, Germany, Israel, South Korea, and New Zealand. We regularly work with testing labs and consumer perception companies to develop protocols and conduct studies to ensure product claims are accurate and properly substantiated, and that advertising claims are defensible.

If litigation does ensue, our trial lawyers are there to vigorously defend clients in state and federal courts throughout the country. In addition to our vast experience defending consumer class actions, we also represent companies against personal injury claims and in competitor actions and general business litigation matters. Our food, cosmetics, and dietary supplements areas of emphasis include:

- FDA and FTC regulatory actions, including responding to enforcement letters and coordinating on-site inspections
- Extensive experience representing personal care clients – including those marketing CBD and dietary supplements – before the National Advertising Division of the Better Business Bureau
- Natural, organic, cruelty free, and other product certifications
- Automatic Renewal programs, including compliance with laws governing subscription and loyalty programs
- Import detentions
- Product recalls

- Privacy and data protection
- Product labeling, marketing and website review to ensure compliance with myriad federal and state laws
- California Prop 65 counseling

Life Sciences

Our lawyers work on the cutting edge of science and medicine to guide our clients through the applicable regulatory climate in an attempt to prevent litigation, including the development of appropriate warnings and the evaluation of pharmacovigilance practices. With our deep experience as national coordinating counsel, regional counsel, and local counsel, we have the structure and team in place to help our clients navigate the often confusing and at times, contradictory world of regulatory compliance. Our team has handled dozens of litigations against pharmaceutical and medical device manufacturers as national counsel and are familiar with the various regulatory pathways utilized to achieve market approval.

In defending our clients when litigation cannot be avoided, we focus on the development and implementation of regulatory defense themes for trial, including through fact witnesses and expert witnesses. We research and analyze the regulatory history through post-marketing phases, and address the impact of publicity generated by litigation, which can lead to increased regulatory oversight and resulting actions. Our life sciences areas of emphasis include:

- Pharmaceutical and medical device product regulations, including working knowledge regulatory authorities outside of the United States
- Life cycle management issues
- Pharmaceutical and medical device monitoring, reporting, and recalls
- Labeling compliance
- Pharmacovigilance
- HIPAA and privacy issues
- Medicare reporting and compliance
- Intellectual property and patent protection
- Biologics
- False Claims Act and anti-kickback laws
- FDA and FTC enforcement actions and government challenges
- Preemption
- Development of regulatory trial themes and preparation of fact and expert witnesses

Transportation

MARITIME

Tucker Ellis LLP

Our Maritime Group represents clients in maritime claims under the Longshore Act, as well as counseling clients in intermodal freight and custom matters, maritime labor, environmental and products liability, Inland Marine Insurance, and criminal investigations. We handle maritime cases on a 24-hour on-call basis on Lake Erie, throughout the Great Lakes, and the West Coast. Our trial lawyers bring Merchant Marine experience to their courtroom capabilities and have tried cases in the jurisdictions around the Great Lakes, as well as in New York, Delaware, Pennsylvania, Guam, California, and Florida.

AVIATION

Today's complex regulatory environment within the field of aviation can be confusing for businesses looking for solutions. Tucker Ellis has decades of in-depth, hands-on experience in a broad range of aviation legal matters. We represent cargo conversion companies, maintenance and repair organizations, financial institutions, high-net worth individuals, and middle-market corporations in connection with the acquisition and disposition of corporate and commercial aircraft portfolios and related financing and/or leasing. We also advise clients on FAA and DOT regulatory matters, and other regulatory matters around the globe.

Experience

Consumer Products

- Advised a consumer product manufacturer in compliance with Consumer Product Safety Commission regulations, including the Federal Hazardous Materials Safety Act, the Consumer Product Safety Improvement Act, and the Consumer Product Safety Act on a wide range of complementary products
- Advised a foreign recreational product manufacturer on U.S. Customs and Border Protection country of origin labeling requirements
- Counseled an industrial paint manufacturer on compliance with product labeling and safety data sheets per OSHA's Hazard Communication Standard
- Represented an insurance carrier in several cases concerning the interpretation and scope of coverage in product tampering, recall, and contamination policies and obtained favorable summary judgment rulings concerning issues in those policies
- Prepared a National Advertising Division (NAD) complaint asserting false and deceptive advertising claims against a retailer's competitor
- Counsel retailers, festivals, and not-for-profits in promotional and advertising campaigns and sponsorship deals
- Obtained dismissal of class action false advertising, unfair competition (Business & Professions Code § 17200), and Consumer Legal Remedies Act case for builder of manufactured homes that were allegedly susceptible to mold Obtained dismissal of class action false advertising, unfair competition (Business & Professions Code § 17200), and

Consumer Legal Remedies Act case for cleaning equipment manufacturer related to excessive shipping and handling charges
- Obtained dismissal of class action false advertising, unfair competition (Business & Professions Code § 17200), and Consumer Legal Remedies Act case alleging invasion of privacy by telephone company
- Negotiated favorable settlement of class action false advertising, unfair competition (Business & Professions Code § 17200), and Consumer Legal Remedies Act case for luxury resort hotel related to Internet advertising

Employment and Employee Benefits

- Defend employers in wage and hour class action litigation matters
- Conduct wage and hour compliance audits and advise on compliance with FLSA and state wage and hour laws
- Conduct investigations of claims of harassment and discrimination
- Advise employers on compliance with federal, state, and local anti-discrimination and harassment laws and regulations
- Defend employers against claims before EEOC and state administrative agencies
- Advise on and prepare employment policies
- Conduct employee anti-discrimination and anti-harassment policies
- Advise private employers on compliance with FMLA and ADA requirements for employees on extended leave
- Assist clients with respect to HIPAA responsibilities, including preparation of policies and procedures, and business associate agreements, and compliance with the ACA, COBRA, FMLA, HIPAA, and related federal and state laws
- Assist clients with the drafting of self-insured medical plans and pharmacy benefit manager agreements to meet continued legal and regulatory requirements, as well as to remain current as to coverage trends
- Advise clients regarding ongoing document and operational compliance requirements of their qualified retirement and other benefit plans, and assist when corrections are necessary, including by use of the DOL's Delinquent Filer Voluntary Compliance Program (DFVCP) and Voluntary Fiduciary Correction Program (VFCP), and the Employee Plans Compliance Resolution System (EPCRS) program, an IRS-sponsored voluntary correction program available to qualified and §403(b) retirement plans
- Represent ESOPs, ESOP-owned companies, boards of directors, trustees, and other service providers in transactions, DOL investigations, and special circumstances
- Educate clients as to their fiduciary and administrative responsibilities and obligations relating to their benefit plans, and costly potential penalties for noncompliance

Environmental

- Represented large manufacturer with locations in multiple states with regard to all aspects of environmental compliance counseling, including EPCRA reporting, TSCA enforcement,

and hazardous waste cleanup

- Represented international auto parts manufacturer in criminal and civil enforcement actions under the Clean Water Act
- Represented chemical manufacturer in successful challenge to U.S. EPA administrative enforcement action under RCRA
- Represented international company in the siting and permitting of its first clean coal facility in the United States
- Represented developer in securing 404/401 permitting for large retail development project
- Represent manufacturers and retailers in actions under California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)
- Represent aerospace manufacturer in state enforcement action brought under the Federal "Superfund" law (Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA))
- Represented major developer with regard to NEPA compliance
- Represented major manufacturing client with performance of environmental audits and compliance counseling

Food, Cosmetics & Dietary Supplements

- Developed recall protocol and procedures on behalf of multiple clients to ensure compliance with FDA guidelines and preparedness for recalls
- Counseled a food processing company through recall by supplier, including collection of damages resulting from recall
- Counseled a food manufacturer concerning potential liability for contaminated products, including FDA inspection and recalls, insurance coverage, and response to FDA 483 Report, resulting in warning of manufacturer rather than fines or other punishment
- Represented a supplement manufacturer in connection with responding to demands for substantiation of the bases of claims made on labeling and in advertisements by the California Food, Drug and Medical Device Task Force – comprised of the district attorneys of the following California Counties: Alameda, Marin, Monterey, Napa, Orange, Santa Clara, Santa Cruz, Shasta, Solano, and Sonoma
- Negotiated non-payment dismissal of class action false advertising, unfair competition (Business & Professions Code § 17200), and Consumer Legal Remedies Act case for anti-wrinkle cream cosmetic manufacturer
- Negotiated favorable settlement of class action false advertising, unfair competition (Business & Professions Code § 17200), and Consumer Legal Remedies Act false labeling case for nut butter manufacturer
- Negotiated favorable pre-litigation settlement of dozens of consumer class action, false advertising, unfair competition cases involving efficacy claims, ingredient content representations (e.g., protein spiking), slack-fill and other quantity misrepresentations, and claims such as "natural," "sustainable" and other product attributes

Life Sciences

- Regularly assist pharmaceutical companies in navigating recalls from the regulatory response perspective, as well as handling claimants and eventual litigation
- Collaborate with pharmaceutical companies and their third-party pharmacovigilance vendors on handling claims arising through litigation, including implementing Standard Operating Procedures and monitoring and advising on new and existing FDA requirements
- Developed regulatory- and preemption-based defenses in litigation involving prescription medications
- Regularly draft and argue motions for summary judgment and to exclude plaintiffs' proffered expert witnesses in consolidated multidistrict litigation involving a complex prescription drug medication that had been part of a recall
- Obtained dismissal of class action false advertising and unfair competition case against prescription drug manufacturer related to alleged manufacturing defects
- Successfully defended appeal of trial court dismissal of class action false advertising and unfair competition case against prescription drug manufacturer
- Obtained summary judgment on the adequacy of the defendants' labeling of a statin medication

Transportation

- Provided advice on the registration (flagging) of vessels in connection with an international transaction, their ability to be brought back into the United States coastal trades, and practical import/export issues such as NAFTA tariff issues and ad valorem fee issues
- Provided compliance advice for hazardous materials transportation issues relating to the shipment of consumer commodities, including but not limited to charcoal and bleach, that are classified as hazardous under the Hazardous Materials Transportation Act (HMTA) and associated regulations
- Experienced with required packaging for various types of hazardous products shipped in interstate commerce falling under HMTA purview international import/export transactions, including NAFTA tariff issues and ad valorem fee issues
- Represented an aircraft conversion company in negotiations with prospective customers from China, Brussels, England, Brazil, and the United States to convert aircraft from passenger to freighter configuration
- Represented an engineering company in joint venture agreement negotiations to engineer and obtain regulatory certification to convert Boeing 757 aircraft from passenger to freighter configuration
- Represented a growing privately held business in structuring the ownership and operations of its aircraft fleet and to negotiate aircraft maintenance and charter relationships