Hyman, Phelps & McNamara PC

Unparalleled expertise in the regulation of drugs, medical devices, biologics, foods, dietary supplements, and cosmetics.

FDA Law Blog

HPM authors the premiere blog on FDA-related matters. The FDA Law Blog (**www.fdalawblog.net**), named by the American Bar Association (ABA) as one of the top 100 law "blawgs," provides timely updates on FDA enforcement actions, court decisions, and new regulations and policies, along with related issues such as healthcare fraud and abuse, drug and device reimbursement, and other topics of interest. Follow us at **twitter.com/fdalawblog.**

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Exceptional Service for Complex Issues

Hyman, Phelps & McNamara, P.C. (HPM) has one of the most comprehensive food and drug practices in the United States. Our goal is to provide exceptional, prompt, and efficient professional services tailored to each client's specific needs. HPM helps clients avoid legal problems when possible and solve them when necessary.

Experience

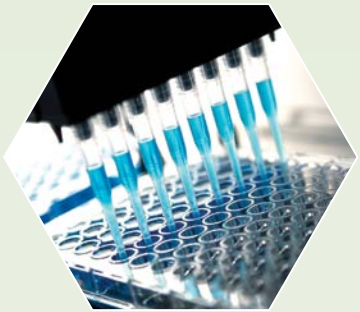
Many of our attorneys have scientific backgrounds that complement our practice, including advanced degrees in areas such as pharmacy, nutritional science, public health, biotechnology, engineering, and clinical research. Additionally, our attorneys boast experience in the government and industry, including the Food and Drug Administration (FDA), the Department of Justice (DOJ), U.S. Attorneys Offices, the Drug Enforcement Administration (DEA), major pharmaceutical companies, and industry trade associations.

Collaboration

To complement our expertise, the firm's attorneys collaborate with a network of physicians, consultants, and scientists. Longstanding relationships with regulatory counsel in foreign jurisdictions also benefit firm clients.

Service

Firm clients are as diverse as the regulatory issues they face, ranging from individuals and startup companies to large multinational corporations. Other law firms often retain HPM to provide targeted expertise for their clients. HPM offers extraordinary experience to assist on the broad range of issues our clients face.



- Drugs and Biologics
- Medical Devices
- Foods and Dietary Supplements
- DEA and Controlled Substances
- Human Cellular and Tissue-Based Products
- Cosmetics
- Tobacco
- Animal Drugs and Feeds
- Combination Products/ Product Jurisdiction
- Advertising and Promotion
- Health Care
- HIPAA Privacy Standards and State Privacy Laws
- Enforcement
- Corporate Transactions

Practice Areas

Drugs and Biologics

HPM is well known for its expertise in all phases of new drug and biologics development, from the investigational stage through the post-approval stage. Specialties include advisory committee meetings, Hatch-Waxman market exclusivity, orphan drugs, bio-research monitoring, Good Manufacturing Practice (GMP) compliance, advertising and promotion, and government inspections. Other areas of expertise include pre-clinical and clinical investigations, fast track and accelerated approvals, user fees, citizen petitions, establishment registration and drug listing, risk evaluation and mitigation strategies (REMS), generic drug approvals, prescription to over-the-counter (OTC) switches, monograph issues, compounding, and appeal of administrative decisions.

Medical Devices

The firm assists medical device manufacturers in all aspects of FDA regulation, from regulatory strategy development to product approval, including manufacture, marketing, and other post-approval obligations. Our areas of expertise include Investigational Device Exemption (IDE) requirements, clinical studies, premarket notifications (510(k)s), premarket approval applications (PMAs), product classification, biomaterials issues, Quality System Regulation compliance, Medical Device Reporting, and product recalls. Clients also rely on HPM when facing the unique regulatory issues applicable to in vitro diagnostic (IVD) devices, and the firm advises both IVD and drug clients on issues relating to companion diagnostics.

Foods and Dietary Supplements

Our practice includes advising and assisting in the development and marketing of conventional foods, medical foods, dietary supplements, food and color additives, food contact substances, and novel food ingredients. HPM was involved in Congressional debates and the enactment of the Dietary Supplement Health and Education Act, and closely follows FDA implementation and enforcement of the statute. We work with clients on a range of issues, including labeling, advertising, health claims, structure/function claim issues, reportable food requirements, food defense and security matters, and current GMP criteria.

DEA and Controlled Substances

We advise clients on federal and state laws and regulations governing the scheduling, manufacture, distribution, dispensing, import, and export of controlled substances and regulated chemicals. HPM has been instrumental in drafting legislation and regulations to address issues affecting the regulated industry. HPM works with clients on these issues in administrative, civil, and criminal matters. HPM also conducts investigations and on-site inspections of registered facilities.

Human Cellular and Tissue-Based Products

HPM attorneys assist companies with all aspects of the human cellular and tissue product regulatory framework, including product jurisdiction and pre-market review procedure, product promotion, and pre- and post-market compliance.

Cosmetics

The firm's lawyers have unique background and experience in the regulation of cosmetics and frequently advise companies on composition, ingredient status, labeling, safety, packaging, advertising, and other regulatory issues related to cosmetics.

Tobacco

HPM assists manufacturers and retailers on matters relating to the Family Smoking Prevention and Tobacco Control Act, including the regulation of cigarettes, smokeless tobacco, modified risk tobacco products, and other tobacco products.

Animal Drugs and Feeds

The firm frequently counsels manufacturers of animal drug and feed products, intended for both food and non-food animals, on FDA and state regulatory matters.

Combination Products/ Product Jurisdiction

We are often called upon to ascertain how new products will be regulated. In some cases, the determination involves the jurisdictional boundary between FDA and another agency, such as the Consumer Product Safety Commission (CPSC) or the Environmental Protection Agency. In other cases, it involves the jurisdictional boundary between various centers at FDA. HPM has assisted numerous companies with

Practice Areas

the development of such combination products and strategies for obtaining approval and designation.

Advertising and Promotion

We regularly advise companies regarding the labeling, advertising, and promotion, including social media issues, of all FDA-regulated products. The firm also handles advertising substantiation matters before the Federal Trade Commission (FTC) and with respect to related state consumer protection and unfair trade practices laws. HPM represents companies in matters involving claims of unfair advertising under the Lanham Act, and in proceedings before the National Advertising Division of the Better Business Bureau.

Health Care

HPM's familiarity with the drug and device industries makes the firm particularly well-equipped to assist manufacturers in understanding how health care laws and regulations affect the marketing of drugs and devices. The firm advises clients on compliance with Medicare and Medicaid laws and other health care laws that affect financial and incentive arrangements among various constituents, including manufacturers, health care practitioners, medical institutions, pharmacy benefit managers, distributors, group purchasing organizations, and patients.

We assist clients with issues relating to the federal health care program anti-kickback law, the Federal False Claims Act and related laws, state marketing prohibitions and reporting laws, state consumer protection laws, state licensing laws, and other laws applicable to drug and device marketing activities.

HPM represents pharmaceutical companies in matters arising under government price reporting and discounting programs, including federal and state government pharmaceutical rebate programs and reporting of average sales price.

The firm also helps drug manufacturers in evaluating the implications of their marketing strategies, as well as in developing contract strategies with respect to commercial customers and other entities in the distribution chain. The firm helps negotiate Federal Supply Schedule contracts with the Department of Veterans Affairs, assists drug manufacturers in matters relating to federal ceiling price restrictions and price reporting, and advises clients on the calculation and payment of refunds under the TRICARE retail pharmacy refund program.

HIPAA Privacy Standards and State Privacy Laws

HPM routinely assists clients on matters relating to Health Insurance Portability and Accountability Act (HIPAA) Privacy Standards and state medical information privacy laws. The firm helps clients design clinical research programs, marketing, patient assistance, and other initiatives to comply with these authorities.

Enforcement

We offer many years of experience helping clients both avoid and respond to all manner of enforcement activities by government agencies. These actions range from government inspections, FDA Form 483s, Warning and Untitled Letters, product seizures, import detentions, and recalls to criminal investigations, proposed requests for consent decrees, subpoena responses, injunctions, criminal prosecutions, and civil penalty actions.

HPM frequently represents clients in matters originated by the FDA, DEA, CPSC, DOJ, FTC, and various state agencies. We defend manufacturers against federal and state False Claims Act actions involving alleged violations of the Federal Food, Drug, and Cosmetic Act, federal health care programs, anti-kickback laws, and other laws.

Corporate Transactions

HPM frequently assists companies engaged in mergers, acquisitions, and other corporate matters by conducting due diligence reviews and advising on FDA-related issues that arise during these transactions. We also help companies with FDA-related aspects of commercial agreements, including supply, distribution, and manufacturing agreements.

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