

## FOOD & DRUG

The firm's Food and Drug Practice, tracing to the firm's founding in 1919, includes two former Chief Counsel of the United States Food and Drug Administration (FDA), and covers every facet of food and drug regulatory law in the United States and Europe, including all matters within the FDA's regulatory purview, federal and state fraud and abuse issues, Medicare, Medicaid, and related reimbursement areas. Over the years, we have provided regulatory advice to a substantial majority of the world's pharmaceutical, biotechnology, medical device, veterinary, and agricultural companies, including nearly all of the multinational companies, and most of the large and mid-size pharmaceutical and biotechnology companies in the United States and Europe.

Covington has represented the major industry associations in the United States and Europe, enabling us to deepen our understanding of – and shape – the complex issues that face the industry. For example, we represent the Pharmaceutical Research and Manufacturers of America (PhRMA), the National Pharmaceutical Council (NPC), the Consumer Healthcare Products Association (CHPA), and the Animal Health Institute (AHI). For PhRMA, as its principal outside counsel, we have worked with the association on a wide variety of public policy matters, including legislation affecting the FDA, medicines regulation in the European Union, and international intellectual property issues. We also advised PhRMA on the establishment of its self-regulatory code of practice governing promotion of prescription drugs to health care professionals.

Covington lawyers also actively advise clients on drug manufacturing, product quality, and FDA inspection matters. The firm has been involved in nearly all of the major FDA pharmaceutical GMP enforcement actions from the landmark Warner-Lambert consent decree of 1993 forward, representing both company and individual defendants. We have a high degree of credibility on these issues with key officials from the FDA and the Office of Consumer Litigation of the Department of Justice. We also have strong working relationships with the leading GMP consultants. Our knowledge of the evolution of FDA's approach to product quality provides a strong platform from which to advise clients proactively on technical GMP requirements, broader quality systems issues, recalls, field alerts, manufacturing supplements and product changes, FDA inspections, and record retention policies. We also have been centrally involved in legislative and regulatory reform on drug quality, including the manufacturing change provisions of the FDA Modernization Act, the rollback of Part 11, the debate over FDA's authority to seek disgorgement, and FDA's recent GMP initiative.

On the enforcement front, we have advised clients on product seizures, recalls, injunctions, and criminal proceedings. We have also negotiated consent decrees and voluntary agreements arising out of FDA's heightened interest in drug and biologic good manufacturing practice and promotion issues.

### EMERGING COMPANY EXPERIENCE

Our lawyers have extensive experience in representing and advising start-up and emerging biotechnology and pharmaceutical companies. Covington's rich and diverse history advising the life sciences industry, enables us the distinct advantage of being uniquely situated to guide emerging companies on the critical issues that arise when they approach commercialization of their first products. Our life sciences regulatory lawyers have strong expertise in advising emerging companies, including: gaining product approval; submitting applications for health care coverage; obtaining regulatory compliance with agencies such as, FDA, USDA, EPA, and DEA; and, assessing environmental impacts. With respect to organizational matters (including formation, employee and shareholder agreements, and stock option plans), our life sciences transactional attorneys assist emerging companies with seed and venture financings, equipment leasing, mergers and acquisitions, and initial public and other offerings of equity and debt securities. We also advise with respect to, and if necessary litigate, issues that arise from non-competition and other restrictive agreements with prior employers, as well as with respect to the ownership and licensing of intellectual property.

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