Experienced Life Sciences Regulatory Attorney Bruce Manheim Joins WilmerHale

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WilmerHale announced today that Bruce Manheim is joining the firm's Washington DC office as a partner in the Regulatory and Government Affairs Department. Bringing more than 30 years of regulatory, legislative and litigation experience, Manheim will further strengthen WilmerHale's representation of life science companies on a wide array of matters, including Food and Drug Administration (FDA) issues, government and internal investigations, administrative and other litigation, transactions, and environmental compliance issues involving biotech products.

With graduate degrees in both science and law, Manheim has a multidisciplinary understanding of the complex issues at the forefront of today's life sciences industry. He also shares a special understanding of the manner in which in-house counsel grapple with issues confronting life science companies. He recently spent almost a year on a secondment as acting general counsel of a major business unit of a large medical device company.

"We are very pleased that Bruce is joining the firm, and we look forward to working with him on life science issues across a range of practice areas," said partner Randy Moss, chair of WilmerHale's Regulatory and Government Affairs Department. "Bruce's FDA expertise will add a further dimension to the firm's existing strengths in assisting clients in the pharmaceutical, biotech, medical device and food sectors."

Manheim has extensive experience representing clients before the FDA and other federal agencies on matters involving drugs, biologics, devices, cosmetics and food products. He routinely counsels clients on issues arising under the new biosimilars legislation and the Hatch-Waxman Amendments, working in close cooperation with intellectual property lawyers.

Manheim also leads internal investigations and compliance assessments, and works closely with government enforcement lawyers in civil and criminal investigations. He has filed numerous petitions with FDA and served as lead counsel in litigation challenging FDA actions. Manheim also assists clients with issues surrounding development of natural products that arise under the Biodiversity Convention and Nagoya Protocol.

“WilmerHale is well-known for its depth and skill in representing life science companies on the most complex and significant legal matters,” said Manheim. “I am truly excited about working with my new colleagues at the firm on the range of issues confronting the life sciences industry.” Manheim added that his “expertise and background on FDA regulatory matters will support multiple practice areas within the firm and further strengthen WilmerHale’s already outstanding service to its clients.”

Manheim is a 1988 graduate of Georgetown University Law Center. He received a MA in Biology from Claremont Graduate School in 1978 and a BA from Pomona College in 1977, graduating Phi Beta Kappa.

Before joining WilmerHale, Manheim was a partner at the Washington DC office of Ropes & Gray and a boutique FDA law firm for almost twenty years. Prior to entering private practice, he served as a senior attorney-scientist at the Environmental Defense Fund where his practice focused on public health and environmental issues arising within both domestic and international legal frameworks.