WilmerHale Adds Leading FDA and Life Sciences Regulatory Partner George O'Brien

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WilmerHale is pleased to announce that George O'Brien, a nationally recognized Food and Drug Administration (FDA) and life sciences regulatory lawyer, has joined the firm as a partner in its Regulatory and Government Affairs Department. He will be based in the firm's Washington DC office and also work alongside the firm's Corporate Group.

O'Brien advises life sciences companies at all stages of growth on the development, approval and commercialization of innovative products regulated by the FDA, including drugs and biologics, medical devices, food and beverage products, dietary supplements, infant formula, and cosmetics products. His practice spans regulatory counseling throughout the product lifecycle, regulatory support for corporate and transactional matters, and strategic regulatory advice for enforcement, investigations, and litigation.

"George has an extraordinary breadth of FDA-related experience across regulatory counseling, transactions, and litigation support," said Anjan Sahni, WilmerHale's managing partner. "As demand continues to grow for sophisticated regulatory advice in the life sciences sector, George brings exactly the kind of judgment, technical expertise, and practical problem-solving capabilities our clients value."

"George is an exceptional addition to our regulatory team and to our broader life sciences platform," said Brian Boynton, Chair of WilmerHale's Regulatory and Government Affairs Department. "George's arrival enhances our ability to support life sciences companies at every stage, particularly as regulatory considerations become increasingly central to business and investment decisions."

"WilmerHale offers a powerful platform for my practice, with the exceptional depth of its life sciences practices spanning regulatory, IP, litigation and corporate work," O'Brien said. "I'm excited to join colleagues who understand both the science and the business of life sciences and to help clients navigate the increasingly complex regulatory and enforcement environment."

O'Brien is a go-to lawyer on FDA regulation of orphan drugs that target rare diseases. He has successfully advocated before the FDA on complex issues involving orphan drug designation and exclusivity, including establishing prevalence, qualifying patient populations, and demonstrating

clinical superiority. He also has deep experience advising on FDA-facing patent and related Hatch-Waxman issues, among other FDA subjects.

O’Brien frequently provides regulatory guidance on mergers and acquisitions, licensing and collaboration agreements, financings, and other strategic transactions involving FDA-regulated products. He has advised on a range of transactions across the life sciences sector, helping clients identify and manage regulatory risk while advancing commercial objectives.

Before WilmerHale, O’Brien spent nearly two decades in private practice at two international law firms. He earned his AB from Dartmouth College and his JD, *magna cum laude*, from the University of Maryland Francis King Carey School of Law, where he was elected to the Order of the Coif.