Brown Rudnick Expands Global Life Sciences Practice Group with Addition of Partner Neil Di Spirito

Brown Rudnick LLP today announced the addition of Neil Di Spirito as a Partner in the Global Life Sciences Practice Group. Di Spirito will focus his practice on a wide range of regulatory and compliance issues in the pharmaceutical, biologics, and medical device industries, particularly those involving the Food and Drug Administration (FDA).

Prior to joining Brown Rudnick, Di Spirito was a Partner at Epstein Becker Green and at Ballard Spahr, where he was a member of the Life Sciences and Technology and Health Care Groups, and established Ballard's FDA practice. Earlier in his career, he spent more than a decade in-house as a managing director at Pharmacia (later acquired by Pfizer).

"In the course of Neil's storied career – both as a pharmaceutical executive and outside counsel representing all types of life sciences companies – he has become a go-to FDA law practitioner," said Adam Schoen, a Practice Group Leader of the Firm's Global Life Sciences Practice Group. "We're thrilled to have him on the team."

For over two decades, Di Spirito has advised his clients on a broad range of U.S. and international regulatory compliance challenges and issues that arise in products liability litigation and other disputes. He has successfully litigated and negotiated against the FDA, defending clients on alleged cGMP violations, marketing, and approval issues. In addition, he has substantial experience negotiating on matters of policy and product approvals with the FDA's Office of Chief Counsel

and with the Regulatory, Compliance, and Review departments within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health.

“Neil has spent his entire career guiding clients through regulatory issues and decisions that are critical to a company’s future,” said Vince Guglielmotti, Managing Director of the Firm’s Corporate & Capital Markets Department. “We look forward to him continuing on this path at Brown Rudnick.”

Thomas Meyers, Chair of the Global Life Science Practice Group, added: “Neil’s experience with a wide range of FDA policy, regulation, product approval, and compliance issues will be invaluable to our clients and to the continued growth of our practice group.”

In addition to his legal practice, Di Spirito teaches pharmaceutical, biologic, and medical device law at the Food and Drug Law Institute (FDLI) and to the FDA’s newly hired attorneys, reviewers, and compliance officers. He also serves on FDLI’s Audit Committee and was co-chair of its 2018 Annual Conference Planning Committee.

“The timing couldn’t be better to welcome Neil to Brown Rudnick,” said James Bedar, Practice Group Leader of the U.S. Corporate Practice Group. “Neil’s unique skillset will be a real asset in strengthening our service offerings to the booming pharmaceutical and biotech sectors.”

Brown Rudnick’s Global Life Sciences Group consists of an international team of lawyers dedicated to the life sciences industry. Members of the team have been involved with leading life sciences companies for over 30 years, serving as in-house executives for national pharmaceutical and biotech companies, including Boston Scientific, Helicos BioSciences, Watson Pharmaceuticals, and Chiron Vision.

Additional biographical information and credentials are

available on Neil Di Spirito’s bio page at brownrudnick.com.