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LIFE SCIENCES

Life sciences companies conquer new frontiers daily — which means each day brings new regulatory, commercial, and legal challenges.

While Goldberg Segalla's Life Sciences practice encompasses the traditional spheres of biotechnology, pharmaceuticals, and medical devices, we understand that these do not represent discrete subspecialties. As a team of attorneys equipped with advanced degrees across the spectrum of biology, chemistry, and biomedical and chemical engineering — as well as real-world experience working in the high-tech and health sciences sectors — we know from experience that drug discovery often involves biotechnological tools, diagnostics combine materials with assay systems, and medical devices often carry drug or biological actives.

That provides a distinct advantage for clients as they develop new technologies that cross scientific disciplines. Our Life Sciences lawyers have the technical and legal experience to assist at any stage — from offering comprehensive regulatory compliance counsel to handling product liability lawsuits or Hatch-Waxman litigation, launching new products, providing risk management analysis, and navigating enforcement actions and crises.

Our team has dozens of years of combined experience counseling and representing U.S. and international companies of all sizes involved with the manufacturing and distribution of medical devices, over-the-counter drugs, prescription pharmaceuticals, nutraceuticals, and other health-related products or services. We help our clients comply with all applicable regulations and structure commercial relationships with an emphasis on avoiding business-disrupting enforcement actions or disputes. When necessary, we put our extensive and highly regarded trial experience to work to protect our clients' interests efficiently and effectively, so they may remain focused on what's most important — their medical, scientific, and business innovations.

With You at Every Stage

Our Life Sciences team partners with other Goldberg Segalla practice groups to offer clients a full array of legal services tailored to each client's specific business as well as the rapidly evolving medical, scientific, and legal issues affecting their industries.

Regulatory compliance — We help clients develop sound regulatory strategies and advise on the full range of applicable regulations, including those of the Food and Drug Administration (FDA), Federal Trade Commission (FTC), Consumer Product Safety Commission (CPSC), and other federal and state agencies.

Litigation — When litigation becomes inevitable, we work tirelessly to protect our clients' interests in disputes regarding product liability, contracts, commercial agreements, intellectual property rights, and other critical areas. We have defended our clients in jurisdictions across the United States, including in some of the most dangerous venues, in single-plaintiff cases, consolidated mass actions and multi-district litigations (MDLs), and class actions. We have a deep understanding of the technical and scientific issues unique to each litigation and are adept at building successful defense strategies that integrate this knowledge. In our experience, most cases settle or are otherwise resolved before a trial, but Goldberg Segalla's trusted and vast trial experience provides clients with a distinct advantage because our opponents know that we're not afraid to try cases when necessary

— and that we know how to win. We also understand that, at times, alternative dispute resolution is preferable to trial, and we have extensive experience with various forms of arbitration and mediation.

Drug approval and Hatch-Waxman litigation — Our attorneys are experienced in handling matters involving the federal Drug Price Competition and Patent Term Restoration Act, or Hatch-Waxman Act. Goldberg Segalla's dedicated Hatch-Waxman litigation team, a part of the Intellectual Property group, fully understands the drug approval process. Our litigators have represented both branded and generic pharmaceutical companies and, therefore, are able to craft an appropriate strategy based on each client's specific goals and needs. We use our experience and technical knowledge to counsel clients on all aspects of Abbreviated New Drug Applications (ANDAs) filed under the Hatch-Waxman Amendments. Our litigators routinely represent and advise pharmaceutical companies on pre-litigation strategies, FDA approval, prior art analysis and opinions, Paragraph IV certifications, trials, and appeals.

Business planning and growth — We can assist with the establishment of U.S. entities and foreign subsidiaries; strategic planning, risk management, and general corporate counseling; mergers, acquisitions, and all types of financing arrangements; licensing, joint venture, and other agreements; and other areas critical to company or product line expansion.

Product development, launch, marketing, and distribution — Our team can assist with new drug applications, clinical trials, monographs, 510(k) filings, and premarket approval applications. We counsel on testing protocols and outcomes, product safety concerns, and the full array of complex packaging, labeling, instruction, and warning requirements. We also advise on advertising and promotional campaigns involving all types of traditional and social media.

Manufacturing and distribution — We have extensive experience drafting and negotiating manufacturing and distribution agreements, and we can advise on a broad range of import and export concerns. We also assist with workplace safety issues, including evaluation of compliance with Occupational Safety and Health Administration (OSHA) standards.

Enforcement actions and crisis management — We utilize our extensive experience negotiating with the FDA to help clients respond to warning letters, notices of inspectional observations, and other enforcement actions. Our team is also experienced in handling enforced or voluntary product recalls, and we can advise clients on effective responses to adverse publicity resulting from recalls or safety concerns.

Foreign considerations — Our ability to assist does not end at the U.S. border. Our team also has experience counseling clients on litigation risks and regulatory compliance in Canada, Europe, and Asia.

Industry Perspective and Trusted Experience

At Goldberg Segalla, we pride ourselves on understanding each client's business and the science behind their products so we are better positioned to advise them on how to achieve their unique goals. Our Life Sciences team members have collectively spent dozens of years representing the pharmaceutical, medical device, and health products industries. They are also current or past bar leaders in life sciences law, not only serving as members of the Product Liability Advisory Council and every national bar organization for this area, but also taking active leadership roles in those

organizations.

With Goldberg Segalla on your side, you receive the combination of legal prowess and industry perspective necessary to help you reach your goals, protect your assets, and gain an advantage in this highly regulated and competitive market.

For an inside look at the latest legal developments involving medical devices, pharmaceuticals, and more, visit our *Life Science Matters* blog.