Life Sciences Practice 2002 Highlights

Ropes & Gray's Life Sciences Practice doubled during 2002 – reflecting rapidly growing industry awareness in the U.S. and abroad of the *breadth of our capabilities* and our unique *cross-disciplinary approach*.

Corporate Transactions and Licensing

- Represented major pharmaceutical companies, larger and smaller biotech and medical device companies, research institutions and others, in this country and overseas, in numerous complex licensing, partnering, supply, co-development and co-marketing transactions.
- Represented a bulge-bracket investment banking firm as underwriter's counsel in the initial public offering of a contract manufacturer to the medical device industry – one of the few medtech IPOs to be completed during 2002.
- Secured financing for a privately held biotechnology company through a "back-door public offering" by merger into a cash-rich publicly traded shell corporation.
- Managed difficult but necessary down-round financings for venture backed companies.
- Simultaneously in-licensed technology from three research institutes, acquired a privately held company and obtained venture financing for a start-up medical technology company pursuing a treatment for spinal cord injury.

FDA and Other Health Care Regulation

- Merged with the former Bennett Turner & Coleman LLP – one of the country's premier FDA and Health Care boutiques – to enhance our national leadership role in addressing rapidly evolving issues such as generic biologics, stem cell research and attacks on Hatch-Waxman patent protections.
- Assisted an international biotechnology company in becoming the first applicant to overcome a competitor's existing orphan drug exclusivity, by having the FDA deem our client's product "clinically superior" due to greater efficacy after developing a novel comparative study approach, that included extensive interactions with the FDA regarding the Orphan Drug Act.
- Developed and implemented sophisticated lifecycle management strategies, with regulatory, intellectual property, legislative and public relations components, and input from scientific opinion leaders, to help ensure the application of proper standards to competing products.
- Counseled research institutes, clinical trials sponsors and product development companies on the practical implications of the Health Insurance Portability and Accountability Act (HIPAA).

Intellectual Property Rights Management

- Negotiated a favorable resolution of two patent interferences and related matters involving fundamental gene research technologies for a major research institution.
- Handled licensing and patent due diligence matters relating to in-licensing technology for a Phase III drug from a publicly-traded biotechnology company on behalf of a global pharmaceutical company.

Government Enforcement and Litigation

- Defended pharmaceutical and biotechnology companies against civil and criminal allegations of violations of anti-kickback laws in marketing and distribution practices, particularly those involving Average Wholesale Price (AWP), marketing arrangements with physicians and off-label promotion activities.
- Defended an SEC informal investigation relating to a biotechnology company's SEC disclosures and FDA correspondence regarding its lead drug candidate.

Legislative Affairs

- Obtained significant industry-supported changes to proposed legislation on reporting requirements for agreements between pioneer and generic drug manufacturers on behalf of a global pharmaceutical company.
- Testified before both houses of the U.S. Congress and the Federal Trade Commission on Hatch-Waxman Reform and the interaction of intellectual property law and antitrust on behalf of the research-based pharmaceutical industry.

Geographic Growth

- Added life sciences specialists to our rapidly expanding offices in New York and San Francisco, and, while other firms were contracting, continued to add significantly to our Life Sciences Practice and overall professional staff in both Boston and Washington, DC.