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Q&A With Morgan Lewis' Steve Mahinka

Law360, New York (June 06, 2012, 1:47 PM ET) -- Stephen Paul Mahinka is a partner in Morgan Lewis & Bockius LLP's Washington, D.C., office, where he chairs the firm's life sciences and health care interdisciplinary practice group.

He is the founder of the firm's U.S. Food and Drug Administration and health care practice and a former leader of its antitrust practice, and has practiced in both the FDA regulatory and the antitrust areas throughout his career.

In the FDA area, he handles regulatory, transactional and compliance matters throughout the product lifecycle for pharmaceuticals, biologics, food and food additives, and medical devices. In the antitrust area, he focuses on mergers, joint ventures, pricing, distribution, marketing and promotion. He frequently writes on the FDA and competition issues.

Q: What is the most challenging case you have worked on and what made it challenging?

A: Much of my life sciences work is with European and Asian clients, greatly increasing the complexity and number of variables involved.

A challenging recent matter for an Asian client involved developing and managing a coordinated effort on three continents of a market withdrawal in the U.S. of an FDA-regulated product, by reason of anecdotal reports of possible adverse reactions in the European Union (EU) and changes in regulatory status of the product in Asia.

The matter required immediate and constant monitoring and advice, on a 24-7 basis in view of the geographic spread of time zones, integrating knowledge of the Asian regulatory and consumer situation, the EU scientific and marketing aspects, and U.S. product status and relations with the U.S. distributor.

We had to promptly develop a crisis-management plan and implement it together with a communications firm, as well as assist in responding to Asian press inquiries and postings on the Internet of items of potential relevance from residents of three continents.

The matter thus required us to have regulatory knowledge, but also the ability to lead a disparate team of client officials and other professionals and to provide immediate practical business guidance.

Our efforts were successful, avoiding adverse regulatory consequences for our client, and this was only possible with the assistance of my partner, Kathleen Sanzo, the leader of our FDA and health care practice, and others in our firm's life sciences group in multiple offices.

Q: What aspects of your practice area are in need of reform and why?

A: From a general standpoint, it is clear that there is a developing crisis regarding regulatory and economic issues that historically have been dealt with discretely in the U.S. by myriad regulatory and enforcement agencies. These often act in an uncoordinated manner.

However effective regulation and enforcement has been in the past, notwithstanding deficiencies in coordination and integration, it seems clear that this situation cannot continue.

Food safety, for example, split among several agencies, including the FDA, the U.S. Department of Agriculture and the U.S. Department of Commerce, must be resolved in order to deal effectively with import safety issues, bioterrorism and new product development concerns.

Pharmaceutical and medical device approvals, essentially divorced from reimbursement reviews and determinations, will become increasingly unwieldy without closer and clear coordination between the FDA and the U.S. Centers for Medicare & Medicaid Services during product development, which will be demanded by both payors and product developers.

For both safety and cost-effectiveness reasons, this redundancy and inconsistent direction, and resulting delays, will become increasingly difficult to support and maintain.

Changing 20th century bureaucratic structures is neither easy nor free from strong resistance, but 21st century safety and cost concerns will increasingly not be met without real changes in our historic regulatory and enforcement structures.

Q: What is an important issue or case relevant to your practice area and why?

A: The most important issue affecting the future development of the life sciences and health care area is the aging of the world population in most developed nations and in China, and the consequent significantly increasing demand for health care products and services, which will substantially increase cost pressures on government and private payors.

This will have significant consequences on legal and regulatory practitioners, requiring much greater attention to and understanding of economics.

These cost pressures can be expected to affect many areas of activity, including clinical trials, through inclusion of comparative and cost-effectiveness research, efforts to approve biosimilars to reduce the costs of biologics, integration of health care delivery, such as through accountable care organizations, increasing consolidation among and within the life sciences and health care industries, including insurer/health care provider mergers, and changing valuation of products/services and companies by acquirers and investors, which will need to take into account payor constraints on products and services in a way different than has been the historical practice.

I have been fortunate to be involved throughout my career in both the FDA and antitrust areas, and able to integrate economic considerations in regulatory and transactional developments; this capability with economic analysis will be an increasingly important additional element of a life sciences lawyer's skills in view of these trends.

Q: Outside your own firm, name an attorney in your field who has impressed you and explain why.

A: Gary Yingling of K&L Gates LLP, who is one of the finest mentors in the theory and practice of FDA law, as well as being highly professional and knowledgeable.

I have known Gary since I began practicing in the life sciences area; he always has time to discuss issues and has unfailingly keen insights into operation of the agencies, enforcement and regulatory trends, and regulators.

Perhaps most importantly, he is genuine, in a field of endeavor where there are pressures not to be.

Q: What is a mistake you made early in your career and what did you learn from it?

A: I often mention to associates working with me that the major mistake I made early in my career, in working on a case with my mentor, Miles W. Kirkpatrick, a former Federal Trade Commission chairman, was to so immerse myself in the facts of a case that I missed the basic theoretical deficiencies of the complaint.

I had spent weeks analyzing the facts of the district court litigation for an appeal we had been asked to take on, and gave a detailed factual analysis. Miles simply asked why we would accept the inference approach of the plaintiff and the district court, when there was clearly no evidence of economic harm.

We took this simple and direct approach, obtained reversal of a multimillion dollar verdict, and established new law in the Third Circuit. I've never forgotten the importance of simplifying complexity since.

This lesson is particularly important today, where clients are inundated with available information; what they need from their advisors is simple and concise distillation of it with clear options for action.

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