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Q&A With Epstein's Mark Lutes

Law360, New York (May 31, 2012, 5:36 PM ET) – Mark Lutes is a senior member of Epstein Becker Green PC's health care and life sciences practice and serves on the firm's board of directors. He is based in Epstein's Washington, D.C., office and has practiced with the firm for 28 years and was previously a legislative adviser to the Federal Trade Commission.

He also provides clients with strategic counsel in health policy and on reimbursement strategy through Epstein's affiliates EBG Advisors Inc. and National Health Advisors LLC.

Lutes is a leader in Epstein's representation of private equity and financial services firms with health care companies in their portfolios. He has been involved in many of the largest transactions in the health care market, including services, pharmaceutical and device companies. He also advises clients on antitrust matters, structuring managed care payment arrangements, hospital and physician joint ventures and information privacy and security.

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

A: In my specialty, health regulatory diligence for private equity investors, the most challenging transaction was taking HCA Inc. private for KKR & Co. LP,Merrill Lynch & Co. and Bain Capital LLC. It was not simply a record-setting monetary transaction ($35B), but one that involved regulatory diligence of hundreds of hospitals.

My partner, Lynn Snyder, and I deployed teams across the country to assess, among other things, existing exposures and the potential for new fraud and abuse exposures within the physician and other financial relationships wrapped up in those hundreds of hospitals.

The issues were not unique to that particular hospital deal, but the scope was daunting and we were blessed to have a deep, experienced bench to call on.

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

A: The health regulatory diligence process works well when we have the opportunity to partner with experienced corporate/transaction counsel that understand where to get front-end input as to regulatory implications of the deal. I have been fortunate to be able to partner with a number of such experienced transactional lawyers.

The process does not work well when someone thinks, at the 11th hour, “should we get a specialist to look at the health regulatory issues?” At that point, precious time has been lost from an optimal structuring perspective, the virtual data room is bereft of compliance oriented documents, exposures that affect the client’s financial model have not been assessed and the preliminary drafts of the deal documents do not have reps and closing conditions reaching the salient health regulatory exposures.

This happens more than you would think, because health care compliance problems intrude on many businesses, particularly technology businesses, not thought to be impacted by health care law.

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

A: The impact of health care regulation on the technology businesses is underappreciated. For example, the U.S. Food and Drug Administration, after years of relative silence, is actively considering the parameters of its regulation of software as a medical device.

Algorithms are at the heart of health care analytics and the electronic medical records that U.S. Congress is counting on to support best practices in patient care management. Software companies, and other companies with algorithms as part of their offerings, need to be watching this space closely.

Technology also impacts heavily in the form of information security regulation. Since the Health Information Technology for Economic and Clinical Health (HITECH) Act, with its security incident reporting requirements and heightened regulatory enforcement, the administrative, physical and technical safeguards protecting “big data” and other data in health care have become immensely important.

Security risk assessments, and verification of the compliance of everyone in the software development and data supply chain, has become a front-burner issue. California has weighed in with a statute presuming damages so that “ordinary” information security incidents can create huge financial exposures.

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

A: I have seen Margaret “Meg” Gibson, with Kirkland & Ellis LLP, do marvelous things for her clients, who are often undertaking large deals in the health care space. She has a deep, talented team supporting her, and it is deployed well to close transactions on a timely basis.

I see her helping everyone in a deal sort through what is important and translate things in a way that is really helpful in framing her clients’ choices. She does this with a polish and calm that clients and other counsel appreciate.

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

A: I have learned to ask questions as to the key drivers in the client’s financial model and make sure that we have addressed all the health regulatory impacts relating to the model, whether they are a new billing code, cuts in payment, change in coverage by local payers or an enforcement action against a supplier.

As regulatory lawyers, we may rush to judgment relative to what we think are the classic exposures in the field — a U.S. Department of Health and Human Services' Office of the Inspector General investigation, a qui tam investigation, etc.

Many times, however, there will be salient exposures as to where the business might go next, how data might be used in the future or how dependent a business might be on a supplier that might have its operations interrupted for regulatory reasons.

Early in my career, I undervalued the importance of an up-front inquiry as to the scope of the clients' assumptions as to what drove the business being invested in and as to what would drive the future portfolio company's success in the future. I have found that, by asking those questions, we get to the heart of what needs to be validated.

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