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Q&A With Reed Smith's Lorraine Campos

Law360, New York (February 21, 2013, 3:24 PM ET) -- Lorraine Campos is a partner in Reed Smith LLP's Washington, D.C., office. She is the leader of the firm's government contracts and grants team and focuses her practice on assisting clients with a variety of issues related to government contracts, government ethics, campaign finance, and lobbying laws. She has particular experience in counseling clients regarding Federal Supply Schedules, creating company ethics and compliance programs related to doing business with the federal government, conducting internal investigations, drafting and negotiating government contracts and subcontracts, and facilitating government contract compliance training. She also counsels clients on bid protest matters, federal grant programs, federal audits, and the application of the Federal Acquisition Regulation and individual agency supplement procurement regulations.

Q. What is the most challenging case you've worked on, and why?

In 2003, one of our clients received a notice of a government audit, which at the time seemed pretty standard. The audit quickly took a turn for the worse and shortly thereafter a subpoena was issued related to government contract pricing. The subpoena led to years of audit activity and eventually a qui tam suit was unsealed. The most challenging aspect of this case was assisting the client on multiple fronts with the years of audits, internal investigation and finally the litigation. Though the aspects of this case were necessarily intertwined, they were also distinct, so few common tactics applied for addressing them. Determining how to leverage what we were doing to ensure a coherent approach to the multifarious legal issues was difficult, but ultimately vital.

Q. What aspects of law in your practice area are in need of reform, and why?

There are so many areas that need reform, but right now the area I believe is most critical is alleviating the challenges associated with becoming a government contractor. I work with a number of companies that are commercial contractors. Unfortunately, they do not understand the intricacies of becoming a government contractor and often look to the government to provide this guidance, or at least steer them in the right direction. Unfortunately, the procurement workforce does not have the headcount to provide this guidance.

These challenges are exacerbated by the fact that once a company becomes a government contractor there are many compliance requirements to remain one. While I believe that company programs that foster appropriate business conduct and compliance are necessary, I think there needs to be a balanced approach to compliance policies, to ensure appropriate accountability in the contracting process without imposing unreasonably burdensome or unfair requirements.

Q. What is an important issue or case relevant to your practice are and why?

My practice involves working with a number of pharmaceutical companies and an important issue right now is the Trade Agreements Act. The TAA essentially provides that the government may acquire only "U.S.-made or designated country end products." Furthermore, the act requires contractors to certify that each end product meets the applicable requirements. The TAA generally applies to the acquisitions of supplies and services valued at or above $202,000. Federal agencies take the position that the threshold applies to the estimated value of sales for Federal Supply Schedule contracts. Accordingly, all General Services Administration and Veterans Affairs FSS contracts are subject to the TAA.

As the world is "getting smaller" and many manufacturers are either moving manufacturing abroad or otherwise obtaining pharmaceutical components from other countries — the fact that China and India are not designated countries within the scope of the TAA is creating a ripple effect. This is an interesting issue because the United States Bureau of Customs and Board Protection provides rulings on whether specific products including pharmaceuticals have been "substantially transformed" thus assisting with the determination regarding the country of manufacturer. However, substantial transformation is a fact-intensive analysis that can vary greatly based on a number of factors related to the products that make up a pharmaceutical.

I think pharmaceutical manufacturers are further confused by the fact that the Federal Food, Drug and Cosmetic Act does not have any express provisions requiring country of origin labeling for pharmaceutical products. However, a drug will be deemed misbranded if "its labeling is false or misleading in any particular." Furthermore, the U.S. Food and Drug Administration approves drugs, and may visit a facility, but does not assess the country of origin of a product in the agency's approval process.

This is an issue that I feel is perplexing for many clients because not only are there various government agencies involved when pharmaceutical are involved, but a contractor that fails to provide TAA compliant products to the government faces potential false claim act liability. Unfortunately, many pharmaceutical manufactures do not fully understand that they too are a government contractor and that the implications for selling such non-TAA products are steep.

Q. Outside your own firm, name one lawyer who's impressed you and tell us why.

Over the past few years I have had the pleasure of working with John Pachter, of Smith Pachter McWharton. I continue to be impressed by John, who is one of the most perceptive government contracts attorneys that I know. He has a keen understanding of changes and challenges in government contracts law and given his broad understanding of the law, he is extremely insightful.

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

One mistake I made early in my career was when I was working on a suspension and debarment matter and was asked by the partner to send the supplemental submission to the Navy's suspension and debarment office. There were a number of documents that we needed to send via PDF. (Note at this point in my career sending a PDF was somewhat new and the hard copies had to be sent to a copying room to be transferred to pdf.)

Anyway, I sent the documents to be created into a PDF and I received the PDF documents via email. I then opened the PDF and looked at the first few pages, unfortunately on page 25 of the PDF was a document that should not have been sent. But I stopped reading at page 10 and sent the email. I received a confused call from the Navy's SDO office a few hours later and had to explain the error, withdraw the supplemental submission, and make a resubmission. I then explained the error to the assigning partner and the client. I felt absolutely horrible and was very embarrassed.

What I learned from that situation was that technology makes everything quicker, but we still need to slow down and be lawyers. To be good lawyers we need to ensure that we take the care of our client needs and that means ensuring that we check everything that we do .. and send. I think the associates that I work with hate it when I ask “did you check it twice,” but it’s good training.

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