

Q&A With Choate's Christine Savage

Law360, New York (June 13, 2012, 1:56 PM ET) – Christine G. Savage chairs Choate Hall & Stewart LLP's health care group in the firm's Boston office. She represents health care services organizations, handling complex regulatory problems and developing practical business solutions. She also defends False Claims Act and off-label marketing cases, and advises private equity/venture capital firms on applying industry and regulatory requirements to proposed ventures with health care companies.

Recently she has been representing pharmaceutical companies and employees in health care fraud investigations, securing first-in-nation hospital settlement under new Stark law self-disclosure protocol, managing federal and state reporting obligations and investigations following a hospital data loss, and advising institutions in response to research misconduct and related false claims allegations.

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

A: My most challenging case of the past several years involved a Stark law self-disclosure on behalf of a community hospital, which was ultimately resolved last year through the Medicare Self Referral Disclosure Protocol (SRDP). While any case involving a strict liability statute that carries with it significant financial consequences when violated is challenging, the client faced the supplemental challenge of deciding which forum to disclose and resolve the matter in since the SRDP had not been created at the time of our initial disclosure. More significantly, the hospital was also in the midst of trying to complete a transaction whereby they would have become part of a larger hospital group.

While we had strong arguments to make had the matter been put before a judge, other business and financial factors required that the client resolve the matter short of litigation. Fortunately I was able to resolve the matter quite favorably for my hospital client, which has enabled them to move forward with their business objectives.

Still, the SRDP process remains somewhat frustrating to me, and the health care bar in general, since it has not yielded clearer guidance to providers as to what will and will not be considered a violation of the law and the importance or weight to be placed on various factors that may be taken into consideration at the time of settlement.

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

A: Health care represents one of the country's most heavily regulated industries, and it is constantly being subjected to some measure of reform, which isn't always a good thing. I would like to see federal and state regulators take a deep breath and look at whether what they have already implemented continues to make sense and is having the desired operational, legal and financial impact before seeking to layer on additional changes.

Right now, we see clients devoting significant time and resources preparing for impending legal changes, only to see lengthy delays in implementation and now the prospect of an unraveling of multiple initiatives in the event that part or all of health care reform as enacted via the Patient Protection and Affordable Care Act is deemed unconstitutional.

The landscape is beginning to feel a bit like someone is throwing mud at the wall hoping enough of it sticks, but with no idea which pieces will or won't be around a few years from now. This approach does not help providers address systemic issues like ensuring access to safe, quality health care services, addressing chronic health care conditions, which have a disproportionate effect on health care expenditures, or implementing adequate information systems.

I'd also like to see much of the Stark law abolished or at least rewritten to introduce an intent element to avoid unnecessary legal entanglements and windfalls to the government where there is no doubt that patients received the right care at the right time from physicians and other providers with only the best of motives.

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

A: An increasingly important issue in my practice has become navigating the intersection between scientific misconduct allegations and the potential for False Claims Act liability. As more and more cases of alleged scientific misconduct (e.g., plagiarism, falsification or fabrication of data) are coming to light, institutions receiving federal funding to support scientific research are becoming ever more mindful of the fact that a resolution with the Office of Research Integrity may not be the end of the story. As a result, the scope of and participants engaged in internal investigations of these matters are changing and becoming more complex.

In particular, amendments to the False Claims Act in 2009 inserting a uniform standard that defines a statement as material if it "has a natural tendency to influence" a decision-maker, and opinions like the one issued in *United States ex rel. Feldman v. Van Gorp & Cornell Univ. Med. College* which upheld a jury's finding that a statement had such a tendency, even when the jury had been presented with uncontroverted evidence that the statement did not actually influence the decision, are keeping me and others busy.

Also, as competition for scarce federal research dollars continues to increase, so will the scrutiny applied to the use of that money. I think we are likely to see more activity in this area over the next few years.

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

A: I've had the opportunity to work collaboratively with Kevin McAnaney, the former chief of the Industry Guidance Branch of the Office of Counsel for the Office of the Inspector General, on a number of projects over the past few years. Kevin's extensive knowledge of the Stark regulations and anti-kickback safe harbors, combined with his practical style and sharp wit have made it a pleasure — or at least more palatable — to tease through even the most complex transactions or business relationships. Clients love him and understand him, as he has a way of explaining things simply without making the listener feel stupid. I'm also impressed, and humbled, by his long-term commitment to public service and teaching and admire his entrepreneurial spirit in starting his own firm.

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

A: I think the biggest mistake I made early in my career was failing to appreciate the importance of simplicity and pragmatism in delivering legal services to health care providers, whether they be institutions or individuals. As a younger lawyer, I spent far too much time and energy writing detailed and comprehensive memos on the law and far too little time focused on what does the client really care about, how does the law inform, if at all, what they want to accomplish, and how can they best accomplish it. When you're told, "hey, that's a great document, but now what do I do?" a few times, your focus begins to shift. I think the client and mentor feedback I received back then has helped me become a better business partner and communicator today.

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