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Q&A With Covington's Gerald Masoudi

Law360, New York (June 25, 2012, 2:07 PM EDT) -- Gerald Masoudi is a partner in Covington & Burling LLP's Washington, D.C, office. He is co-chairman of the firm's food and drug practice group. He most recently served as chief counsel of the U.S. Food and Drug Administration. In that capacity he was responsible for supervising the FDA's involvement in civil and criminal litigation and investigations; providing legal review of warning letters, guidances and regulations; and providing advice to the FDA commissioner and senior leadership on matters relating to the products regulated by FDA. Before joining the FDA, Masoudi served as deputy assistant attorney general for international, policy and appellate matters in the Antitrust Division at the U.S. Department of Justice.

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

A: While I was chief counsel at FDA, I was involved in cases raising the question of whether failure-to-warn claims under state law brought against drug manufacturers are preempted by federal law governing labeling of drugs. FDA carefully considers labeling of drugs and approves a package insert that contains only those statements (including warnings) that FDA believes are supported by evidence.

In some cases, FDA denies companies the ability to warn against certain risks in their package inserts. I strongly believe that this kind of regulatory system is inconsistent with products liability cases premised on a failure to warn of risks associated with drugs. For that reason, while I was at FDA I worked to try to ensure that drugmakers were not punished under state tort law for failing to warn of risks that FDA did not allow to be stated in the drug's labeling, in cases where FDA had been apprised of the relevant risks. I worked on a final rule clarifying FDA's approach to labeling requirements and was on the solicitor general's briefs in preemption cases in the Supreme Court.

In Wyeth v. Levine, the plaintiff was a musician who lost an arm because of how an intravenous drug was administered to her. Although the drug's labeling provided safety information about this method of administration, her lawyers argued that the drugmaker should have instructed physicians not to use that method at all, and therefore that the drugmaker was liable for her injuries.

On behalf of FDA, we argued that a state court should not be permitted to punish a drugmaker for failing to provide a warning when FDA had been made aware of the risk and did not require the warning, and where the drugmaker could not have changed its labeling unilaterally. The Supreme Court did not agree with us, leaving open only a narrow opening for a preemption argument where FDA has

specifically rejected a warning. The case was challenging not only on the merits, but also because of the very sympathetic plaintiff.

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

A: I think the government's regulation of pharmaceutical marketing, especially in the off-label context, is ripe for reform. Drug companies very much want to get accurate and helpful information to patients and physicians, but they face a thicket of regulatory requirements governing their speech about their own products. FDA acknowledges that physicians may lawfully prescribe drugs for uses other than those set forth in the FDA-approved labeling, and virtually everyone is free to disseminate information about these uses — everyone, that is, except the drug companies.

Companies can face prosecution for off-label marketing, even if they are disseminating completely accurate information about their products. The Supreme Court recently decided a case in which it held that speech in furtherance of pharmaceutical marketing is protected by the First Amendment, and that a speaker-based, content-based restriction on the use of data in furtherance of such marketing was unconstitutional.

There is a pending case in the Second Circuit in which the court may find that some portion of FDA's restrictions on off-label speech are unconstitutional. Even in the absence of a decision in the Second Circuit, industry very much needs reasonable guidance that is constitutionally sound, and there are a variety of promotional areas in which FDA could provide this guidance.

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

A: Shortages of lifesaving drugs are a major issue for regulators and industry. Standards and expectations for manufacturing these drugs seem to be getting ever stricter, even sometimes in the absence of evidence that stricter standards are necessary to make products materially safer or better, and reimbursement rates are heavily restricted. FDA is trying to get more involved by requiring manufacturers to give notice when they might have upcoming shortages, but I don't think putting FDA in the role of a central planner is the answer.

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

A: Liz Dickinson at FDA is one of the very finest food and drug lawyers. For years she handled generic approvals for the agency. She knows the Hatch-Waxman provisions probably better than anyone because she has been involved in every major decision for such a long time. Now that she is chief counsel, she can apply her talents to a broader range of food and drug issues. I think she is also proving to be a great manager and has the right personal touch for the job.

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

A: As a young litigator, I was responsible for preparing and submitting responses to requests for admission in one of my first cases. The schedule set by the court counted all deadlines backward from the trial date, and responses to requests to admit were due some number of days before trial. Because

of the duration of the period, holidays did not count toward the calculation, and there was a holiday between the deadline and the trial date. Ordinarily, having a holiday in the calculation means more time, but in this case it meant less. I discovered the miscalculation late on the afternoon of the actual due date and was not in a position to submit the responses on time. I immediately went to the partner in charge who fixed the problem by calling the other side and announcing "We're going to be serving our responses tomorrow. Would you like them by email or fax?" The other side was never the wiser, and the problem went away. What I learned: (1) always triple-check deadlines; (2) if you make a mistake, own up right away and get help; and (3) a little chutzpah can go a long way.

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