

## Forest Decision Does Little To Remove Exclusion Threat

By Ian Thoms

Law360, New York (August 8, 2011) -- While U.S. health care regulators have backed down from their bold threat to ban Forest Laboratories Inc.'s CEO from contracting with the government in the wake of the drugmaker's alleged off-label marketing, the relief may be short-lived, defense attorneys fear, as regulators remain poised to bring other such cases.

During the time Forest was fined \$313 million in September for off-label marketing of Celexa and other violations, controversy broke out after the U.S. Department of Health and Human Services threatened Forest CEO Howard Solomon with exclusion from government contracting, despite the fact that he was never accused of knowing about the wrongdoing.

But on Friday, the Office of the Inspector General at HHS retreated from its earlier stance, telling the 83-year-old Solomon in a terse letter that it had closed its case against him, leaving some attorneys heartened but wary.

"I'm definitely encouraged by it and I wish I had a crystal ball, but I don't think it will change the way government lawyers do business," said Lisa Noller, a partner at Foley & Lardner LLP in Chicago. "Individual exclusions, like the one HHS pursued in the Forest Labs case, are still scary to me."

Since at least early 2010, health care executives have been put on notice that they are now in the crosshair like never before — potentially facing criminal charges and exclusion from lucrative government contracting because they're "responsible corporate officers" who should have stopped fraud, even if they didn't know it was happening.

In March 2010, the OIG at HHS said the government would more closely scrutinize individuals and would bring more actions against them, including administrative actions against executives and criminal pleas for responsible corporate officers. Officials also said there would be an increasing number of False Claims Act cases, criminal actions and exclusions.

Though the OIG has now abandoned its exclusion proceedings against Solomon, the mere warning "sent a shock wave through the industry," said the CEO's attorney, Martine Beamon of Davis Polk & Wardwell LLP. Nevertheless, the OIG's dropping of the case showed attorneys that regulators were willing to wield its powerful weapon with some caution.

"If I were an executive at a pharmaceutical company, I would be cautiously optimistic, but I don't think anyone is going to breathe a big sigh of relief," Beamon said.

Part of the reason for the remaining apprehension is that HHS and the OIG never made public the details of their case against Solomon, nor their specific reasoning for abandoning it.

"They didn't say, 'Oh, our bad, we made a mistake,'" Noller said. "We're really not sure why they decided not to pursue it."

And HHS and OIG made it clear that they would bring similar exclusion proceedings in the future, taking the unusual step of issuing a statement, albeit a rather cryptic one, after they dropped the case against Solomon.

"OIG takes its exclusion authority seriously and exercises it judiciously," the agency said. "We remain committed to investigating and, when appropriate, sanctioning executives and managers of health care entities who engage in health care fraud. This includes individuals who directly commit fraud as well as the executives in a position of responsibility at the time of the fraud."

Though the agency's case never came to fruition, adversaries like investor Carl Icahn, who is seeking to put four directors on the Forest board, have already benefited from the move. The Delaware Court of Chancery recently ordered the public disclosure of papers related to the government's bid to bar Solomon, which Icahn contends is symptomatic of larger governance problems at the company.

Whatever the outcome of that proceeding, the Solomon case in general underscores the importance for companies to have strong regulatory compliance programs in place, even if they are not government contractors in the strictest sense, according to Bryan Cave LLP partner William Weisberg.

"We still advise our clients to be especially careful with government contracting because government is an unusual customer — it's a customer that can arrest you," Weisberg said.

And one way the government will continue to pursue executives at the helm of wayward companies is through expulsion proceedings, even if it dropped this first high-profile attempt to go after a pharmaceutical CEO, according to Michael K. Loucks, a partner at Skadden Arps Slate Meagher & Flom LLP.

"The government will continue to look at exclusion as a tool to use. The power's there in the statute and it's a power that can be exercised," Loucks said. "It's a little hard to say what impact this might have and I think it's a mistake to try to. One decision isn't a pattern. It's just one decision."

--Additional reporting by Hilary Russ and Lance Daroni. Editing by Anne Urda and Andrew Park.