Securities Regulation Daily Wrap Up, TOP STORY—9th Cir.: Studies that smelled a rat about drug's safety should have been disclosed, (Nov. 1, 2016)

Securities Regulation Daily Wrap Up

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A drug company that referred to positive animal study results was obligated to disclose negative results as well, a Ninth Circuit panel said. When the company affirmatively represented that, based on all of the animal studies that had been completed, a weight-loss drug was safe and likely to be approved by the FDA, it was obligated to disclose that rats given the drug got cancer. While there may have been a good-faith scientific disagreement about the study's results, the FDA's concerns about it were material to the market's assessment of the likelihood of the drug's approval (*Schueneman v. Arena Pharmaceuticals, Inc.*, October 26, 2016, Bybee, J.).

Lorcaserin. Arena Pharmaceuticals, Inc. developed a weight-loss drug called lorcaserin. The drug is a serotonin agonist, a class of drugs that is given close scrutiny by the FDA due to the potential for cardiovascular problems and other health consequences.

At the same time Arena was conducting Phase III clinical tests on human patients, it also conducted a nonclinical study on rats to test lorcaserin's carcinogenicity. Initial results indicated that lorcaserin caused tumors and cancer in the rats, and follow-up studies made at the FDA's urging substantiated that the cause was an increase in prolactin, a hormone linked to cancer in rats. A final report on the rat studies was submitted to the FDA in February 2009.

In March 2009, Arena's CEO told investors that he was confident that lorcaserin would be approved. In this and other statements in 2009, Arena indicated that the drug's safety and efficacy was demonstrated in part via animal studies. In September 2010, however, the FDA published briefing documents that for the first time disclosed the existence of the rat study and the possible carcinogenic effects of lorcaserin. Investors were caught completely off-guard, and Arena's stock dropped by 40 percent in a single day.

Arena later supplied to the FDA an interpretation of the data that supported lorcaserin's safety, based on the high dosages given to the rats. The FDA initially disagreed and declined to approve lorcaserin. Later, after a review by an independent panel, the FDA found that there was a high-enough safety margin for the drug and, in June 2012, approved lorcaserin for the market.

In the district court. A suit alleging fraud under the Exchange Act was filed soon after the FDA posted the briefing documents. The complaint was dismissed after the court found that was more plausible that Arena reasonably believed that the rat study results were positive and did not act with deliberate recklessness in omitting them. The court also dismissed amended complaints, concluding that the case boiled down to a difference of scientific opinion between the FDA and Arena.

Rat study plagues Arena. On appeal, the investor argued that once Arena raised the animal studies in support of lorcaserin's safety, they were obligated to disclose the existence of the rat study. The failure to do so, the investor maintained, demonstrated scienter. The panel agreed.

The panel noted that the securities laws do not create a duty to disclose any and all material information. But, once a company chooses to tout positive information, they have a duty to not mislead investors and are bound to disclose any adverse information as well. There was no question, the panel said, that the Arena defendants were aware of the rat study and that they still told investors that they were confident that lorcaserin would be approved based on "all the animal studies that have been completed."

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If Arena did not represent that animal studies supported lorcaserin's safety and likelihood of FDA approval, the panel continued, it may not have had a duty to disclose the rat study. Having done so, however, the failure to disclose the FDA's concerns about the rat study was an extreme departure from the standards of ordinary care. The panel noted further that Arena knew that the FDA's request for follow-up reports and studies was highly unusual and not part of the normal FDA process.

Finally, Arena argued that the case was really a good-faith disagreement between it and the FDA about the meaning of the rat study. The panel said Arena had a choice to remain silent or address the dispute with the FDA, but Arena could not represent that there was no controversy because all the data was favorable. What really mattered in this case, the panel said in conclusion, was not who was right about the underlying science, but whether information material to the market's assessment of lorcaserin's likelihood of approval was intentionally withheld.

The case is No. 14-55633.

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Companies: Arena Pharmaceuticals, Inc.

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