ALERT
JANUARY 18, 2011

LIFE SCIENCES
News Concerning Recent Developments
Impacting the Life Sciences Industry

COZEN O'CONNOR
www.cozen.com

ADVERSE INCIDENT REPORTS: HOW MANY IS TOO MANY?

Sarah D. Schlossberg • 215.665.3727 • *sschlossberg@cozen.com*

On January 10, 2011, the U.S. Supreme Court heard argument in the matter *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167 (9th Cir. 2009), and suggested that some major changes may be in store for pharmaceutical companies which could forever alter how they handle adverse reports.

Siracusano involved allegations by shareholder plaintiffs that the defendant manufacturer, Matrixx, violated the Securities and Exchange Act of 1934 by failing to disclose material information regarding Zicam Cold Remedy. The Securities and Exchange Act prohibits "any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security." Specifically, the shareholders claimed that defendant Matrixx knew that many Zicam users had lost their sense of smell after inhaling the drug; nevertheless, Matrixx failed to disclose this health risk to shareholders, repeatedly assured investors that revenues were on the rise, and falsely disclaimed the existence of any pending lawsuits.

On the district court level, the court found the shareholder plaintiffs failed to establish the existence of two essential elements of a securities violation: they could not prove that Matrixx made a material misrepresentation or omission of fact or that Matrixx acted with scienter. On these bases, Matrixx's motion to dismiss was granted. On appeal, the Ninth Circuit disagreed, finding that the shareholders had sufficiently alleged materiality. In particular, the Ninth Circuit rejected the notion that materiality equated to "statistical significance," and instead engaged in a fact-specific inquiry to determine whether a reasonable investor would have considered the facts withheld by Matrixx to be material. With regard to scienter, again the Court took a holistic view of the facts as pleaded and determined that the conclusion that Matrixx acted intentionally or with deliberate recklessness was "at least as compelling" as the inference that it acted innocently.

During the recent oral argument before the Supreme Court, it quickly became clear that many of the justices are inclined to side with the Ninth Circuit on these issues. The justices seemed unpersuaded by Matrixx's argument that the shareholders should only be permitted to establish materiality by proving that the company was aware of a statistically significant number of adverse reports. Chief Justice Roberts went so far as to say that he would consider the premonitions of a psychic to be "material" if they were going to cause a 20 percent decline in a company's stock. However, several of the justices did voice practical concerns of constructing a test that would result in increased disclosure requirements for pharmaceutical companies. Specifically, Justice Breyer pondered whether increased disclosures would desensitize the public.

Although the Supreme Court has not yet ruled on this case, pharmaceutical companies and executives are officially on notice that they too could be held to this heightened standard of disclosure. Although there is always a question as to the veracity or substantiation of these reports, companies can no longer ignore adverse incident reports that slowly increase over time. A single report will not likely trigger a heightened disclosure requirement, but companies need to ensure that they are receiving comprehensive reports regarding adverse incidents and take affirmative steps to notify their shareholders when these incidents become repetitive or cumulative. The point at which that balance tips is a difficult one to determine, so the Court's decision in *Siracusano* will be an important one to watch.