Client Alert.

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Supreme Court Will Decide If Statistical Significance Forms Part of the Legal Standard for Proving Securities Fraud Against Life Science Companies

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Statistical significance is generally cited as the gold standard by which pharmaceutical companies decide whether information is scientifically meaningful. Should it also be part of the legal standard for proving securities fraud under the federal securities laws? The United States Supreme Court will resolve that question in its next term, which starts in October 2010.

On Monday, June 14, 2010, the Supreme Court granted certiorari in *Matrixx Initiatives, Inc. v. Siracusano*, No. 09-1156, to decide: "Whether a plaintiff can state a claim under § 10(b) of the Securities Exchange Act and SEC Rule 10b-5 based on a pharmaceutical company's nondisclosure of adverse event reports even though the reports are not alleged to be statistically significant."

The underlying lawsuit arises from allegations that Matrixx Initiatives, Inc. (ticker MTXX) and its executives intentionally misled the market by concealing information that its over-the-counter cold remedy Zicam caused patients to lose their sense of smell. According to the plaintiffs, who filed the original complaint in Arizona in April 2004, Matrixx received more than a dozen complaints from doctors and users about temporary or permanent loss of the sense of smell after patients used a nasal formulation of Matrixx's over-the-counter remedy. The plaintiffs alleged that Matrixx went on a vigorous public relations campaign that falsely touted Zicam's safety as news of the events became public, and that this caused Matrixx's stock to trade at false, inflated prices.[1]

On a motion to dismiss pursuant to the Private Securities Litigation Reform Act of 1995, the district court dismissed the lawsuit. The district court explained that that the complaint failed to allege that the *ad hoc* reports regarding patients' loss of smell reflected a statistically significant relationship to the use of Zicam. Relying on precedent from the First, Second, and Third Circuits, the district court held that an allegation showing statistical significance was a requirement for plaintiffs to bring a federal securities class action based on alleged misstatements about a product's safety. *See New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35 (1st Cir. 2008); *In re Carter-Wallace, Inc. Sec. Litig.,* 220 F.3d 36 (2d Cir. 2000); *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000).

On appeal, the Ninth Circuit reversed. The panel concluded: "The district court's reliance on the statistical significance standard to conclude that Appellants failed to establish materiality is inconsistent with the Supreme Court's rejection of

[1] For purposes of the legal record, these factual allegations were viewed as being true, although no one has yet tested the evidence that supports them in court. In a separate development unrelated to any court's ruling, the United States Food & Drug Administration later issued a warning letter to Matrixx in June 2009 that resulted in a decision by the company to recall multiple formulations of the Zicam product.

bright-line rules and its emphasis on having materiality determined by the trier of fact." *Siracusano v. Matrix Initiatives, Inc.*, 585 F.3d 1167, 1183 (9th Cir. 2009). The Ninth Circuit panel concluded that the allegations in the complaint, taken as a whole, satisfied the standards required to plead materiality and scienter according to the United States Supreme Court's decisions in *Basic Inc. v. Levinson,* 485 U.S. 224 (1988) and *Tellabs Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007).

Product safety is a subject frequently on the minds of regulators, consumers, and plaintiff class action lawyers. In 2008 alone, the United States Food and Drug Administration received more than 525,000 adverse event reports for drugs and therapeutic biologic products. In the same year, the Center for Drug Evaluation and Review at the FDA issued 379 product recalls and 87 warning letters. And in 2008, plaintiffs filed at least six securities class action lawsuits that alleged that life sciences companies misrepresented the safety of their products.

When has a company acquired enough information about a product's potential adverse events that it must disclose them when it makes otherwise positive comments about the product's prospects, sales or safety profile? The question arises routinely. History has proven that mistakes can result in costly claims of securities fraud. Companies and defense attorneys would like a bright line answer. Plaintiffs will push for an amorphous case-by-case determination. Within the next year, the Supreme Court will tell us which view represents the law in the United States.

For more information on this case or on Morrison & Foerster's Securities Litigation or Life Sciences practices, contact **Erik J. Olson** (EJOlson@mofo.com; 650.813.5825) or **Stephen B. Thau** (SThau@mofo.com; 650.813.5640).

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