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Pharmaceutical and Other Companies Beware: New Supreme Court Decision Weighs in on Adverse Event Reports and Potential Liability Under Federal Securities Laws

In 2010 the US Supreme Court agreed to hear another securities fraud case – *Matrixx Initiatives, Inc. v. Siracusano* – which could significantly increase pharmaceutical and other companies' exposure under federal securities laws, especially those companies that make disclosure decisions based on the statistical significance of certain events. On March 22, 2011 the Court spoke, unanimously rejecting the "bright-line" rule that many companies were hoping for.

The issue in *Matrixx* was straightforward: May a shareholder maintain a lawsuit for securities fraud based on a pharmaceutical company's failure to disclose adverse event reports (AERs) if the reports did not disclose a *statistically significant* number of adverse events relating to a product (in this case, a cold medicine)?

Given the split of judicial authority, pharmaceutical and other companies were faced with mounting uncertainty regarding whether, and to what extent, to publicly disclose AERs.

The district court dismissed the case, holding that the allegations of user complaints were not "material" because they were not statistically significant. The Ninth Circuit Court of Appeals disagreed. "The district court

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erred in relying on the statistical significance standard to conclude that Appellants failed adequately to allege materiality…. In relying on the statistical significance standard to determine materiality, the district court made a decision that should have been left to the trier of fact."

A *unanimous* Supreme Court affirmed the decision of the Ninth Circuit, agreed with the shareholder plaintiff and refused to craft a bright-line rule urged by Matrixx; namely, that AERs are not material unless there are enough reports to establish a statistically significant risk that the product is causing the events. "A lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events." Justice Sotomayor, who delivered the Opinion of the Court, further stated that while there are many cases where a reasonable investor would not consider reports of adverse events to be material information, the shareholder in this case alleged facts plausibly suggesting that a reasonable investor would have viewed these particular reports as material.

The Court relied on, among other things, the allegation that "Matrixx received information that plausibly indicated a reliable causal link between Zicam and anosmia. That information included reports from three medical professionals and researchers about more than 10 patients who had lost their sense of smell after using Zicam." The Court also pointed out that "nine plaintiffs commenced four product liability lawsuits against Matrixx alleging a causal link between Zicam use and anosmia." In the end, the Court found that the shareholder's allegations were sufficient to "raise a reasonable expectation that discovery will reveal evidence" satisfying the materiality requirement.

The Court did caution, however, that the "mere existence of reports of adverse events – which says nothing in and of itself about whether the drug is causing the adverse events – will not satisfy this standard. *Something more* is needed, but that something more is not limited to statistical significance and can come from the source, content, and context of the reports." (emphasis added)

But what is "something more"?

When is disclosure under the securities laws now required?

And are these always questions for a finder of fact?

Without a bright-line rule, these pivotal questions remain unanswered and the uncertainty continues. What is certain, though, is that a company will not prevail on a motion to dismiss brought under the federal securities laws by simply pointing out that there was no statistically significant data to establish an inference of causation when a product is alleged to be defective in some way. This is especially important since discovery in securities fraud cases can be onerous and coerce companies to settle even meritless claims.

Companies will be required, according to the Court, to look beyond the statistics and more carefully – and arguably subjectively – evaluate the "source, content, and context of the reports" and determine whether a "reasonable investor" would view the information "as having significantly altered the 'total mix' of information made available." Companies must scrutinize all possible "causal link" evidence and make an informed disclosure determination. In other words, while statistical significance (or the lack thereof) will not be irrelevant, it will also not be "dispositive of every case." This decision will also make more complex pharmaceutical companies' already extensive pharmacovigilance assessment and reporting requirements.

If you have any questions about the *Matrixx* decision or how it will affect your business, please contact your primary Squire Sanders lawyer or one of the individuals listed in this Alert.