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Client Alert

FDA & Life Sciences Practice Group

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Supreme Court Issues Opinion in Important Securities Fraud Case Concerning Pharmaceutical Manufacturers' Obligations to Disclose Adverse Incident Reports

On March 22, 2011, the U.S. Supreme Court issued its opinion in *Matrixx Initiatives, Inc. v. Siracusano*, 562 U.S. ___ (2011), an important securities fraud class action with potential implications for pharmaceutical and device manufacturers and others.

Matrixx Initiatives, Inc. v. Siracusano

The plaintiffs in *Matrixx* alleged that the drug manufacturer Matrixx Initiatives and three of its corporate officers (collectively "Matrixx") violated § 10(b) of the Securities Exchange Act of 1934 and Securities and Exchange Commission Rule 10b-5. Matrixx, through a subsidiary, manufactured and sold Zicam, an over-the-counter nasal spray and gel used to treat the common cold. Zicam accounted for approximately 70% of Matrixx' revenues. Between 1999 and 2003, Matrixx received several reports from medical researchers indicating that patients using Zicam had developed anosmia, the loss of the sense of smell. Between late 2003 and early 2004, Matrixx made several public statements regarding potential earnings growth and the safety of Zicam. Following a Good Morning America report revealing product liability suits against Matrixx as well as a doctor's discovery or more than a dozen patients who developed anosmia after using Zicam, Matrixx' share price fell sharply and investors filed suit.

Plaintiffs alleged that Matrixx' failure to disclose the adverse reports that it had received about Zicam rendered Matrixx' statements regarding earnings growth and the safety of Zicam to be misleading. Matrixx moved to dismiss, arguing that while it knew of anecdotal reports from doctors that patients using Zicam had developed anosmia, the number of these adverse events were not statistically significant. Matrixx contended that because they were not statistically significant, the adverse events did not suggest that Zicam caused anosmia and thus were not "material" and did not have to be disclosed. In addition, Matrixx argued that Plaintiffs could not establish scienter because of the absence of insider stock sales or other indicia of fraud, and because the absence of statistical significance meant that the failure to disclose the adverse events could not have been reckless

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In a unanimous opinion by Justice Sotomayor, the Supreme Court rejected Matrixx' arguments and held that the plaintiffs had alleged a violation of the securities laws sufficient to survive a motion to dismiss.

The Court rejected Matrixx' argument that in order to be material, adverse events must be statistically significant. Rejecting Matrixx' arguments for such a "bright-line" test, the Court reaffirmed its traditional articulation of the materiality standard; the "materiality requirement is satisfied when there is '"a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available."' Slip op. at 10 (quoting *Basic Inc., v. Levinson*, 485 U.S. 224, 231 (1988) (quoting *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438, 448-449 (1976))). Applying this standard, the Court noted that scientists, medical professionals, and government regulatory agencies, including the FDA, often rely and act upon information that is not statistically significant when assessing causation. The Court saw no reason to think that reasonable investors would behave any differently. Thus, the Court reasoned, Matrixx' proposed bright-line rule would "artificially exclude information that would otherwise be considered significant to the trading decision of a reasonable investor." Slip op. at 11 (alteration and internal quotation marks omitted).

The Court stressed, however, that its opinion did not require pharmaceutical manufacturers to disclose all reports of adverse events. It is only where the "source, content, or context of the reports" provides some reason for a reasonable investor to conclude that the drug may be causing the adverse event that the reports become material. Slip op. at 15. The Court also noted that the securities laws "do not create an affirmative duty to disclose any and all material information." *Id.* at 16. Rather, the law only requires disclosure when it is necessary to prevent a statement made by or on behalf of the company from being false or misleading. "Even with respect to information that a reasonable investor might consider material, companies can control what they have to disclose . . . by controlling what they say to the market."

The Court concluded that the plaintiffs had adequately alleged a material omission by Matrixx. The reports provided to Matrixx had revealed a "plausible causal connection between" Zicam and anosmia. *Id.* at 18. Matrixx triggered a duty to speak when it forecast increased sales of Zicam and professed its safety. The Court found it substantially likely that a reasonable investor would have viewed the information regarding adverse events as having significantly altered the total mix of information made available, and that the information could have made Matrixx' public statements misleading. Finally, even in the absence of any insider stock sales, the Court concluded that the plaintiffs had adequately alleged that the defendants had acted with the requisite scienter (which the Court assumed without deciding was "deliberate recklessness") by alleging that Matrixx elected not to disclose the reports because of their likely effect on the market for Zicam.

The Impact of Matrixx and Practical Considerations

Matrixx does create some obvious risks for pharmaceutical and device companies in terms of determining whether and when to report adverse events occurring in connection with their products. Any suggestion that Matrixx requires affirmative disclosure of adverse events when and as they occur must be tempered by consideration of several significant observations.

First, Matrixx presented a fairly unique set of facts. Matrixx depended on Zicam for 70% of its sales. When the company learned that medical researchers planned to make a poster presentation at a Rhinologic Society conference, the

company refused to allow the presenters to use the Zicam name in their presentation. When concerns were publicly reported, Matrixx characterized them as "unfounded" and "misleading" and stressed that the safety of Zicam was "well established." Matrixx seemed to have been unaware of older studies linking the use of zinc, the active ingredient of Zicam, with anosmia and, upon learning of the link, did not change its public statements and did nothing to investigate it. Ultimately, the FDA issued a warning letter to Matrixx on the basis of the very adverse event reports that Matrixx argued to the Supreme Court were statistically insignificant. Finally, given the risk (anosmia) and the reward (remediation of cold symptoms), together with the vast number of alternative therapies available to consumers, the likely impact on sales of the suppressed information was significant. As illustrated below, it is likely that some of the significance of Matrixx will be limited by its peculiar facts.

Second, the materiality assessment, at least in the securities law context, is on a company-wide basis rather than a drug-by-drug or device-by-device basis. Put another way, investors care about the financial results of an entity as a whole, not on the efficacy or risk profiles of individual drugs. This distinction gets lost in the Matrixx decision because Zicam comprised 70% of Matrixx' sales; if Zicam comprised only 2% of revenues, it is highly unlikely that the Court would have reached a similar result. Thus, in assessing disclosure duties with respect to adverse events in connection with any particular drug or device, the issuer should assess the potential impact of the adverse event on a company-wide basis.

Third, as the Court observed, the securities laws "do not create a duty to disclose any and all material information"; rather, they require that when statements are made, the statements not be misleading by omission. Thus, "companies can control what they have to disclose…by controlling what they say to the market." *Id.* at 16. Had Matrixx remained silent regarding the safety of Zicam, it is unlikely that the Court would have reached the same result. Instead, Matrixx touted Zicam's safety while being aware of, but omitting to disclose, evidence that contradicted those assurances.

Fourth, disclosure is only appropriate where a given fact "significantly alter[s] the 'total mix' of information." *Id*. at 15. Where an adverse event is consistent with the existing public information regarding a product or device, no disclosure is warranted. It is only where one or more adverse events credibly suggest the existence of a new risk, or a significantly elevated risk of a previously known effect, that disclosure might be appropriate.

With the foregoing considerations in mind, pharmaceutical and device companies should consider disclosure of adverse events where: (1) the "source, content, and context" of such events credibly suggest causation; (2) of a previously unknown, under-reported or under-estimated risk; (3) in connection with a product that generates a material part of the entity's revenues: and (4) the company has previously spoken publicly regarding the product's safety or risk profile. Stating and summarizing such a guideline, however, is far different than applying it in the real world and, until the lower courts apply *Matrixx'* fact-specific analysis to new fact patterns and clarify its significance, pharmaceutical and device companies will likely continue to struggle with balancing the need for disclosure of material information against the harm to the company and its investors from disclosure of isolated adverse events of questionable validity.

The Court's opinion is available here.