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Supreme Court Holds Materiality of Adverse Events Not Dependent on Statistical Significance

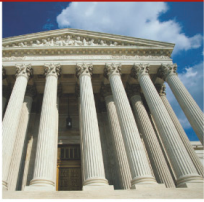
In a case closely watched by the pharmaceutical industry, the U.S. Supreme Court unanimously held on March 22, 2011, that a plaintiff may state a claim for securities fraud under § 10(b) of the Securities Exchange Act of 1934 and Securities Exchange Commission Rule 10b-5 based on an issuer's failure to disclose reports of adverse events associated with a product even if the adverse events are not statistically significant. *See Matrixx Initiatives, Inc. v. Siracusano*, No. 09-1156 (Mar. 22, 2011). The Court reaffirmed its adherence to the "total mix" standard of materiality, under which a fact is material if "there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having altered the 'total mix' of information made available." Slip op. 10 (quoting *Basic v. Levinson*, 485 U.S. 224, 231-32 (1988)). It rejected a bright-line rule that only statistically significant adverse events can be material to investors or raise a strong inference of scienter. This decision has important consequences not only for companies in the pharmaceutical and other life science industries but more broadly for other issuers as well.

THE COURT'S DECISION

The plaintiffs alleged that between 1999 and 2003 Matrixx failed to disclose at least a dozen reported instances of anosmia (lost sense of smell) suffered by users of Matrixx's Zicam Cold Remedy, and at the same time continued to make positive statements about Zicam and Matrixx's business prospects. Many of the adverse events were reported to Matrixx by three research and clinical physicians. Two of the physicians also gave a medical society presentation, which was to be titled "Zicam[®] Induced Anosmia" until Matrixx warned them that they did not have permission to use its or its products' names. One physician directed Matrixx to studies "from the 1930's and 1980's" that "confirmed '[z]inc's toxicity.'" Slip op. 3. During the class period, nine Zicam users had also filed lawsuits against Matrixx claiming anosmia.

In early 2004 Matrixx responded to a Dow Jones report that the FDA was investigating complaints linking Zicam and anosmia by saying that the reports were "completely unfounded and misleading," and that "the safety and efficacy" of Zicam's active ingredient had "been well established in two double-blind, placebo-controlled, randomized clinical trials." Slip op. 6, 19. Days later, *Good Morning America* reported that one physician had found more than a dozen patients who suffered anosmia after using Zicam, and that lawsuits had been filed against Matrixx. The company's stock price fell 26 percent the same day, and the plaintiffs sued.

The district court granted Matrixx's motion to dismiss on the ground that the plaintiffs failed to allege materiality and scienter because the complaint did not allege that Matrixx knew of a



statistically significant number of adverse events linking Zicam to anosmia. The Ninth Circuit reversed.

The Supreme Court affirmed the Ninth Circuit, refusing to adopt a bright-line rule requiring statistical significance of undisclosed adverse events to establish materiality under § 10(b) and Rule 10b-5. A bright-line rule, the Court concluded, would “artificially exclud[e] information that ‘would otherwise be considered significant to the trading decision of a reasonable investor.’” Slip op. 11 (quoting *Basic*, 485 U.S. at 236). The Court reasoned in part that materiality to investors cannot depend solely on the statistical significance of adverse events, because “medical professionals and regulators [*i.e.*, the FDA] act on the basis of evidence of causation that is not statistically significant” but meets other criteria for causation assessment. Slip op. 15. “As a result, assessing the materiality of adverse event reports is a ‘fact-specific’ inquiry ... that requires consideration of the source, content, and context of the reports. This is not to say that statistical significance (or the lack thereof) is irrelevant – only that it is not dispositive of every case.” *Id.*

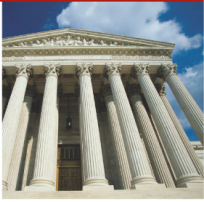
The Court emphasized, however, that “[a]pplication of *Basic*’s ‘total mix’ standard does not mean that pharmaceutical manufacturers must disclose all reports of adverse events.” *Id.* Rather, “the mere existence of reports of adverse events – which says nothing in and of itself about whether the drug 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.’” Slip op. 16 (quoting *Basic*, 485 U.S. at 236).

Similarly, the Court reaffirmed the longstanding principle “that § 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information” but rather impose liability only for failure to disclose information “necessary ‘to make ... statements made, in the light of the circumstances under which they were made, not misleading.[.]’” Slip op. 16. Companies can therefore “control what they have to disclose under these provisions by controlling what they say to the market.” *Id.*

The Court also refused to adopt a bright-line test for scienter based on statistical significance, finding that an inference of reckless or intentional conduct by Matrixx was supported by actions it took after the adverse publicity to review and study the anosmia link, by the fact that Matrixx was concerned enough to prevent physicians from naming it or Zicam in their presentation to a medical society, and by the fact that “Matrixx issued a press release that suggested that studies had confirmed that Zicam does not cause anosmia when, in fact, it had not conducted any studies relating to anosmia and the scientific evidence at that time, according to the panel of scientists, was insufficient to determine whether Zicam did or did not cause anosmia.” Slip op. 21.

KEY LESSONS

Matrixx bears several important lessons for pharmaceutical and other companies.



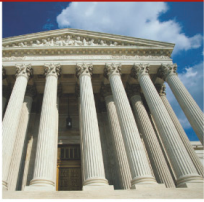
The first and clearest is that companies should not rely on bright-line rules of statistical significance (or, by inference, other single, objective criteria) in evaluating what safety and efficacy information about their products is material to investors and required to be disclosed. They should instead evaluate the totality of information relating to adverse events, including their “source, content, and context.”

Second, internal communication and vetting of public statements about product safety and efficacy – and product performance and quality more generally – are critical. Investor relations personnel, public relations personnel and others responsible for public comment about business prospects and products should communicate and coordinate with medical, research and drug safety surveillance personnel to ensure accuracy, fairness and balance in the company’s public disclosures and comments. *Matrixx* was hurt in this case by the categorical and unqualified character of its denial in response to initial publicity about the adverse events.

Third, those defending against securities fraud litigation arising from undisclosed adverse events can still prevail on motions to dismiss (and at later stages) with respect to materiality and scienter, although they cannot rely on statistical significance alone and will likely have to distinguish the facts of *Matrixx*. In that regard, the Supreme Court emphasized a number of allegations in finding that the complaint against *Matrixx* stated a claim for securities fraud: research and clinical physicians reported anosmia in multiple patients; two of the physicians presented findings to a national medical society, and *Matrixx* prevented them from using its name or that of *Zicam*; multiple product liability lawsuits were filed against *Matrixx*; and *Matrixx* categorically denied the existence of a causal link between *Zicam* and anosmia and claimed that clinical studies proved its safety, although it had not conducted its own studies and it later convened a panel of physicians who concluded that there was insufficient scientific evidence to exclude a causal link.

In summary:

- Neither materiality nor scienter under Rule 10b-5 depends solely on bright-line rules of the statistical significance of adverse events (or, by inference, comparable information).
- In evaluating their disclosure obligations, companies should instead consider the totality of information relating to adverse events, including their source, content and context.
- Public statements about health care products should be accurate, fair and balanced as a result of appropriate internal communication and review among public and investor relations, medical, drug safety and other relevant personnel.
- *Matrixx* leaves room for defendants in securities fraud cases to prevail on the elements of materiality and scienter because of the specific and distinguishable facts on which the Supreme Court’s decision is based.



FOR MORE INFORMATION

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