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U.S. Supreme Court: Manufacturer Can Be Sued for Failing to Disclose Adverse Reports

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On March 22, the U.S. Supreme Court rejected a line of lower-court cases holding that statistically insignificant adverse event reports could not be material to the reasonable investor, *see In re Carter-Wallace, Inc., Sec. Litig.*, 220 F.3d 36 (2d Cir. 2000), and ruled in a unanimous opinion that such reports must be evaluated under the Court's traditional, fact-specific jurisprudence on materiality in securities cases. As a result of the Court's decision, a putative securities fraud class action lawsuit by investors against Matrixx Initiatives, Inc. (Matrixx) may proceed past the pleading stage. *Matrixx Initiatives, Inc. v. Siracusano*, — S. Ct. —, 2011 WL 977060 (Mar. 22, 2011). The investors based their claims on Matrixx's alleged failure to disclose initial reports of adverse side effects from one of its products, Zicam Cold Remedy. A federal district court judge initially dismissed the investor lawsuit, but the U.S. Court of Appeals for the Ninth Circuit concluded that the alleged reports of adverse side effects were material and that investors had alleged facts giving rise to a strong inference that the company acted with the required state of mind. The Supreme Court affirmed the Ninth Circuit's decision.

Background

Matrixx develops, manufactures, and markets over-the-counter pharmaceutical products, with its core brand of products sold under the Zicam name. The Zicam brand included Zicam Cold Remedy, which was sold as a nasal spray and gel and accounted for approximately 70% of Matrixx's sales. The investors contended that Matrixx violated federal securities law by failing to disclose by early 2004 that there were as many as 23 reports of people losing their sense of smell after using Zicam Cold Remedy. In 2009, more than 130 reports of the same problem prompted U.S. regulators to warn Matrixx to stop selling the two intranasal forms of Zicam Cold Remedy. Matrixx pulled those versions of Zicam from the market but publicly disputed claims that the product was unsafe.

Determining Materiality of Statistically Insignificant Adverse Event Reports

Matrixx argued that it did not have to disclose the initial reports about Zicam because those reports were not statistically significant. The Supreme Court rejected that argument, describing it as an effort to reduce the test for materiality of adverse event reports to a bright-line rule. While there may be "many cases [where] reasonable investors would not consider reports of adverse events to be material information," the Court concluded that these investors had "alleged facts plausibly suggesting that reasonable investors would have viewed these particular reports as material." *Id.* at *3. The decision further noted that courts frequently allow expert testimony on causation based on evidence other than statistical significance and that the FDA does not limit the evidence it considers for purposes of

assessing causation and taking regulatory action to statistically significant events. *Id.* at *9–10. Given this use of causation evidence in other situations, "it stands to reason that in certain cases reasonable investors would [rely on such evidence] as well." *Id.* at *10.

Nevertheless, the Court emphasized that "assessing the materiality of adverse event reports is a 'fact-specific' inquiry that requires consideration of the source, content, and context of the reports." *Id.* at *11. That is, the Court did not hold that "statistical significance (or the lack thereof) is irrelevant—only that it is not dispositive of every case," nor did the Court hold that "pharmaceutical manufacturers must disclose all reports of adverse events." *Id.* "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 the [materiality test]." *Id.* The Court explained that in *Matrixx* the investors had pleaded "[s]omething more," namely, that Matrixx had received information that plausibly indicated a causal link between Zicam and a loss of sense of smell. *Id.* This allowed the Court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at *12 (quoting *Ashcroft v. Iqbal*, 556 U.S. —, slip op., at 14 (2009)).

In addition, the Court emphasized that its analysis of the materiality of adverse event reports does not change the Court's previous conclusion that "[Section] 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information." *Id.* at *11. The Court reiterated its longstanding view that disclosure of material information is required, as it was in *Matrixx*, "only when necessary to make . . . statements made, in the light of the circumstances under which they were made, not misleading." *Id.* (internal quotations and citation omitted).[1] This lack of an affirmative duty to disclose applies "[e]ven with respect to information that a reasonable investor might consider material." *Id.* "Companies can control what they have to disclose under these provisions by controlling what they say to the market." *Id.*

Scienter

Matrixx did not seek review of the Ninth Circuit's ruling that scienter may be demonstrated by a showing of "deliberate recklessness," and the Court "assume[d], without deciding," that allegations of recklessness were sufficient to establish scienter. *Id.* at *13. Applying this standard, the Court held that the Matrixx investors had pleaded a strong inference of scienter. *Id.* at *13–14. The Court was not persuaded by Matrixx's claim that the most compelling inference as to why it had not disclosed the adverse event reports was that Matrixx "believed [the adverse events] were far too few . . . to indicate anything meaningful about adverse reactions to use of Zicam." *Id.* at *13. Again, the Court rejected this claim as an effort to impose a bright-line rule. *Id.* The Court specifically pointed to allegations contending that Matrixx had acted to address the purported problem based on reports claiming a connection between Zicam and a loss of sense of smell. *Id.* at *14. Based on these allegations, the Court concluded that the inference that Matrixx acted recklessly or intentionally was at least as compelling as the inference that it thought the adverse reports were not meaningful. *Id.*

Conclusion

The Court held in *Matrixx* that the materiality of adverse event reports can only be evaluated on a case-

1. In Matrixx's case, the Court pointed to the company's statements predicting that its revenues were going to rise 50% to 80% while minimizing reports of Zicam-related side effects as having been made potentially misleading by the undisclosed information. *Id.* at *12.

by-case basis, considering the full context of those reports. Public companies should consider the Court's opinion when deciding whether they must disclose reports of adverse events, paying particular attention to the relationship between the undisclosed information and the other information that they have put into the marketplace.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact any of the following Morgan Lewis attorneys:

Philadelphia

Jill M. Baisinger	215.963.5251	jbaisinger@morganlewis.com
Karen Pieslak Pohlmann	215.963.5740	kpohlmann@morganlewis.com
Marc J. Sonnenfeld	215.963.5572	msonnenfeld@morganlewis.com
Jason H. Wilson	215.963.5768	jason.wilson@morganlewis.com

New York

Ben A. Indek	212.309.6109	bindek@morganlewis.com

Washington, D.C.

Christian J. Mixter	202.739.5575	cmixter@morganlewis.com

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