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Client Alert

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Supreme Court Rules Securities Fraud Claims May Be Brought When Pharmaceutical Company Fails to Disclose Reports of Adverse Events

The U.S. Supreme Court on March 22, 2011, ruled that a claim for securities fraud under §10(b) of the Securities Exchange Act of 1934 and the Securities Exchange Commission (SEC) Rule 10b-5, based on a public pharmaceutical company's failure to disclose reports of adverse events associated with a product, can proceed even if the reports do not disclose a statistically significant number of adverse events.[1]

The case involved allegations that Matrixx Initiatives and three of its executives (collectively Matrixx) made misleading statements about Zicam Cold Remedy in light of reports Matrixx had received, but did not disclose, about consumers who had lost their sense of smell (a condition called anosmia) after using Zicam. In particular, the plaintiffs pointed to the fact that Matrixx had issued favorable future earnings reports even though at the time the company knew that two product liability lawsuits had been filed alleging that Zicam had damaged the plaintiffs' sense of smell, and a study by physicians from the University of Colorado had been published linking the use of Zicam to a loss of smell.

Matrixx moved to dismiss the securities fraud complaint, arguing that the plaintiffs had failed to plead the elements of a material misstatement or omission and scienter (a mental state embracing intent to deceive, manipulate or defraud). The District Court granted the motion to dismiss, holding that the plaintiffs had not alleged a statistically significant correlation between the use of Zicam and anosmia, and the plaintiffs had not stated with particularity facts giving rise to a strong inference of scienter.

The U.S. Court of Appeals for the Ninth Circuit reversed, finding that the District Court had erred in requiring an allegation of statistical significance to establish materiality. It concluded, to the contrary, that the complaint adequately alleged information regarding the possible link between Zicam and anosmia that would have been significant to a "reasonable investor." Turning to scienter, the Court of Appeals concluded that withholding reports of adverse effects and lawsuits concerning the product responsible for the company's remarkable sales increase was an extreme departure from the standards of ordinary care.

1 *Matrixx Initiatives Inc.*, et al, *v. James Siracusano*, No. 09-1156 (Mar.22,2011)

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The Supreme Court granted certiorari and affirmed the Ninth Circuit decision. The Court rejected Matrixx's position that the Court should apply a "bright-line" rule that reports of adverse events associated with a pharmaceutical company's products cannot be material absent a sufficient number of such reports to establish a statistically significant risk that the product in fact caused the events. Absent statistical significance, Mattrix argued, adverse event reports provide only "anecdotal" evidence that the user of a drug experienced an adverse event at some point during or following the use of that drug. Accordingly, Mattrix contended that reasonable investors would not consider such reports relevant unless they are statistically significant because only then do they reflect a scientifically reliable basis for inferring a potential causal link between the product use and the adverse event.

The Supreme Court found Matrixx's argument flawed, holding that 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. The Court's conclusion was based, in part, on the recognition that the Food and Drug Administration (FDA) does not limit the evidence it considers for purposes of assessing causation and taking regulatory action to statistically significant data, and in fact, the Court noted the agency sometimes acts on a basis that suggests, but does not prove, causation. For example, the FDA requires manufacturers of over-the-counter drugs to revise their labeling to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.

The Court noted this case proves the point because in 2009, the FDA issued a warning letter to Matrixx stating that a significant and growing body of evidence substantiates that the Zicam Cold Remedy intranasal products may pose a serious risk to consumers who use them. The letter cited as evidence 130 reports of anosmia the FDA had received, the fact FDA had received few reports of anosmia associated with other intranasal cold remedies, and evidence in the scientific literature that zinc gluconate (the active ingredient in Zicam) can damage olfactory functions in animals and humans. None of this evidence constituted statistically significant data.

Given that medical professionals and the FDA act on the basis of evidence of causation that is not statistically significant, the Court concluded that it stands to reason that in certain cases reasonable investors would, as well. As a result, assessing the materiality of adverse events in a securities fraud case is a fact-specific inquiry that requires consideration of the source, content and context of the adverse event reports. The Court concluded this "contextual inquiry" does not mean that pharmaceutical manufacturers must disclose all reports of adverse events. Indeed, the Court stated that adverse events are daily events in the pharmaceutical industry, and the fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused the event. However, at the time Matrixx issued its favorable earnings projections it had received information that plausibly indicated a reliable causal link between Zicam and anosmia. The Court held these were material facts that should have been disclosed in information released to shareholders.

As to the issue of scienter, the Court held that the inference that Matrixx acted recklessly (or intentionally for that matter) in failing to disclose this information was at least as compelling, if not more compelling, than the inference it simply thought the reports did not indicate anything meaningful about adverse reactions.

The Court found significant the fact that Matrixx issued a press release that suggested that studies had confirmed Zicam did not cause anosmia when the company had not conducted any studies relating to anosmia and the scientific evidence was insufficient to determine that fact.

The lesson for public pharmaceutical, medical device and biotech companies is clear. In issuing press releases and making required reports to investors and the SEC, care must be given to the strength of the association between a drug or device and adverse events associated with the product.

Section 10(b) of the Securities Exchange Act makes it unlawful for any person to "use or employ, in connection with the purchase or sale of any security […] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors."[2] SEC Rule 10b-5 implements this provision by making it unlawful to, among other things, make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.[3]

Applying the Supreme Court's reasoning in *Matrixx* does not mean that the mere existence of reports of adverse events will always be considered a "material" fact. Rather the proper inquiry is whether a "reasonable" investor will view the information concerning the adverse events to significantly alter the "total mix" of information made available about the company such that the information becomes "material" and "necessary" to make other statements about the company's business not misleading.

2 15 U.S.C.§78j(b)
3 17 C.F.R. §240.10b-5(b)

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