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Public Companies E-Alert - Do You Have To Disclose Product Related Adverse Events?

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Executive Summary: In January the Supreme Court heard arguments in a case that may affect Rule 10b-5 disclosures by any company that collects and reports product related adverse event data to the government. The case revolves around whether such events must be "statistically significant" in order to be material. If the Supreme Court determines that such events may be material, even if they are not statistically significant, then affected companies will need to review each adverse event involving its products and determine whether it should be disclosed as material. Affected companies may include not only drug and medical device companies, but automobile, tire and plane manufacturers, consumer product companies and other companies that collect and report adverse event data to the government. The Supreme Court decision is expected to be rendered by some time this summer.

Discussion: In *Matrixx Initiatives v. Siracusano* stockholders sued a pharmaceutical company for its failure to disclose reports to the government of adverse events involving one of its drugs, even though the reports were not statistically significant. Drug companies are required by law to report to the FDA all "adverse events" associated with the use of their drugs. If enough reports link adverse events with a drug, the link becomes "statistically significant" and there is an assumption that there may be a causal link to the drug as opposed to simply an incidental link. Matrixx argued that a "reasonable investor's" investment or voting decision will not be affected by adverse events until they become statistically significant and thus material. The stockholders and the federal government argued that such information may be material, even if the events are not statistically significant. The stockholders argued that a reasonable investor may still want to consider how a reported adverse event would affect consumer demand for a product, as consumers may make decisions on less than statistically significant data. The company also argued that the industry needs a bright line test to ensure uniform application of the fraud laws and to discourage frivolous suits for failure to disclose adverse events.

Aside from the materiality issue, the case also involves an issue as to the facts supporting the scienter required for the Rule 10b-5 violation. A Rule 10b-5 violation requires that the defendant intend to deceive, defraud, or manipulate by intentionally or deliberately recklessly making misleading or false statements. The parties argued whether the company's actions and its failure to disclose was sufficient to infer intent to deceive.

Depending upon the Supreme Court's decision, companies that gather information on adverse events involving their products may have to decide whether it will disclose such events, even in the absence of any clear statistical proof that there is a problem with the product.

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