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Passing the Smell Test — Practical Guidance on Materiality and Disclosure After *Matrixx* Decision

A careful review of the Supreme Court's recent Matrixx *decision offers issuers a number of practical steps to both reduce the risk of losing a stock-drop case and increase the likelihood of having such a case dismissed at the early pleading stages.*

In its recent *Matrixx* decision, the U.S. Supreme Court unanimously declined to adopt a bright-line standard for proving the materiality of adverse event reports for pharmaceutical products based solely on whether there was "statistically significant" risk of the adverse event resulting from the use of the product. The case addressed a securities fraud suit stemming from a significant drop in Matrixx's stock price after the manufacturer's failure to disclose growing reports of a potential link between its Zicam nasal spray and loss of smell in users.

"Materiality" determinations, which form the core of securities claims and therefore many disclosure decisions, will remain a vexing issue for public companies. The Supreme Court has continued to shy away from bright-line standards in applying the traditional test for materiality — whether a reasonable investor would view the relevant information as significantly altering the total mix of available information. Unfortunately, a company's judgments on this question are inevitably critically assessed in hindsight once the contingency in question has in fact had a material impact. While a company's disclosure decision will be judicially reviewed based on the information available at the time of disclosure, it is often hard to ignore subsequent developments in adjudicating the adequacy and accuracy of the original disclosure.

The Supreme Court emphasized that it was not implying that there is an ongoing and continuous duty to disclose all material information. However, when a company, or its senior executives or directors, engage in a securities transaction (buying or selling) or when a company does choose to speak to the market, it has an affirmative duty to ensure that all relevant material information is disclosed. In the Zicam case, the fraud claim preserved by the court's decision resulted from the company's failure to disclose the adverse events as it publicized bullish earnings guidance at a time when it allegedly knew of the increasing reports of problems from the use of its key product.

While the decision was not unexpected and focused on a limited technical question of whether, in determining materiality for securities fraud claims, a particular standard should be applied to a specific category of products, public companies should heed a number of important lessons applicable to all issuers in the healthcare industry and beyond:

- Companies should evaluate the frequency of interactions with the market (whether by securities transactions or communications) which require an assessment of whether all material information is out in the public realm. This is particularly true of forward-looking statements such as future earnings guidance, where the risk is highest that what is at the time a borderline risk factor may develop in a manner that seriously impacts the accuracy of the original statement. Moreover, the frequency with which healthcare industry executives figure prominently in SEC insider trading cases alleging sales ahead of the release of negative information shows that these risks merit particular attention in certain industries which, by their nature, are susceptible to hindsight second-guessing of disclosure decisions.
- Recognizing that some market interactions are desirable and/or inevitable, companies should ensure that robust disclosure controls are in place so that the appropriate senior executives are aware of developing risk factors and can make informed and timely judgments about the advisability of disclosure (or abstaining from the trade or public statement). While most companies have formal processes to address these issues in the context of preparing annual and quarterly SEC reports, it is important that these mechanisms are extended to apply on a continuing basis, particularly during "open-window" trading periods and before

any earnings calls or releases, investor/analyst presentations, etc. There is no doubt that this is a challenging proposition, particularly for large companies — however, a properly scaled set of controls designed to identify nascent risks for key products or segments is an important component of adequate disclosure controls.

- Issuers should consider whether it is advisable to prophylactically beef up risk factor and "safe harbor" disclosures to err on the side of disclosure for borderline risk factors applicable to its key products, services or business. Obviously this approach does not necessarily solve for suddenly-arising risks, but a certain measure of protection can be acquired by being more expansive about potential risks. For example, a manufacturer of brand-name drugs may want to consider disclosing a list of adverse side effects (particularly if serious) associated with a key product, even if the statistical significance or causation link of such side effects has not yet been fully proven. As the Supreme Court noted, the materiality test for disclosure may not always follow the standard applicable for FDA labeling or adverse event reporting purposes. It bears noting that risk factor or safe harbor disclosure is not a guarantee of immunity from disclosure claims; that said, thoughtful disclosure, even if speculative and especially if specific and periodically updated, provides a strong basis to construct a valid defense that the relevant forward-looking statements were accompanied by meaningful cautionary disclosure.

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While the statutory safe harbors under the Private Securities Litigation Reform Act and subsequent court decisions (including the Supreme Court decisions on heightened pleading standards in *Tellabs* and *Dura*) have significantly reduced the incidence and success of vexatious and frivolous securities lawsuits, an active plaintiffs bar ensures that stock-drop cases will continue to be a feature of public company life. A careful review of the Supreme Court's decision in the recent *Matrixx* case offers issuers a number of concrete practical steps to both reduce the risk of losing such a case and increase the likelihood of having such a case dismissed at the early pleading stages.

If you have any questions about the matters addressed in this *M&A Update*, please contact the following Kirkland authors or your regular Kirkland contact.

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