Published on *The National Law Review* https://natlawreview.com

A MATRIXX Revolution, Part II: Supreme Court affirms Ninth Circuit's holding that Life Science Companies Cannot Rely On a Statistical Significance Standard When Deciding Whether Adverse Event Reports are Material for the Purpose of Securities Disclosures

Article By:

Peter S. Reichertz

On March 22, the U.S. Supreme Court affirmed the Ninth Circuit's ruling in Matrixx Initiatives, Inc. v. Siracusano, 09-1156. See our prior blog article from November 18, 2010.

Matrixx Initiatives, Inc. ("Matrixx") is a manufacturer of over-the-counter pharmaceuticals. Its core brand of products is Zicam, a popular cold remedy. NECA-IBEW Pension Fund and named plaintiff James Siracusano brought a securities fraud class action lawsuit against Matrixx in 2005, alleging that Matrixx and three of its executives made certain misleading public statements about the company's projected growth in light of information it had that Zicam's nasal spray had been linked to several cases of anosmia, or loss of the sense of smell. To prevail on a §10(b) claim, a plaintiff must show that the defendant made a statement that was "misleading as to a material fact." *See* 17 C.F.R. 240.10b. The Plaintiffs argued that these adverse events were material and that the company's failure to report them in its SEC filings violated the Securities Exchange Act of 1934 ("the Act").

Matrixx countered that the reports of anosmia it received were not numerous enough to be "statistically significant" and therefore Matrixx was not required to report them. Matrixx urged the Court to adopt 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 is in fact causing the events." *Matrixx*, at 11. Absent statistical significance, Matrixx viewed adverse event reports as merely "anecdotal evidence" of a possibly coincidental event.

The Court disagreed with this argument. Justice Sotomayor, writing for the Court, explained 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 event." *Id*. at 12.

The Court reiterated its prior holding in *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), where it found that the §10(b) materiality requirement is satisfied when there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having

significantly altered the ‘total mix’ of information made available.”

Here, the court reasoned, “Given that medical professionals and regulators act on the basis of evidence of causation that is not statistically significant, it stands to reason that in certain cases reasonable investors would as well.” *Matrixx*, at 15.

The Ninth Circuit decision, which the Supreme Court affirmed here, drew considerable concern from members of the life sciences industry who feared that requiring manufacturers to disclose every adverse event report would be both a logistical nightmare due to the volume of reports typically received by manufacturers, and confusing or misleading to the general public because people would be unable to distinguish the legitimate reports of potential concern from the unreliable or anecdotal ones.

In response to the industry’s anxiety on this point, Justice Sotomayor explained:

Application of *Basic*’s “total mix” standard does not mean that pharmaceutical manufacturers must disclose all reports of adverse events. Adverse event reports are daily events in the pharmaceutical industry; in 2009, the FDA entered nearly 500,000 such reports into its reporting system. … The fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused that event. … The question remains whether a *reasonable* investor would have viewed the nondisclosed information “as having *significantly* altered the “total mix” of information made available.” … [T]he 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.

… Moreover, it bears emphasis that §10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary to make statements made, in the light of the circumstances under which they were made, not misleading. Even with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under these provisions by controlling what they say to the market. *Id.* at 15-16 (internal citations and quotation marks omitted, emphasis in original).

Ultimately, the Court found for the plaintiffs, holding that they successfully argued both (1) that a reasonable investor would view the adverse event reports in this particular situation as being material, and (2) facts giving rise to a strong inference of scienter, or a knowledge of wrongdoing on the part of Matrixx. The opinion emphasized the Court’s refusal to establish a bright line rule for determining when adverse event reports are significant enough to mandate disclosure. It remains to be seen how this ruling will impact a manufacturer’s evaluation of which adverse event reports it believes it must disclose; the lack of a bright line rule will leave the decision of materiality to each company.

National Law Review, Volume I, Number 88