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Highlight Legal Issues Regarding the Life Sciences Industry

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A MATRIXX Revolution? Is there a need to describe all adverse event reports in SEC filings of life sciences companies?

By Peter S. Reichertz

The U.S. Supreme Court has scheduled oral argument for January 10, 2011, in the case of *Matrixx Initiatives et al v. Siracusano*, Case Number 09-1156, on appeal from the decision of the Ninth Circuit in *Siracusano v. Matrixx Initiatives, Inc.*, 585 F3d 1167 (9th Cir. 2008). The court granted certiorari on July 14, 2010.

In this case, plaintiff NECA-IBEW Pension Fund and the named plaintiff James Siracusano alleged that Matrixx and certain executives failed to describe in required SEC filings reports of adverse events associated with its nasal spray product ZICAM® Cold Remedy. Plaintiffs alleged that the reports in question were material and the failure to report them in 10-K's, 10-Q's and other SEC filings violated the Securities Exchange Act of 1934 ("the Act").

The case has created a large degree of consternation in the pharmaceutical, medical device and biotechnology sectors, as the Ninth Circuit declined to adopt a scientific standard for a determination of "materiality" of reports, holding instead that the determination of materiality is a question of fact that should be left to the trier of fact. Id, at 1178. The District Court below had applied a statistical significance standard previously set forth in other cases[1], and found that the plaintiffs had not sufficiently pleaded materiality, an essential element of a violation of Section 10b of the Act and Rule 10b-5.[2] The issue of whether scienter was sufficiently pleaded was also reviewed by the Ninth Circuit, but the issue that has prompted the filing of numerous amicus briefs by life sciences industry groups is when adverse events become sufficiently material that they must be reported in SEC filings.

Among the groups filing amicus briefs are the Consumer Healthcare Products Association, the Council for Responsible Nutrition, the National Products Association, BayBio, the Advanced Medical Technology Association and the Pharmaceutical Research and Manufacturers Association. Universally, life sciences associations have expressed great concern about the Ninth Circuit ruling. An example of the concern, as expressed by BayBio, is as follows:

> The Nation's leading biotechnology companies produce and develop important as well as life-saving drugs. They are constantly inundated with adverse event reports and other data about the efficacy and safety of their products in clinical trials and on the market. These companies—many of which are members of amicus BayBio—thoroughly investigate these reports and, when required by law, transmit the reports to government regulators for further analysis.

> The process by which these reports are analyzed is often not expedient. Nor can it be. Anecdotal evidence of an adverse event, without more, is almost never a statistically significant measure of risk correlated with a drug's use. While anecdotal evidence might warrant further investigation, that investigation often requires controlled experiments or sophisticated observational studies to determine whether the adverse event is associated with, or caused by, use of the drug. At the same time, there are strong countervailing interests in keeping a drug on the market or not prematurely warning the public against its use. If the drug already has been approved and is on the market, government regulators already have made an assessment—based on rigorous scientific data—that the drug's public health benefits outweigh any risk.
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> But the ruling below circumvents that deliberative process. To avoid liability for securities fraud, the Ninth Circuit's ruling requires biotechnology companies to more broadly disseminate and emphasize isolated adverse event reports that ultimately might prove to be entirely unrelated to the drug in question. Not only is that result inconsistent with this Nation's securities laws, but it will cause significant harm to the public by discouraging beneficial, and often necessary, use of the drug.

These concerns are echoed in the briefs of other life sciences industry trade associations.

If the Ninth Circuit decision is upheld on appeal, it could truly revolutionize SEC filings for life sciences companies, essentially requiring them to report every adverse event reported to them, whether serious or not serious, expected or unexpected. Quarterly and yearly SEC filings, already voluminous, could swell in size to the unmanageable. Given that such filings already contain much detail, it is uncertain what all of this additional information would mean to the investing public. Furthermore, such a rule potentially raises privacy concerns, depending upon what is required to be disclosed.

A decision on the appeal is likely by the end of June 2011. Publicly traded life sciences companies will be anxiously awaiting a decision.

Authored By:

Peter S. Reichertz
(202) 772-5333
preichertz@sheppardmullin.com

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[1]See e.g., *In re Carter-Wallace Securities Litigation*, 150 F.3d 153, 157 (2d. Cir. 1998) and *In re Carter-Wallace Securities Litigation*, 220 F3d. 361(2d Cir. 2000).

[2]In order adequately to allege a violation of 10b-5, "a plaintiff must [allege] '(1) a material misrepresentation or omission of the fact, (2) scienter, (3) a connection with a purchase or sale of a security, (4)a transaction and loss causation, and (5) economic loss.'"