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SECURITIES DISCLOSURE

Disclosing Product Developments to Investors

Publicly traded life science companies are faced with challenges when making disclosures concerning product development. In view of the increased scrutiny the FDA and SEC are giving these disclosures and the ImClone scandal, companies need to know whether courts will find their cautionary language sufficient to protect them from charges that disclosures about product development are false or misleading.

by **Marc J. Sonnenfeld, Karen Pieslak Pohlmann, and Dr. Phoebe Mounts**

In disclosing progress on product development, publicly traded life science companies, including biotechnology, pharmaceutical, and medical device firms, must constantly balance the demands of investors who seek information, the uncertainties of research and development, and the restraints imposed by the Food and Drug Administration (FDA) on pre-approval promotion of investigational products. Many companies include cautionary language in their

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announcements of new research, clinical trial results, or regulatory developments such as fast track designation¹ and orphan designation.² Companies believe that such cautionary language not only adequately informs the investors, but also provide the companies with protection should their announcements ever be challenged as false or misleading. However, as several recent decisions in shareholder suits reveal, courts have not always viewed this type of cautionary language as sufficient.

Judicial and Statutory Protection Based on Cautionary Language

Cautionary language and identification of forward-looking statements have been important in protecting companies from liability when they make public predictions or statements about future events. Courts have taken the position that cautionary language, when it is sufficient, will render an alleged misstatement or omission that is forward-looking immaterial as a matter of law under the “bespeaks caution” doctrine. Congress also wanted to encourage “companies to disclose forward-looking information” so it enacted a “safe harbor” as part of the Private Securities Litigation Reform Act of 1995 (PSLRA).³ Congress was concerned about the “muzzling effect” that “abusive litigation” was having on companies’ disclosure; “[f]ear that inaccurate projections will trigger the filing of securities class action lawsuit has muzzled corporate management.”⁴

In general, under the “safe harbor,” no person shall be liable for a “forward-looking” statement if the statement is identified as a forward-looking statement and

accompanied by “meaningful cautionary statements,” or if plaintiffs fail to prove the forward-looking statement was made with actual knowledge of its falsity.⁵ A “forward-looking” statement is defined to include, among other things, statements containing projections of revenue, income, earnings or other financial items, and statements of the plans and objectives of management including plans or objectives relating to the company’s products or services.⁶

Cautionary Language: When Warnings Are Not Enough

In a number of securities fraud class actions involving life sciences companies during the past few years, courts have declined to dismiss complaints from shareholders even though the allegedly fraudulent statements were accompanied by cautionary language. In the securities fraud class action arising as a result of alleged misrepresentations relating to biotechnology product development by ImClone Systems, Inc., *Irvine v. ImClone Systems, Inc.*,⁷ the court found that warnings about risks and uncertainties in obtaining marketing approval from the FDA were not sufficiently specific to protect the statements from a securities fraud claim. In *ImClone*, the company’s disclosures that its business was “subject to regulation primarily by the FDA,” that “[n]oncompliance with applicable requirements can result in refusal to approve product licenses or other applications,” that there are “risks and uncertainties associated with completing pre-clinical and clinical trials . . .” and that “actual results may differ materially” from those predicted did not bring the statements within the safe harbor provisions of the PSLRA.⁸

In another recent case, *In re Amylin Pharmaceuticals, Inc. Securities Litigation*,⁹ the court found that the discussion in press releases and SEC filings did not provide meaningful information to investors about the FDA’s concerns regarding the clinical trial designs. While the company disclosed that “[r]esults from our clinical trials may not be sufficient to obtain regulatory clearance” and “the FDA may also require additional testing for safety and efficacy,” it failed to disclose “the FDA’s concern that the trial designs were inconsistent with clinical practice and that data from such trials would not be considered pivotal data for NDA approval.”¹⁰ The court found the company’s disclosures insufficient, cautioning that

[a] company seeking FDA approval of a new drug clearly is not under any obligation to disclose every single issue raised by the FDA throughout the process. However, if the FDA expresses significant concerns regarding the sufficiency of the trials, the company cannot make affirmative representations regarding the completeness or sufficiency of the trials without full disclosure.¹¹

The concern about whether the company provided sufficient cautionary language when making public statements about the status of clinical trials was also considered in the decision of *In re ViroPharma, Inc., Securities Litigation*.¹² According to the court, the cautionary language there was “verbose” and did not address “any specific risks.” It “only states that future clinical trials may fail, this does not caution investors that the results of the clinical trial reported in the press release could be interpreted to show that the drug was ineffective.”¹³

The courts continue to scrutinize claims against life science companies closely.

In another case relating to clinical trials regulated by the FDA, *In re Neopharmaceuticals, Inc. Securities Litigation*¹⁴ the court ruled that even statements that are technically correct can form the basis of a securities fraud claim if they are misleading. In that case, the defendants correctly described the results of a Phase I trial,¹⁵ but allegedly omitted to disclose that the Phase II¹⁶ tests had failed to such a degree that the Phase I results would be affected because the product would need to be reformulated.¹⁷ Further, when the company did disclose delays in its timetable, it purportedly withheld the full extent of its problems, which exposed it to liability for those statements as well.¹⁸

In *In re Noven Pharmaceuticals, Inc. Securities Litigation*,¹⁹ the plaintiffs claimed that a pharmaceutical company subject to regulation by the FDA knew that its distributor was not honoring the distribution agreement, and was directly competing with its product. The court ruled that the cautionary language was not sufficient. Nevertheless, because the plaintiffs did not specifically identify the information that allegedly should have alerted the company that its distributor was not marketing its

product, the court found that the complaint did not state a claim and gave plaintiffs leave to amend.²⁰

The courts continue to scrutinize claims against life science companies closely. In August 2003, the Court of Appeals for the Ninth Circuit, in *Broudo v. Dura Pharmaceuticals, Inc.*,²¹ reversed a decision by the lower court that had granted a motion to dismiss a securities fraud complaint against a company based on alleged misleading and untrue statements about its product development, FDA filings, and existing sales. Although the decision focused on pleading requirements, the Court of Appeals specifically declined the company's request that even if it found the district court had erred, it could affirm on other grounds, including the existence of cautionary language and the safe harbor. The Court of Appeals sent the case back to the district court and ordered that the plaintiffs be allowed to file an amended complaint.

Cautionary Language: The Courts Have Ruled That Some Warnings Are Sufficient

In contrast, the courts have ruled in favor of the defendant in a number of cases. For example, the court found that cautionary language that "actual results may vary markedly from those set forth in the statements" was sufficient to protect predictive statements, and granted the motion to dismiss in *In re Empyrean Bioscience, Inc. Securities Litigation*.²² Similarly, language warning, among other things, that there can be no assurances that the company will be able to develop its products commercially, "that necessary regulatory approvals will be obtained, that any clinical trials will be successful," and that actual results may differ from those projected, served as one of the bases for a successful motion to dismiss in *Meyer v. Biopure Corp.*²³

Evaluating the Adequacy of Warnings Is Not an Easy Task

It is difficult to draw distinctions between the cautionary language that courts found was not sufficiently meaningful or specific, and the language that was upheld as adequate in other decisions. That uncertainty may, indeed, be the most important lesson for a life science company to remember in drafting its public statements. Companies should not assume that generic

cautionary language will be sufficient, or that the same cautionary language can be applied to every press release, filing with the SEC, or investment document. To the contrary, companies should make sure that cautionary language adequately addresses the specific issues being discussed in the announcement, and incorporates any new developments or uncertainties that have arisen since the last time cautionary language was prepared. This is particularly true when the company is making a major announcement, such as the results of clinical trials, FDA designations, or its plans for FDA filings.

FDA and SEC Focus on Enforcement

As a result of the ImClone controversy, the FDA has been encouraged by Congress and investors to take a more active role in policing communications to potential investors, for example, to identify misrepresentations about a company's discussions with the FDA, or about the status of the FDA's review of an investigational product. Consequently, FDA Commissioner Mark McClellan, and FDA Chief Counsel Daniel Troy commented in speeches that a formal relationship is being established between the SEC and FDA so that the FDA can provide more formal support for the SEC's investigations and enforcement actions beyond that which currently exists.

In early February 2004, the FDA and the SEC jointly announced efforts to improve communication and information-sharing.

The SEC and FDA focus on policing misleading statements made by public companies developing pharmaceuticals and medical devices. The ability of manufacturers to disseminate information regarding products that are investigational, or not yet approved for marketing by the FDA, is very limited. For example, a manufacturer may not describe an investigational product, either directly or through discussion of test results, as being safe or effective, which can only be established by final FDA approval. Any statement implying safety or effectiveness prior to final approval is considered false or misleading, and a violation of the Federal Food, Drug, and Cosmetic Act.

In early February 2004, the FDA and the SEC jointly announced efforts to improve communication and information-sharing to prevent companies subject to FDA regulation from disseminating false or misleading information about a product's regulatory status or FDA reviews. Under the new plan, each agency is expected to appoint a designated liaison, along with individual agency contacts for specific matters.²⁴ While the new procedures are not likely to loosen FDA restrictions regarding disclosure of proprietary information, the increased communications between the agencies could result in enhanced enforcement efforts.

A Practical Guide for Companies: Points to Consider in Drafting Cautionary Language

These recent judicial decisions and formalized inter-agency communications are significant, and suggest that companies should take particular care with respect to preparation of public statements about products in development. They should consider the following:

- Identification of forward-looking statements and cautionary language should be specific to the issues being discussed;
- Statements involving timelines for regulatory approval, *e.g.*, approval for initiating clinical trials, or for receiving marketing approval, should be identified clearly as forward-looking statements with meaningful cautionary language;
- Meaningful cautionary language should be included to indicate the inherent risks involved in research and development, including non-clinical and clinical test results, which are uncertain and subject to differing interpretation;
- As companies prepare more substantive and specific public disclosures to address concerns identified in recent court decisions, it will be important

to avoid violations of the FDA's regulations on preapproval promotion.

NOTES

1. FDA's fast track designation program is designed to facilitate the development, and expedite the review of, new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Benefits include more frequent meetings with FDA and eligibility for priority review of marketing applications.
2. FDA grants orphan drug designation to a product that is being developed for a disease that is rare in the United States, *i.e.*, affects fewer than 200,000 people. Benefits include seven years of marketing exclusivity and certain tax credits for research costs.
3. H.R. Conf. Rep. 104-369, at 43 (1995), *reprinted in* 1995 U.S.C.C.A.N. 730.
4. *Id.* at 42-43.
5. Section 21E of the Securities Exchange Act of 1934 (Exchange Act).
6. *Id.*
7. *Irvine v. ImClone Sys., Inc.*, Nos. 02 Civ. 109 RO, 7499 RO, 2003 WL 21297285, at *1 (S.D.N.Y. June 4, 2003).
8. *Id.* at *1.
9. *In re Amylin Pharm., Inc. Sec. Litig.*, No. 01CV1455 BTM (NLS) 2003 WL 21500525 (S.D. Cal. May 1, 2003).
10. *Id.* at *8.
11. *Id.*
12. *In re ViroPharma, Inc. Sec. Litig.*, No. Civ. A. 02-1627, 2003 WL 1824914 (E.D. Pa. Apr. 7, 2003).
13. *Id.* at *8.
14. *In re Neopharm., Inc. Sec. Litig.*, No. 02 C 2976, 2003 WL 262369 (N.D. Ill. Feb. 7, 2003).
15. Phase I includes the initial introduction of an investigational new drug into humans. Phase I studies are designed to determine the metabolism of the drug in humans and the side effects associated with increasing doses. The subjects may be patients or normal volunteers.
16. Phase II studies are controlled trials to evaluate the safety and effectiveness of the drug for a particular disease.
17. *Neopharm., Inc.* at *10-11.
18. *Id.* at *13.
19. *In re Noven Pharm., Inc. Sec. Litig.*, 238 F. Supp. 2d 1315 (S.D. Fla. 2002).
20. *Id.* at 1321-1322.
21. *Broudo v. Dura Pharm., Inc.*, 339 F.3d 933 (9th Cir. 2003).
22. *In re Empyrean Bioscience, Inc. Sec. Litig.*, 255 F. Supp. 2d 751, 765 (N.D. Ohio 2003).
23. *Meyer v. Biopure Corp.*, 221 F. Supp. 2d 195, 203-204 (D. Mass. 2002).
24. Press Release, Securities and Exchange Commission, SEC and FDA Take Steps to Enhance Inter-Agency Cooperation (Feb. 5, 2004).

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