Addressing the Growing Threat of Securities Class Actions in the Life Sciences Sector

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Life Sciences Companies Are Being Targeted

- Life Sciences companies are increasingly targets of securities class action suits.
- Class action suits against such companies have increased and are up 20% since 2013.
- Biotechnology, pharmaceutical and healthcare companies made up nearly 25% of all defendants in securities class actions in 2015.

Circumstances Vary But the Theory of Liability Is Often the Same

- The company and its senior executives are accused of painting too favorable a picture of a developing product or drug and/or for failing to disclose information that plaintiffs' lawyers argue undercut the product's prospects for regulatory approval, clinical efficacy or commercial success.

The Supreme Court's *Omnicare* Decision

- In 2015, the United States Supreme Court decided a case known as *Omnicare*.
- The case addressed when a company may be liable under the federal securities laws for allegedly misleading statements of opinions.

The Importance of *Omnicare* to the Life Sciences Sector

- Many securities class action claims against life sciences companies assert that the company's opinion statements were somehow misleading. Application of the *Omnicare* standard often will be critical to a successful defense of these claims.
- In addition, *Omnicare* (and the growing number of lower court decisions interpreting the *Omnicare* decision) provide important guidance for ensuring that public statements are materially accurate and complete and do not expose a company and its senior executives to securities class action liability.
- **Attached is an appendix providing a summary of the relevant authorities in this area. It may be worthwhile to discuss this summary with in-house legal personnel having responsibility for managing the defense of securities class action claims or your Davis Polk Contact.**

APPENDIX

Understanding and Applying *Omnicare* in Defending Pharmaceutical, Biotechnology and Medical Device Companies from Securities Class Action Suits

Life sciences companies are frequent targets of securities class action lawsuits. These cases commonly assert that the company (1) painted too rosy a picture of one of its drugs or products, and/or (2) failed to disclose negative information about the FDA approval process, clinical trials or legal compliance. The plaintiffs' bar has filed these suits against large, well-known and established pharmaceutical companies and biotech start-ups alike.

An effective defense of these suits usually starts with a well-thought-out motion to dismiss. Because these cases often focus on the company's statements of opinion, such motions often turn on the application of the Supreme Court's 2015 decision in *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*,[1] which articulates the standard a plaintiff must meet to base a securities fraud claim on a statement of opinion. Below is a summary of important decisions and modes of analysis that have emerged in the pharmaceutical, biotech and medical device context since the *Omnicare* decision.

Omnicare Decision

In last year's *Omnicare* decision, the Supreme Court clarified the standard of liability for opinion statements under Section 11 of the Securities Act. *Omnicare* affirmed prior case law holding that expressions of opinion can be actionable either where they (a) were not honestly held, or (b) included misstatements of fact. In addition, *Omnicare* clarified the standard for assessing when omissions from statements of even honestly held opinions can be actionable.

Omnicare, a pharmacy services provider for nursing homes, stated in its registration statement for a public offering of stock that it believed its contractual arrangements with other healthcare providers and suppliers were in compliance with applicable legal requirements. The Federal Government later sued Omnicare in relation to alleged kickback schemes with manufacturers. The Supreme Court explained that an opinion statement may be understood by a reasonable investor, depending on the context, to convey facts about the speaker's basis for holding that view. For example, the Court noted that if a company set forth an opinion of legal compliance in a registration statement, a reasonable investor would expect that the company had made a meaningful legal inquiry; the statement would be misleading if the company had not done so.[2] The Court therefore held that an opinion statement can be actionable where it omits facts about the speaker's *basis* for an opinion that differ from what a reasonable investor would understand or conclude from the statement itself.[3] A reasonable investor expects that the opinion expressed "fairly aligns" with the information in the issuer's possession at the time.[4]

At the same time, the Supreme Court cautioned that meeting the newly announced standard "is no small task" for a plaintiff.[5] Furthermore, Defendants do not have a duty to disclose all facts cutting against the opinion.[6] *Omnicare* has since been applied by courts in cases brought under both Section 11 of the

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[1] *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1332 (2015).

[2] *Id.* at 1328-29.

[3] *Id.*

[4] *Id.* at 1329.

[5] *Id.* at 1332.

[6] *Id.* at 1329.

Securities Act and Section 10(b) of the Securities Exchange Act in the life sciences context. These cases largely demonstrate that courts have heeded the Supreme Court's caution and have declined to vastly expand liability for expressions of opinion.

FDA Interim Feedback

In the first appellate decision to examine the impact of *Omnicare* in detail, the United States Court of Appeals for the Second Circuit affirmed the dismissal of claims against Sanofi based on its opinion statements that it expected the FDA to approve its multiple sclerosis drug, Lemtrada. Plaintiffs claimed that Sanofi failed to disclose concerns expressed by the FDA regarding Sanofi's use of single-blind (as opposed to double-blind) clinical trials during the FDA approval process.[7] The court reasoned that, since there were conditions under which single-blind studies would be sufficient for FDA approval (such as significant treatment effect, which Lemtrada had achieved), there was an "absence of any serious conflict" between the FDA's interim statements and Sanofi's optimism regarding Lemtrada's approval.[8]

Several district courts applying the *Omnicare* standard have also granted motions to dismiss securities claims based on an alleged failure to disclose interim FDA feedback.

- The court in *Gillis v. QRX Pharma Limited*[9] granted a motion to dismiss relating to QRX's optimistic opinion statements regarding the likelihood of FDA approval of its drug MoxDuo, a combination of morphine and oxycodone. The FDA ultimately refused to approve the drug. Plaintiffs claimed that QRX should have disclosed the FDA's stated interpretation of its "superiority requirement," which required QRX to demonstrate that the new drug combination offered a safety or efficacy advantage over comparable doses of its individual components. The court found that while QRX had not communicated the "nuances" of the agency's interpretation, QRX's other disclosures, such as the fact that the FDA requested additional information on a study designed to demonstrate superiority, left the public "well aware" of the relevant FDA hurdle.[10] Because QRX still had the chance to satisfy the requirement through the additional superiority study, the court did not see a conflict between QRX's optimistic public statements and the requirements communicated by the FDA.
- Similarly, in *In re Amarin Corp. PLC Securities Litigation*,[11] the court decided that Amarin's failure to disclose an FDA comment that long-term studies on its drug Vascepa would provide important information was not actionable, since the FDA never told Amarin that completion of a long-term study was required for approval of Vascepa for the desired indication.
- Plaintiffs in *Battle Construction Co. v. InVivo Therapeutics Holdings Corp*. complained that InVivo made overly optimistic statements regarding the expected timing for completion of a clinical study. Specifically, InVivo did not disclose certain conditions the FDA required be met before the studies could commence. InVivo then failed to meet its publicly announced schedule for commencing and completing the studies. However, the court found that the conditions

[7] *Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016).

[8] *Id*. at 212.

[9] No. 15 Civ. 4868, 2016 U.S. Dist. LEXIS 87489 (S.D.N.Y. July 6, 2016).

[10] *Id*. at *44.

[11] No. 13-cv-6663, 2015 U.S. Dist. LEXIS 84080 (D.N.J. June 29, 2015).

themselves posed "no material barriers" to timely completion of the study, and plaintiffs nowhere alleged that InVivo did not believe it could complete the study in the announced time frame.[12]

- The court in *Vallabhaneni v. Endocyte, Inc.*[13] addressed plaintiffs' argument that the relevant inquiry under *Omnicare* is whether the defendant had a "reasonable basis" for its opinion. While stating that it was "not persuaded" that this was the actual standard propounded under *Omnicare* (indeed only Justice Scalia's concurring opinion used this phrase), the court determined that Endocyte was "reasonable" and "honestly believed" its optimistic opinion statements regarding the robustness of its Phase II trial results and regarding a Phase III study—notwithstanding that the FDA had questioned and directed it to change one of its study protocols. The court noted that its decision was consistent with a long line of prior, pre-*Omnicare* cases holding that companies need not always disclose interim FDA criticism regarding study design.[14]

These decisions together suggest that *Omnicare* has not changed the principle that issuers do not need to disclose all interim FDA feedback or all facts in their possession that may cut against optimistic opinions, particularly in cases where the omitted information was not closely tied to the FDA's later rejection of a drug. As the *Omnicare* opinion recognized, reasonable investors understand that, in forming opinions, issuers often need to weigh competing facts, and there is no expectation that an issuer would disclose all adverse facts.[15]

In its recent *Schueneman v. Arena Pharmaceuticals, Inc.*[16] decision, however, the United States Court of Appeals for the Ninth Circuit highlighted an important caveat relating to disclosure of FDA feedback. In general, while an issuer need not disclose all material information to the public—including feedback from the FDA—if an issuer does choose to discuss positive material information, it must do so in a way that is materially complete and not misleading.[17] In *Schueneman*, Arena made statements to the public touting the likelihood that the FDA would approve its weight-loss drug, lorcaserin. As support, Arena pointed to its pre-clinical toxicity and carcinogenicity studies in animals. It did not, however, disclose that the FDA expressed concern about the level of tumors and cancer seen in the animal study and had asked Arena to provide a defense of its clinical trials.

While recognizing that it was a "close case," the Ninth Circuit reversed the lower court decision and found that plaintiffs had adequately pleaded scienter. While Arena would not have otherwise necessarily needed to disclose the FDA feedback regarding the non-clinical animal study results, the Ninth Circuit held that once it publicly touted that feedback as support for likely FDA approval, it was misleading for Arena to omit the FDA concerns.

Though it did not involve interim feedback from the FDA as such, another case applied similar analysis in connection with a pharmaceutical company's statements that it was "on track" to submit the NDA for a new drug. Plaintiffs alleged that a pharmaceutical company's statements were materially misleading under the Omnicare omissions standard because the company failed to disclose that it had not yet undertaken a meaningful assessment of its manufacturing and quality assurance systems, a critical component of the NDA approval process. The court accepted plaintiffs' position, reasoning that a

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[12] *Battle Construction Co. v. InVivo Therapeutics Holding Corp.*, 101 F. Supp. 3d 135 (D. Mass. 2015).

[13] No. 1:14-cv-01048, 2016 U.S. Dist. LEXIS 673 (S.D. Ind. Jan. 4, 2016).

[14] *See, e.g.*, *In re Sanofi Secs. Litig.*, 87 F. Supp. 3d 510, 541-42 (S.D.N.Y. 2015).

[15] *Omnicare*, 135 S. Ct. at 1329.

[16] No. 14-55633, 2016 U.S. App. LEXIS 19318 (9th Cir. Oct. 28, 2016).

[17] *Id.* at *16 (citing *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44-45 (2011)).

reasonable investor would have expected the company to have done so prior to stating that it was "on track." See *Rihn v. Acadia Pharm., Inc.*[18]

Statements of Compliance

A number of courts recently have also considered statements of opinion concerning legal and regulatory compliance.

In *Cody v. ConforMIS, Inc.*,[19] the district court granted a motion to dismiss a securities class action alleging misleading statements of compliance. In *Cody*, the issuer—a manufacturer of custom-designed joint replacement devices—stated in its initial public offering registration statement that it believed it was compliant with the FDA's Quality System Regulation protocol for manufacturing medical devices. ConforMIS also listed various risk factors relating to the possibility that manufacturing issues could arise in the future. ConforMIS later announced a voluntary recall of certain products due to issues with its sterilization process. The court determined that plaintiffs had not adequately alleged what particular facts were missing from the company's disclosures. While plaintiffs vaguely alleged that the company had lax manufacturing procedures, plaintiffs did not allege that manufacturing problems were already occurring, or that the company was aware of any sterilization issues at the time of the initial public offering.

In contrast, courts have permitted claims about compliance to survive motions to dismiss where defendants failed to disclose active government or regulatory investigations. For example, in *In re BioScrip, Inc. Securities Litigation*,[20] the company made legal compliance statements in connection with two separate public offerings, at a time when it was in receipt of a government Civil Investigative Demand ("**CID**") relating to sales practices involving a particular drug's producer and distributor. BioScrip's disclosures to the effect that it *may* receive subpoenas or government requests for information were held to be insufficient under *Omnicare* because a reasonable investor could read those disclosures to conclude that BioScrip was not in receipt of a CID at the time. The court noted that even under pre-*Omnicare* law, the allegations regarding the CID and other facts then known to the company were sufficient to indicate that the statements of compliance were both false and also not believed at the time they were made.

Though not analyzed as an opinion statement case, *Flynn v. Sientra, Inc.*[21] similarly cited Omnicare in its analysis of risk factors in Sientra's secondary offering prospectus, which described the possibility that the company's implant products may not be manufactured in compliance with regulatory requirements. The court found that this disclosure omitted the material fact that the company was already aware of serious regulatory issues with respect to its implant manufacturing, including that the German central health authority had issued a 90-day suspension of its ability to sell its goods.[22]

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[18] No. 15-cv-00575, 2016 U.S. Dist. LEXIS 128291 (S.D. Cal. Sept. 19, 2016).

[19] No. 15-13295, 2016 U.S. Dist. LEXIS 101754 (D. Mass. Aug. 3, 2016).

[20] 95 F. Supp. 3d 711 (S.D.N.Y. 2015).

[21] No. 15-07548, 2016 U.S. Dist. LEXIS 83409 (C.D. Cal. Jun. 9, 2016).

[22] *See also In re Salix Pharms., Ltd.*, No. 14-CV-8925, 2016 U.S. Dist. LEXIS 54202, at *5-6, *38-41 (S.D.N.Y. Apr. 22, 2016) (citing *Omnicare* in finding that defendant's stated expectation of increased demand from wholesalers was misleading because it allegedly knew that inventory levels were above normal due to its participation in an alleged "channel stuffing" scheme).

Clinical Study Results

A company's discussion of clinical or medical study results can also lead to omissions claims under *Omnicare*. Several courts since *Omnicare* have permitted claims to go forward where the company allegedly omitted material information from such statements.

In *In re Merck & Co.*,[23] the court denied Merck's motion for summary judgment relating to its opinion statements explaining results of a clinical study in which Vioxx users were found to suffer increased rates of cardiovascular events compared to naproxen users. While the company espoused a "naproxen hypothesis"—i.e., a theory that naproxen had cardio-*protective* effects, rather than Vioxx having adverse cardiovascular effects—the court found that there was mixed evidence regarding whether, in Merck's public statements regarding the study results, the defendants had a reasonable basis to believe their statements. One of the strongest pieces of evidence considered by the court was an FDA warning reprimanding Merck for continuing to selectively present the "naproxen hypothesis" to the public despite its lack of proof and the alternative explanation that Vioxx had adverse cardiovascular effects.

In *In re Iso Ray, Inc. Securities Litigation*,[24] plaintiffs adequately alleged that IsoRay omitted material information in touting the "exceptional" and "outstanding" results of a medical journal study on its cancer treatment, Cesium-131. Plaintiffs claimed the statements were materially misleading because they failed to mention that two other treatments discussed in the article were found to demonstrate equivalent results. Under *Omnicare*, the court agreed that describing the results as "outstanding" suggested that Cesium-131 achieved superior results compared to other methods.[25]

Recent cases analyzing the scienter prong in Section 10(b) and Rule 10b-5 actions concerning descriptions of clinical study results are consistent with the reasoning in *Omnicare*. In October, the First Circuit affirmed the dismissal of claims brought against Vertex Pharmaceuticals[26] arising out of the company's release of positive clinical trial results for an experimental drug combination to treat cystic fibrosis. Several days after the release of the information, the company determined that the results were based on an erroneous interpretation of pulmonological data and modified its public disclosures. The First Circuit affirmed dismissal of the claims because, despite allegations regarding various defendants' motivations to paint an overly optimistic picture of the data, the obviousness of the error and the importance of the study to the company, the plaintiffs' "brushstrokes . . . [did] not paint the required strong inference of scienter."[27]

In contrast, in *Hsu v. Puma Biotechnology, Inc.*,[28] the court denied a motion to dismiss claims that defendants misrepresented percentages of improvement experienced in clinical trials for a breast cancer treatment. Puma argued that the disclosed results were not false, at least under one measure of evaluation. However, the court concluded that plaintiffs had sufficiently alleged at the motion to dismiss stage that there was a clear contradiction between the alleged "real" data known to defendants and the statements made, and found that plaintiffs had alleged scienter adequately.

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[23] No. 05-1151, 2015 U.S. Dist. LEXIS 62983 (D.N.J. May 13, 2015).

[24] No. CV-15-5046, 2016 U.S. Dist. LEXIS 71953 (E.D. Wa. June 1, 2016).

[25] In a more straightforward case, the court in *Corban v. Sarepta Therapeutics, Inc.*, No. 14-cv-10201-IT, 2015 U.S. Dist. LEXIS 42688 (D. Mass. Mar. 31, 2015), dismissed plaintiffs' claims where the information defendant allegedly failed to disclose regarding the patient population for its clinical studies had in fact been made public in the company's earlier press releases, investor presentations and conference calls.

[26] *Local No. 8 IBEW Ret. Plan & Tr. v. Vertex Pharms., Inc.*, No. 15-2250, 2016 U.S. App. LEXIS 17832 (1st Cir. Oct. 3, 2016).

[27] *Id.* at 24.

[28] No. SACV 15-0865 AG, 2016 U.S. Dist. LEXIS 136527 (C.D. Cal. Sept. 30, 2016).

Conclusion

Together, these post-*Omnicare* cases suggest a few conclusions:

(1) Because it is often easier for companies to defend opinions than assertions of fact, companies should take care to make clear when they are offering one versus the other, and should not casually combine factual assertions with statements of opinion.

(2) The protection afforded opinions is far from unlimited. Companies should exercise caution in providing updates on the FDA-approval process and on study results. While every statement need not disclose every negative fact that the company knows, companies cannot avoid liability simply by introducing an overly optimistic statement with a phrase like "we believe that . . . ."

(3) Risk factor disclosures can offer substantial protection but must be tailored to actual facts, and should be updated as circumstances change. For instance, a simple disclosure that the FDA may not approve a drug or that the government may conduct an investigation could be construed to be misleading where the company already possesses concrete information about the approval process or the existence of an ongoing inquiry.

Any of the Davis Polk securities law team below would be happy to discuss these issues with you.

If you have any questions regarding the matters covered in this publication, please contact any of the lawyers listed below or your regular Davis Polk contact.

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