Increased Activity and Emerging Patterns in Securities Litigation Against Life Sciences Companies

July 19, 2017

We previously outlined the growing threat of securities class action lawsuits against life sciences companies and the importance of the United States Supreme Court's decision in *Omnicare.*[1] In that case, the Supreme Court addressed liability under the federal securities laws for statements of opinion, and gave important guidance for defending actions based on such statements. Since our last report, securities litigation against life sciences companies has continued to be highly active. Core filings (i.e., non-M&A filings) against life sciences and healthcare companies more than doubled between the first quarter of 2016 and the first quarter of 2017: from 15 in Q1 2016 to 36 in Q1 2017.[2] There is no indication that this trend is likely to abate soon.

This memorandum addresses recent decisions in securities actions involving life sciences companies, which suggest that companies continue to face an elevated threat of claims over statements falling within certain familiar categories, including statements involving: (a) the design, methodology, or results of ongoing clinical trials; (b) interactions with or feedback from the FDA; and (c) the prospects for obtaining regulatory approval. The memorandum explores some emerging trends reflected by these recent decisions, and the appendix contains brief summaries of the decisions.

Statements About the Design, Methodology, or Results of Ongoing Clinical Trials

Several courts recently have addressed allegations that a company's statements about ongoing clinical trials were false or misleading because they did not accurately report information about the design of the trials or the results of the studies, including interim results reported before the studies concluded. In these cases, defendants have prevailed on motions to dismiss because plaintiffs have not adequately pleaded either that the statements actually were false or misleading at the time made, or that there was a strong inference of the defendants' scienter (or both).

For example, in *Brennan v. Zafgen, Inc.*,[3] the First Circuit affirmed the lower court's dismissal of claims based on the failure to disclose "superficial" adverse events identified during a clinical drug trial, holding that such failure is not, by itself, enough to establish a securities claim. The court held that even if the defendants were aware of some potential connection between the drug and the adverse events, the key question for determining if scienter had been pleaded sufficiently was whether the plaintiffs had alleged that the defendants knew or should have known that they risked misleading investors by not disclosing the adverse events, which the plaintiffs had not done.

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

[2] Cornerstone Research, Record Number of Federal Securities Class Actions Filed in First Quarter of 2017, *available at* https://www.cornerstone.com/Publications/Research/1Q-2017-Filings-Record-Number-of-Actions.

[3] 853 F.3d 606 (1st Cir. Apr. 2017).

The Central District of California held in *Crihfield v. CytRx Corp.*[4] that statements about the effect of a partial clinical hold on a trial were inactionable because the statements were not incompatible with the defendants' alleged knowledge at the time of the statements. Additionally, the court concluded that forward-looking statements about the timeline for the trials were protected by the PSLRA's safe-harbor provisions because they were accompanied by cautionary statements directly related to the risks that allegedly materialized.

The District of Massachusetts held in *Harrington v. Tetraphase Pharmaceuticals, Inc.*[5] that optimistic statements about the potential efficacy of a drug based on the results of an ongoing clinical trial were not actionable in the absence of allegations establishing that the statements were actually contrary to the data and facts existing and known at the time. Moreover, the court held that because the statements at issue were forward-looking and qualified by cautionary statements identifying specific risk factors that could impact the drug's expected success, they were protected by the PSLRA's safe-harbor provisions.

In *Lerner v. Northwest Biotherapeutics*,[6] the District of Maryland held that a plaintiff's disagreement with the design, methodology, or interpretation of the results of a company's clinical trials is not sufficient to create securities liability so long as the company accurately describes the trials and accurately reports its conclusions. The court explained that plaintiffs must do more than allege a difference of opinion as to the method of analyzing clinical data to establish the falsity and scienter necessary to support a claim.[7]

And in *Fortunato v. Akebia Therapeutics, Inc.*,[8] the Superior Court of Massachusetts held that a biopharmaceutical company could not be liable for failure to disclose the serious adverse events that occurred during an ongoing clinical trial where it did not (and could not) know the results at the time of the relevant securities offering (*i.e.*, because the trial was ongoing and blinded).

In *Medina v. Clovis Oncology, Inc.*,[9] however, the District of Colorado recently permitted securities claims to proceed where a company reported interim results of a clinical trial based on initial or "unconfirmed" response rates even though the drug's overall response rate was a primary endpoint of the clinical study and the study was governed by protocols requiring "confirmed" responses. Accepting the allegations as true at the pleading stage, the court was convinced that reporting the initial response rates was sufficiently misleading to support a claim. The court determined that plaintiffs had pleaded facts sufficient to warrant discovery into the actual results of the clinical trial so that the "hard data" could "prove or disprove" plaintiffs' claims.

Statements Involving or Related to Communications with the FDA

Other recent cases have addressed claims that companies misled investors by omitting or misrepresenting critical feedback received from the FDA. Courts continue to make clear that companies

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[4] Nos. CV 16-05519, 16-05666 SJO (SKx), 2017 WL 2819834 (C.D. Cal. June 14, 2017).

[5] Civil No. 16-10133-LTS, 2017 WL 1946305 (D. Mass. May 9, 2017).

[6] Case No. GJH-15-2532, 2017 WL 1229710 (D. Md. Mar. 31, 2017).

[7] *See also Kader v. Sarepta Therapeutics, Inc.*, No. 1:14-CV-14318-ADB, 2017 WL 72396 (D. Mass. Jan. 6, 2017).

[8] No. 1584CV02665-BLS2, 2017 WL 716356 (Mass. Super. Ct. Feb. 21, 2017).

[9] 215 F. Supp. 3d 1094 (D. Colo. 2017).

need not disclose every detail of their communications with or interim feedback from the FDA, but when a company chooses to make positive statements about a product, the regulatory process, or its communications with the FDA, those statements will be scrutinized both for accuracy and completeness.

For example, in *Ganem v. InVivo Therapeutics Holdings Corp.*,[10] the First Circuit confirmed that a company does not need to disclose every conceivable stumbling block to meeting an aggressive estimated schedule for clinical trials, including certain conditions imposed or recommendations made by the FDA in communicating its approval of the trials. But the court carefully considered the company's statements about its schedule in light of the FDA's alleged feedback to ensure that it was possible to meet the publicly disclosed schedule when the schedule was reported or confirmed by the company.

The court in *In re Amarin Corp.*[11] addressed whether the failure to disclose the FDA's "reservations" about the design, methodology, and sufficiency (for approval purposes) of a clinical trial supported an actionable omissions claim. Affirming the district court's decision, the Third Circuit determined that none of the statements respecting the FDA's feedback were misleading because the study remained scientifically viable at the time the statements were made—*i.e.*, the FDA did not decisively indicate that the study would be insufficient for approval—so the defendants did not have a duty to disclose all of the details of the feedback in connection with their statements related thereto.

In *Kader v. Sarepta Therapeutics, Inc.*,[12] the District of Massachusetts considered whether a company's public statements about its efforts to obtain FDA approval for a drug and the sufficiency of its clinical data were misleading where the company allegedly did not disclose certain specific "concerns" expressed by the FDA about the underlying clinical study's methodology and results. The court determined that the allegations failed to establish the requisite falsity or scienter because the company included many cautionary statements making clear to investors that there was an ongoing discussion underway with the FDA regarding the necessary clinical trial data. That the drug was ultimately approved based on the data further undermined any inference that the statements were inaccurate.

In *Dougherty v. Esperion Therapeutics, Inc.*,[13] the Eastern District of Michigan examined whether statements that a cardiovascular outcomes trial would not need to be completed before seeking FDA approval, which were based on feedback provided during a meeting with the FDA, were false or misleading at the time made. The final minutes of that meeting later indicated that the FDA "encouraged" the company to initiate such a trial (so that it would be in process when the New Drug Application was submitted), which the company reported publicly when it received the minutes. The court determined that the company's disclosures prior to receiving the minutes were not actionable because nothing suggested the company intentionally or recklessly misstated its understanding of the FDA's communications. The statements also were protected by the PSLRA's safe-harbor provisions as forward-looking statements accompanied by sufficiently specific cautionary statements.

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[10] 845 F.3d 447 (1st Cir. 2017).

[11] No. 16-2640, 2017 WL 2258548 (3d Cir. May 23, 2017).

[12] Civil Action No. 1:14-CV-14318-ADB, 2017 WL 72396 (D. Mass. Jan. 6, 2017).

[13] Case No. 16-10089, 2016 WL 7439196 (E.D. Mich. Dec. 27, 2016).

Statements About the Prospects for Regulatory Approval

In several recent cases, defendants have prevailed on motions to dismiss claims that a company has been overly optimistic in its public statements regarding the likelihood of securing regulatory approval for a product. Courts have continued to hold that optimistic statements about the prospects for obtaining FDA approval are inactionable where they are based on an honest belief with a reasonable basis (*i.e.*, are not knowingly false or misleading) or qualify as forward-looking statements accompanied by cautionary statements about the specific risks related to the reported prospects.

For example, in *In re Amarin Corp.*,[14] the Third Circuit held that optimistic projections that the FDA will approve a drug for a particular indication are not actionable where the complaint does not sufficiently allege that the company did not honestly believe its projections or did not have a reasonable basis for its belief given feedback from the FDA, even if the FDA later rejected the indication after reviewing "new" scientific data.

In *Bauer v. Eagle Pharm., Inc.*,[15] the District of New Jersey recently held that optimistic statements about obtaining regulatory approval for a drug partly in reliance on the FDA's prior findings of safety and efficacy for an existing product fall within the safe-harbor provisions of the PSLRA where they are "tempered" by extensive, specific, and tailored cautionary statements about the regulatory pathway, even if the cautionary statements are made separately (*e.g.*, in Form 10-Qs and Form 10-Ks).

Similarly, in *Dougherty v. Esperion Therapeutics, Inc.*,[16] the Eastern District of Michigan held that optimistic statements about obtaining regulatory approval for a drug without having to complete additional clinical studies fall within the safe-harbor provisions of the PSLRA where they are accompanied by warnings about the risks and uncertainties of drug development and the FDA approval process, including the specific risk that the FDA may require additional studies prior to approval.

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We will continue to monitor new cases and developments involving securities claims against life sciences companies and to provide periodic updates. In the meantime, if you have questions or issues that you would like to discuss regarding securities litigation against life sciences companies, any of the Davis Polk partners identified at the end of the appendix would be happy to discuss them.

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[14] No. 16-2640, 2017 WL 2258548 (3d Cir. May 23, 2017).

[15] Civil Action No. 16-3091 (JLL), 2017 WL 2213147 (D.N.J. May 19, 2017).

[16] Case No. 16-10089, 2016 WL 7439196 (E.D. Mich. Dec. 27, 2016).

APPENDIX

This appendix provides brief summaries of the recent decisions addressed above. The cases are discussed in alphabetical order.

***In re Amarin Corp.*,**
No. 16-2640, 2017 WL 2258548 (3d Cir. May 23, 2017)

In the course of its development of a triglycerides-regulating drug, Amarin undertook a 12-week trial to demonstrate the efficacy of the drug. Because it could not monitor cardiovascular outcomes directly in such a short period, Amarin proposed to measure triglyceride ("TG") levels as a "surrogate endpoint." In 2008, Amarin met with the FDA, which provided feedback to the effect that it was not aware of any long-term studies linking TG levels to improved cardiovascular outcomes and stating that Amarin would have to initiate an appropriate cardiovascular outcomes study before it could be granted an indication. In 2009, Amarin entered a Special Protocol Assessment ("SPA") with the FDA in which the FDA agreed with Amarin's design for the study; however, it said that whether the 12-week trial would be sufficient was a "review issue." These "reservations" expressed by the FDA in the 2009 SPA and minutes from the 2008 meeting were not disclosed to investors. In 2013, the FDA rescinded Amarin's SPA, concluding that results from other long-term studies provided insufficient support for using TG levels as a surrogate endpoint for cardiovascular outcomes. On appeal, plaintiffs argued that by failing to disclose the FDA's reservations, Amarin had intentionally misled investors as to the risk that it would have to carry out new expensive and time-consuming studies that would delay FDA approval.

The Third Circuit affirmed the district court's dismissal of the complaint. The court determined that Amarin's statements were not misleading because the FDA's use of the term "review issue" indicated that it was possible, but not certain, that Amarin's 12-week trial would be sufficient. In affirming the dismissal, the Third Circuit ruled that plaintiffs mischaracterized the FDA's feedback during the class period, and that using TG levels as an endpoint was scientifically viable until 2013. Given that the methodology was viable at the time the statements were made and the FDA had not definitively indicated otherwise, the statements were not false or misleading. Moreover, to the extent the statements were optimistic projections about obtaining FDA approval, nothing suggested that Amarin did not honestly believe its projections or lacked a reasonable basis for its beliefs, and they therefore were not actionable.

***Bauer v. Eagle Pharm., Inc.*,**
Civil Action No. 16-3091 (JLL), 2017 WL 2213147 (D.N.J. May 19, 2017)

Eagle developed a ready-to-use liquid version of an already approved drug for which it intended to seek FDA approval under the 505(b)(2) pathway by relying in part on the FDA's prior approval of the reference drug. Ultimately, the FDA declined to approve the product based on the New Drug Application ("NDA") as submitted. Plaintiffs claimed that defendants violated the securities laws by making a series of allegedly misleading statements and omissions concerning the failed attempt to secure FDA approval of the product without having to conduct human trials. The alleged misrepresentations fell into two main categories: (1) statements related to the drug's chemical makeup and similarity to the previously approved reference drug; and (2) statements about the likelihood of obtaining FDA approval.

The district court granted the defendants' motion to dismiss. First, the court concluded that plaintiffs had not pleaded with sufficient particularity any facts showing that the statements about the

product's makeup were false. Second, the court determined that the statements about the prospects for FDA approval fell within the PSLRA's safe-harbor provision because they were forward-looking and "tempered" by sufficiently extensive and specific cautionary language in Form 10-Qs and Form 10-Ks filed during the relevant period. The cautionary statements warned investors that FDA approval through the 505(b)(2) regulatory pathway is not guaranteed, that the FDA may require additional studies, and that the FDA could determine that the new product is not sufficiently comparable to the previously approved drug. Finally, the court held that statements touting the new drug as "unique" and "far superior," among other similar statements, were inactionable statements of opinion or puffery.

***Brennan v. Zafgen, Inc.*,**
853 F.3d 606 (1st Cir. Apr. 7, 2017)

Plaintiffs alleged that Zafgen made misleading statements regarding an anti-obesity drug by disclosing some, but not all, of the thrombosis-related adverse events that occurred during a Phase 2 clinical trial prior to the company's IPO. Specifically, plaintiffs alleged that of the four adverse "thrombotic" (*i.e.*, blood-clotting) events that occurred during the trial, Zafgen disclosed only the two classified as "serious" and did not disclose the two classified as "superficial," while simultaneously stating that the results of the Phase 2 trial at issue did not suggest that the drug increases the risk of cardiovascular disease. After a clinical patient died and the FDA put the drug on a partial clinical hold, Zafgen disclosed the two "superficial" thrombotic adverse events from the Phase 2 trial (and two new adverse events), and plaintiffs filed suit. Plaintiffs alleged that the defendants knew or should have known about news and scientific articles that discussed some connection between the drug and thrombotic events and had a motive to commit securities fraud because of the company's compensation structure and insider sales prior to the disclosure.

The district court dismissed the complaint, and the First Circuit affirmed, on the grounds that plaintiffs had not sufficiently pleaded a strong inference of scienter. The First Circuit explained that the mere existence of articles that may have suggested some knowledge of a link between the drug and thrombotic events did not show that the defendants deliberately or reckless risked misleading investors by not disclosing the two superficial adverse thrombotic events, which were only marginally material and would not have significantly altered the information available had they been disclosed. The court reaffirmed that, in the omissions context, plaintiffs must sufficiently allege that the defendants knew that omission of the allegedly material fact risked misleading investors to permit a strong inference of scienter. Moreover, the court reiterated that a motive to "shade the truth" in order to maximize compensation is not, without more, enough to satisfy the PSLRA's requirements for pleading scienter.

***Crihfield v. CytRx Corp.*,**
Nos. CV 16-05519, 16-05666 SJO (SKx), 2017 WL 2819834 (C.D. Cal. June 14, 2017)

In the course of developing a cancer medication, CytRx entered into a Special Protocol Assessment ("SPA") agreement with the FDA for a Phase 3 clinical trial. In the midst of the trial, the FDA placed a "partial clinical hold" on the trial following a patient death due to acidosis. The company issued a press release stating that during the hold all current trial participants could continue receiving the drug, but no new patients would be enrolled, and that the company would modify its study parameters in response to the hold. The release also indicated that previously announced enrollment rates and timelines remained materially unchanged. After commissioning a report on the incident leading to the hold, CytRx determined that it would test all current and future patients for acidosis before those patients

could resume or begin treatment. A few months later, CytRx announced that the FDA had lifted the hold with modified study parameters. The company also stated that it believed enrollment rates and timelines would remain materially unchanged by the hold. The study achieved its target enrollment as scheduled and realized enough progression events to begin data analysis in April 2016. The results of that data analysis, released a few months later, revealed that there was not a significant difference in outcomes between the new drug and existing options. In a press release, CytRx blamed the results on the data's lack of maturity due to the hold, and announced that it expected improved results once it had more time for patient follow-up. CytRx's stock price dropped on this announcement, and plaintiffs filed a securities action alleging that CytRx made false and misleading statements regarding (1) continued treatment of enrolled patients post-hold, (2) CytRx's compliance with certain assumptions underlying the SPA, and (3) the trial's projected timeline.

The district court granted the defendants' motion to dismiss. Although the court determined that the company's statements about the continued dosing of enrolled patients after the hold was initiated may have been misleading, plaintiffs failed to establish a strong inference of scienter because no allegations demonstrated that the company knew that the modified study parameters would materially risk jeopardizing the study. The court also concluded that CytRx did not misrepresent its compliance with the SPA because its statements about certain "assumptions" underlying the SPA did not mean that the company was obligated to adhere to those assumptions, and the company never affirmatively stated that it was in compliance with all aspects of the SPA. Finally, the court held that CytRx's statements regarding the trial timeline were not actionable because (a) some of the statements fell within the PSLRA's safe-harbor provisions as forward-looking and accompanied by disclosed risk factors indicating how results may differ materially from what was anticipated; and (b) the complaint did not more likely than not suggest that the company knew the statements were misleading at the time they were made.

***Dougherty v. Esperion Therapeutics, Inc.*,**
Case No. 16-10089, 2016 WL 7439196 (E.D. Mich. Dec. 27, 2016)

Plaintiffs filed a putative securities-fraud class action against Esperion based on allegedly misleading statements about what occurred at a meeting between the company and the FDA and the prospects for obtaining FDA approval without completing a cardiovascular outcomes trial ("CVOT"). In August 2015, the company published a press release, which was based on a meeting with the FDA, indicating that the FDA would not require the *completion* of a CVOT before approving the company's cholesterol drug. In September 2015, after receiving the final minutes of that FDA meeting, the company issued a press release indicating that the FDA was encouraging that a CVOT be *initiated* promptly so that the trial would be underway at the time of the New Drug Application submission and review process. The stock price dropped 48% after the September press release, spurring the suit.

The district court granted the defendants' motion to dismiss and dismissed the case. First, the court held that scienter had not been pleaded because there were no allegations suggesting that the company knew that it was not accurately reporting the FDA's view or that the company actually understood the FDA's communications differently than was reported publicly. Second, the court held that the statements about the approval process fell under the PSLRA's safe-harbor provisions because they were forward-looking and were accompanied by appropriate cautionary language, including a specific warning that the FDA may require additional studies prior to approval that could delay approval.

***Fortunato v. Akebia Therapeutics, Inc.*,**
No. 1584CV02665-BLS2, 2017 WL 716356 (Mass. Super. Feb. 21, 2017)

Plaintiff brought a putative class action asserting that Akebia's final registration statement and prospectus for its IPO were misleading because they did not disclose interim results from a clinical drug trial that was in process at the time of the IPO. Specifically, plaintiff claimed that the materials were misleading because they did not report preliminary information from Akebia's ongoing Phase 2b clinical trial of its first potential pharmaceutical product, which suggested that patients receiving the test drug were more likely to experience serious adverse events than patients who received a placebo. Defendants—Akebia, its directors and senior executives, and its IPO underwriters—claimed that the offering documents were not misleading because they indicated that a double-blind study was ongoing and that it was not therefore feasible to provide preliminary information about the results. The study was not complete and unblinded until six months *after* the IPO.

The court dismissed the complaint because plaintiff had failed to allege any facts plausibly suggesting that defendants knew or could have known about the serious adverse events experienced by patients actually taking the drug as part of the clinical trial before the study was complete and unblinded. In the absence of allegations that Akebia had disregarded the FDA's rules requiring that double-blind clinical data remain blinded until the study is finished, plaintiff had not pleaded that the defendants were aware or could have been aware of the very information that supposedly should have been disclosed.

***Ganem v. InVivo Therapeutics Holdings*,**
845 F.3d 447 (1st Cir. Jan. 9, 2017)

Plaintiffs asserted that InVivo made false and misleading statements in press releases concerning the FDA's approval of the company's first human trials for a new device being developed to treat patients with spinal-cord injuries. After laying out in the press releases an aggressive schedule for conducting the trials, the company, under new management, revised and extended the schedule. Plaintiffs alleged that the press releases were false or misleading because they did not disclose that the FDA's approval was subject to certain conditions or explain that the FDA had recommended changes to the study protocol, and because the disclosed timeline for conducting the trials and submitting data to the FDA was unrealistically optimistic given the FDA's feedback.

After the district court dismissed the complaint and plaintiffs appealed, the First Circuit affirmed the dismissal. The court agreed with the district court that none of the statements were false or misleading in light of the FDA's feedback, which did not make it impossible for the company to achieve the timeline originally disclosed. As the court explained, even if the original timeline was aggressive, the company could have met the temporal predictions set forth in the relevant press release, and a company is not required to disclose every conceivable risk or stumbling block to realizing a projected schedule. Failure to exercise "greater clairvoyance" about timing and to propose a more conservative schedule is insufficient to support a securities claim.

***Harrington v. Tetraphase Pharms.*,**
Civil No. 16-10133-LTS, 2017 WL 1946305 (D. Mass. May 9, 2017)

Plaintiffs asserted securities claims based on Tetraphase's public statements about a synthetic antibiotic being developed to treat, among other things, complicated urinary tract infections after the drug failed to demonstrate superiority to competing treatments during a Phase 3 clinical trial. At the heart of

plaintiffs' claims was their argument that Tetraphase had overstated the expected efficacy of the drug and knew that the drug was ineffective months before disclosing that the trial had failed. In an effort to plead scienter, plaintiffs alleged that Tetraphase knew the results of the Phase 3 trial earlier than reported and should have known that the drug would not be effective based on disagreement in the scientific community about the potential benefits of the drug and the data observed in an earlier clinical trial.

The district court dismissed the complaint primarily based on plaintiffs' failure to establish a strong inference of scienter because the timeline they presented for Tetraphase's supposed knowledge of ineffectiveness relied on math that was "just wrong." Moreover, plaintiffs had not sufficiently pleaded any basis for concluding that Tetraphase should have known about the drug's inefficacy because neither the conflicting scientific opinions nor the data from the earlier trial established that the drug was ineffective. The court also determined that many of the statements, including those about the drug's prospects as an effective antibiotic, were forward-looking statements qualified by other cautionary statements identifying specific risk factors and, therefore, were protected under the PSLRA's safe-harbor provisions. Finally, the court held that statements about the potential efficacy of the drug were not actionable because there was no basis to conclude that the statements were contrary to known facts at the time they were made.

***Kader v. Sarepta Therapeutics, Inc.*,**
Civil Action No. 1:14-CV-14318-ADB, 2017 WL 72396 (D. Mass. Jan. 6, 2017)

Sarepta, a biopharmaceutical company focused on developing RNA-based therapies for the treatment of rare and infectious diseases, developed a drug to treat Duchenne muscular dystrophy ("DMD") for which it sought FDA approval. Plaintiffs filed a complaint alleging that the company misstated guidance and omitted from its public statements information that the FDA purportedly provided about the sufficiency of clinical data for the drug. After plaintiffs' original complaint was dismissed for failure to plead any materially misleading statements or facts sufficient to support a strong inference of scienter, plaintiffs sought leave to file an amended complaint based on an FDA briefing document that allegedly reflected "concerns" and "criticism" communicated by the FDA about the methodology of and data from the clinical studies, including about the company's supposed discarding of data that failed to yield positive results. While the motion was pending, the FDA approved the drug for use on DMD patients.

The district court denied the motion to amend because the amendment would be futile (and because of plaintiffs' undue delay), holding that "disagreements with or criticism of drug study methodology is insufficient to state a claim for securities fraud, particularly where there is no showing of an intent to deceive or improper manipulation of results." The court determined that the company's "course of conduct" permitted an inference that it believed that the methodology and results of the clinical trials would be sufficient for the FDA and its "many cautionary statements" made clear that there was an ongoing discussion with the FDA about the data that would be necessary to obtain approval. Plaintiffs failed to allege how any of the company's statements were false or misleading, including by failing to allege how not disclosing the specific details of the FDA's feedback was problematic where the company disclosed that the FDA had some concerns about the clinical data. Given the cautionary language used by the company in its public statements, and in the absence of any allegations showing that the company knew or recklessly disregarded definitive FDA guidance, the court could not conclude that the company was engaging in efforts to deceive investors.

***Lerner v. Nw. Biotherapeutics*,**
Case No. GJH-15-2532, 2017 WL 1229710 (D. Md. Mar. 31, 2017)

Plaintiffs brought a putative class action asserting Section 10(b) and Rule 10b-5 claims based on a litany of alleged misrepresentations related to a biopharmaceutical company's development of immunotherapy cancer treatments. Most of the allegedly false and misleading statements related to clinical trials for the company's two primary products and the results thereof, including statements expressing the company's conclusions based on the results of the trials.

The district court dismissed the claims because plaintiff had failed to allege that any of the statements were actually false or misleading. As the court explained, that plaintiff may have disagreed with the design, methodology, or the company's interpretation of the results of the clinical trials did not render the company's accurate statements about the trials or expressions of optimism about the results false or misleading. Plaintiff did not adequately explain how the alleged statements regarding the company's interpretation of the data and conclusions based on the studies were not simply reflective of differences between two permissible judgments regarding the results or mere differences of opinion. Companies are not required to take a pessimistic view regarding the results of a study, so long as they report the results accurately. Additionally, the court held that plaintiff had failed to plead scienter because merely being in a position of control in a company, without more, is insufficient to establish scienter, defendants did not act recklessly, and a desire to raise capital to support business ventures does not, by itself, establish the requisite fraudulent intent.

***Medina v. Clovis Oncology, Inc.*,**
215 F. Supp. 3d 1094 (D. Colo. 2017)

Plaintiffs asserted that a biopharmaceutical company developing a treatment for lung cancer made false and misleading statements about the results of a Phase 2 clinical trial by reporting "unconfirmed" objective response rates ("ORRs") rather than the "confirmed" ORRs that were identified later and were "significantly lower." Plaintiffs alleged that the statements were misleading because "unconfirmed" ORRs would not be accepted by the FDA, did not comply with the rules supposedly governing the clinical trial, and were inconsistent with industry standards. Defendants argued that the statements were not false or misleading because they never claimed that the ORRs were confirmed, but rather, disclosed that the results were "interim," "preliminary," and "initial."

The district court dismissed some of the claims but permitted others to proceed, concluding that discovery would be instrumental in assessing whether the statements were accurate, which would determine the outcome of the case. The court explained that discovery would reveal the hard data from the relevant clinical trial that could be used to determine whether the initial ORRs were later "confirmed" or, instead, the initial responses were followed by unfavorable results, and those less favorable results were knowingly left undisclosed. In those circumstances, the court saw "no reason why th[e] case should be dismissed *before* the actual data . . . is disclosed." The court dismissed claims based on statements of optimism that were "incapable of objective verification," but permitted numerous other claims to move forward, including claims based on statements about the drug's safety.

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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